

**OMNIBUS SOLICITATION OF THE
NATIONAL INSTITUTES OF HEALTH,
CENTERS FOR DISEASE CONTROL AND PREVENTION, AND
FOOD AND DRUG ADMINISTRATION FOR**

**SMALL BUSINESS INNOVATION
RESEARCH (SBIR)**

AND

**SMALL BUSINESS TECHNOLOGY
TRANSFER (STTR)**

GRANT APPLICATIONS

**NIH, CDC, and FDA Program Descriptions and
Research Topics**

SUBMISSION DATES

**SEPTEMBER 5, 2019, JANUARY 6, 2020, AND
APRIL 6, 2020**

**National Institutes of Health (SBIR and STTR)
Centers for Disease Control and Prevention (SBIR)
Food and Drug Administration (SBIR)**

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Funding Opportunity Announcements, Application Instructions, and Appendices are contained in separate files. Follow the links below to view these documents.

FUNDING OPPORTUNITY ANNOUNCEMENTS

REMINDER: ALL APPLICATIONS MUST BE SUBMITTED IN RESPONSE TO A FUNDING OPPORTUNITY ANNOUNCEMENT THROUGH GRANTS.GOV

PHS 2019-02 OMNIBUS SOLICITATION OF THE NIH, CDC, AND FDA FOR SMALL BUSINESS INNOVATION RESEARCH GRANT APPLICATIONS (PARENT SBIR [R43/R44] CLINICAL TRIAL NOT ALLOWED)

[HTTP://GRANTS.NIH.GOV/GRANTS/GUIDE/PA-FILES/PA-19-272.HTML](http://grants.nih.gov/grants/guide/pa-files/pa-19-272.html)

PHS 2019-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS TECHNOLOGY TRANSFER GRANT APPLICATIONS (PARENT STTR [R41/R42] CLINICAL TRIAL NOT ALLOWED)

[HTTP://GRANTS.NIH.GOV/GRANTS/GUIDE/PA-FILES/PA-19-270.HTML](http://grants.nih.gov/grants/guide/pa-files/pa-19-270.html)

PHS 2019-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS INNOVATION RESEARCH GRANT APPLICATIONS (PARENT SBIR [R43/R44] CLINICAL TRIAL REQUIRED)

[HTTP://GRANTS.NIH.GOV/GRANTS/GUIDE/PA-FILES/PA-19-273.HTML](http://grants.nih.gov/grants/guide/pa-files/pa-19-273.html)

PHS 2019-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS TECHNOLOGY TRANSFER GRANT APPLICATIONS (PARENT STTR [R41/R42] CLINICAL TRIAL REQUIRED)

[HTTP://GRANTS.NIH.GOV/GRANTS/GUIDE/PA-FILES/PA-19-271.HTML](http://grants.nih.gov/grants/guide/pa-files/pa-19-271.html)

ADDITIONAL SPECIAL ANNOUNCEMENTS FOR SMALL BUSINESS RESEARCH OPPORTUNITIES [HTTPS://SBIR.NIH.GOV/FUNDING/INDIVIDUAL-ANNOUNCEMENTS](https://sbir.nih.gov/funding/individual-announcements)

APPLICATION INSTRUCTIONS

SF424 (R&R) APPLICATION INSTRUCTIONS AND ELECTRONIC SUBMISSION INFORMATION ([HTTPS://GRANTS.NIH.GOV/GRANTS/HOW-TO-APPLY-APPLICATION-GUIDE.HTML](https://grants.nih.gov/grants/how-to-apply-application-guide.html))

APPENDICES

STTR MODEL AGREEMENT ([MS WORD](#))

**EXTRAMURAL INVENTION REPORTING COMPLIANCE RESPONSIBILITIES
([HTTPS://S-EDISON.INFO.NIH.GOV/IEDISON/TIMELINE.JSP](https://s-edison.info.nih.gov/iedison/timeline.jsp))**

PROGRAM DESCRIPTIONS AND RESEARCH GRANT TOPICS

The research topics shown in this solicitation represent program areas that may be of interest to applicant small business concerns in the development of projects that have potential for commercialization. Small business concerns are encouraged to submit SBIR/STTR grant applications in these areas.

APPLICABLE TO NIH ONLY: SBIR and STTR grant applications will be accepted and considered in any area within the mission of the awarding components (i.e., Institutes and Centers (ICs)) identified in this solicitation.

Applicants are strongly encouraged to subscribe to the NIH Guide for Grants and Contracts LISTSERV (<http://grants.nih.gov/grants/guide/listserv.htm>) or query program administrators periodically via email to learn of new or emerging scientific interests of the NIH, CDC, and FDA awarding components.

You may also subscribe to the SBIR-STTR LISTSERV list to get timely information about the NIH SBIR/STTR Programs (<https://sbir.nih.gov/engage/listserv>).

Additional information on each of the awarding components (ICs) and their research interests is available electronically on the home pages shown throughout the “Research Topics” section of the solicitation.

The Fogarty International Center, which provides support only for conferences, postdoctoral fellowships for research in the United States and abroad, and senior scientist exchanges between the United States and other countries, does not participate in the SBIR/STTR program.

NATIONAL INSTITUTES OF HEALTH (NIH)

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

The goals of the agency are as follows:

1. to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
2. to develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease;
3. to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
4. to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research:

- in the causes, diagnosis, prevention, and cure of human diseases;
- in the processes of human growth and development;
- in the biological effects of environmental contaminants;
- in the understanding of mental, addictive and physical disorders; and
- in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

In addition, the NIH sponsors training of research personnel; career development of new and established scientists; construction and renovation of research facilities and provision of other research resources.

To carry out these responsibilities, the NIH is organized into awarding components (Institutes/Centers). Those components that have an extramural element, that is, those that provide funds for research and research training activities in organizations external to the NIH, are shown below. The NIH makes every effort to finance worthy applications, including the co-funding of such applications by one or more awarding components having relevance in the projects.

Funding levels for projects are determined through the combined interaction among peer review, grants management, program, budget, and other Institute and/or Centers (IC) staff. These levels are based on allowable costs that are consistent with the principles of sound cost management and in consideration of IC priorities, constraints on the growth of average grant costs, and the availability of funds.

Before considering and/or preparing an application to the SBIR & STTR programs, all applicants are **strongly encouraged** to review the agencies' and NIH Institutes' and Centers' websites and to contact the SBIR-STTR program coordinators listed in the Omnibus Solicitation.

TRANS-NIH RESEARCH PROGRAMS

Phase IIB Competing Renewal Awards

Some NIH Institutes/Centers (ICs) offer Phase II SBIR/STTR awardees the opportunity to apply for Phase IIB Competing Renewal awards. These are available for those projects that require extraordinary time and effort in the R&D phase and may or may not require FDA approval for the development of such projects, including drugs, devices, vaccines, therapeutics, and medical implants related to the mission of the IC. Some ICs have announced this opportunity through the NIH Guide for Grants and Contracts (see link below), and some are using this Omnibus SBIR/STTR Grant Solicitation. Only those small business concerns who have been awarded a Phase II are eligible to apply for a Phase IIB Competing Renewal award. Prospective applicants are strongly encouraged to contact NIH staff prior to submission. Additional requirements and instructions (e.g., submission of a letter of intent) are available in the specific IC research topics section and in the specific [IC Program Funding Opportunity Announcements](#). The following NIH ICs will accept applications for Phase IIB Competing Renewal awards: **NIA**, **NIAAA**, **NIAID**, **NICHD** (SBIR only), **NIDCD**, **NIDDK** (only Competing Renewals of NIDDK-supported Phase II awards), **NEI** (SBIR only), **NIGMS** (SBIR only), **NIMH**, **NCATS** (SBIR only and only Competing Renewals of NCATS-supported Phase II awards), and **ORIP** (SBIR only and only Competing Renewals of ORIP-supported Phase II awards). **NCI** offers Phase IIB opportunities that focus on the commercialization of SBIR-developed technologies. Contact the NCI SBIR Development Center at 240-276-5300, NCISBIR@mail.nih.gov for additional information. **NHLBI** offers Phase IIB Competing Renewals that focus on the commercialization of technologies requiring regulatory approval through the NHLBI Phase IIB Bridge Awards and the Phase IIB Small Market Awards: <https://www.nhlbi.nih.gov/grants-and-training/funding-opportunities-and-contacts/small-business-program>. Contact NHLBI nhlbi_sbir@mail.nih.gov for additional information. **NINDS** accepts Phase IIB SBIR/STTR Competing Renewal applications through specific opportunities that focus on the commercialization of SBIR and STTR developed technologies. These opportunities can be found on the NINDS Funding Opportunities webpage: <https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities>. Contact Stephanie Fertig, M.B.A., at fertigs@ninds.nih.gov for additional information.

Research Supplements to Promote Diversity in Health-Related Research

(See Funding Opportunity Announcement at <https://grants.nih.gov/grants/guide/pa-files/PA-18-906.html>)

Every facet of the United States scientific research enterprise—from basic laboratory research to clinical and translational research to policy formation—requires superior intellect, creativity, and a wide range of skill sets and viewpoints. NIH's ability to help ensure that the nation remains a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further NIH's mission. Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the researchers, advancing the likelihood that underserved or health disparate populations participate in, and benefit from, health research, and enhancing public trust. In spite of tremendous advancements in scientific research, information, educational and research opportunities are not equally available to all. The NIH seeks to diversify the scientific workforce by enhancing the participation of individuals from groups identified as nationally underrepresented in the biomedical, clinical, behavioral and social sciences.

The NIH notifies Principal Investigators holding specific types of NIH research grants (including SBIR and STTR awards) that funds are available for administrative supplements to improve diversity by supporting and recruiting students, postdoctorates, and eligible investigators from groups that have been shown to be nationally underrepresented in the biomedical, behavioral, clinical, and social sciences research workforce. Although the administrative supplements supported under this program provide funding for less than one percent of all individuals involved in NIH supported research, the NIH has found these awards to be an effective means of encouraging institutions to recruit from currently underrepresented groups. Further information on the NIH diversity policy and the groups that have been identified as underrepresented in biomedical research can be found at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html>. Administrative supplements must support work within the scope of the original project.

All NIH awarding components and the National Institute for Occupational Safety and Health at the CDC participate in this program. Candidates eligible for support under this supplement program include individuals at various career levels who come from groups that have been shown to be nationally underrepresented in science. Such candidates include individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds. Detailed eligibility criteria are described in the full announcement.

An application for a supplement may be submitted at any time. Administrative supplements normally end with the competitive cycle of the parent grant.

TECHNICAL ASSISTANCE PROGRAMS (SUBJECT TO CHANGE)

Available to HHS SBIR/STTR Awardees

One of the goals of the SBIR and STTR programs is to “increase private sector commercialization of innovations developed through Federal Research and Development.” To help HHS SBIR/STTR awardees move their products into the marketplace, NIH has developed assistance programs that provide technical and/or commercialization assistance specific to the individual needs of HHS SBIR/STTR awardees. In accordance with the SBIR/STTR Reauthorization Act of 2011, applicants can also identify and utilize their own technical assistance vendor, however they are required to include this as a consultant in the budget section with a detailed budget justification. See SF424 (R&R) SBIR/STTR Application Guide for instructions. Please note, if funds are requested to utilize your own technical assistance vendor and an award is made, the awardee cannot apply for the NIH-provided technical assistance program for the phase of their award.

Additional information about these programs is available at <https://sbir.nih.gov/tap>. Questions may be addressed to the NIH SBIR/STTR Office at sbir@od.nih.gov.

Niche Assessment Program

(FOR HHS SBIR/STTR PHASE I AWARDEES)

The Niche Assessment Program focuses on providing strategic information about the technology's market and customer opportunities. Often, a research scientist does not have the entrepreneurial skills to assess whether there are other applications or market niches for their SBIR/STTR-developed technology. As a result, they may underestimate its true market value. This program assesses the market opportunities, needs and concerns of end-users and helps to discover new markets for possible entry for the SBIR/STTR-developed technology. With the assistance of the participant, a contractor helps identify niches and potential partners. The contractor performs the due diligence and provides an in-depth report that assesses such items as the potential end-users needs, the competing technologies and products, the competitive advantage, the market size and share that the participant might expect, etc. Targets (end users) are contacted to ensure they are viable leads and their contact information is included in the report for possible follow-up. Participants may find this report helpful in preparing the requisite Commercialization Plan required for a Phase II application. For detailed information about the Niche Assessment Program, see <https://sbir.nih.gov/nap>.

Participation in this program is open to active HHS SBIR and STTR Phase I awardees (grants, cooperative agreements, and contracts) and participants need only commit a few hours to inform and make the contractor fully conversant on their technology and the niche they would like to have investigated. There is no cost to the HHS awardee to participate in this program.

Commercialization Accelerator Program (CAP)

(FOR HHS SBIR/STTR PHASE II AWARDEES)

The Commercialization Accelerator Program (CAP) assists small companies with getting their SBIR/STTR-developed technologies more rapidly into the marketplace. It provides assistance with developing and implementing an appropriate business strategy aimed at commercializing the products or services that have resulted from HHS-supported SBIR/STTR awards.

CAP can include distinctive tracks that offer customized assistance to meet the specific needs of both early stage and seasoned companies: 1) Commercialization Transition Track (CTT), 2) Advanced Commercialization Track (ACT), and 3) Regulatory Training track (RTT).

The CTT is suitable and relevant for the majority of HHS SBIR/STTR Phase II companies. In this track, participants will receive the tools to understand and put into practice the commercialization plans and activities critical to your company's stage, level, and background. It also provides you with the opportunity to receive direct industry feedback in a live (in-person) session.

The ACT is suitable and relevant to companies that have some history of accomplishment in commercializing products and/or services, generating and maintaining revenue streams, or servicing a well-defined and steady customer base, and that have established partnerships. In this track, participants will focus on addressing a specific "gap" or applicable issue, which resolution is crucial for your continued progress and development. These issues may include (provided as examples only): Financial Issues and Valuation (financial modeling, budget analysis), Intellectual Property (license-focused IP strategy, refresh of patent portfolio), Market Strategy (related to a specific customer or opportunity), Marketing/Branding (marketing materials, branding/website), and Strategic Partnering (investor/go to market presentation, term sheet for investor/partnership).

The RTT is suitable and relevant to companies that have some history of accomplishment in commercializing products and/or services, generating and maintaining revenue streams, or servicing a well-defined and steady customer base, and that have established partnerships. In this track, participants will focus on addressing a specific “gap” or applicable issue, which resolution is crucial for your continued progress and development. These issues may include (provided as examples only): developing a detailed regulatory plan in anticipation of near-term FDA submission, addressing feedback from the FDA on a current regulatory application, preparing for 510k approval, etc.

Participation in CAP is open to HHS SBIR and STTR Phase II awardees (grants, cooperative agreements, and contracts) from the previous five years. Participation is free to the HHS SBIR/STTR awardee; however, participants are responsible for travel and lodging expenses associated with attending workshops and partnering events. Detailed information about the CAP is available at <https://sbir.nih.gov/cap>.

NIH, CDC, AND FDA AWARDED COMPONENT CONTACT INFORMATION

Questions of a general nature about the NIH SBIR/STTR program may be directed to:

NIH SBIR/STTR Program Office
Telephone: 301-435-2688
Email: sbir@od.nih.gov

For Agency, Institute and Center Scientific/Research (Program) and Financial/Grants Management contacts, please see here:

<https://sbir.nih.gov/engage/ic-contacts>

NATIONAL INSTITUTE ON AGING (NIA)

NIA's mission is to:

- Support and conduct genetic, biological, clinical, behavioral, social, and economic research on aging.
- Foster the development of research and clinician scientists in aging.
- Provide research resources.
- Disseminate information about aging and advances in research to the public, health care professionals, and the scientific community, among a variety of audiences.

The NIA SBIR-STTR Programs support research and product development focusing on aging and aging-related condition and diseases, as well as other problems and needs unique to older Americans. NIA supports SBIR and STTR research and product development under four divisions: Behavioral and Social Research, Biology of Aging (Aging Biology), Geriatrics and Clinical Gerontology, and Neuroscience.

For additional information about NIA's SBIR and STTR programs please visit:

<https://www.nia.nih.gov/nia-small-business-programs-sbir-sttr>.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, the NIA may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. For topics listed in APPENDIX A: National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations, the NIA generally will not fund Phase I applications greater than \$300,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years. For all other topics, the NIA does not generally fund Phase I applications greater than \$225,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$1,500,000 total costs or project periods greater than 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

NIA-Supported Funding Opportunity Announcements (FOAs)

In addition to this Omnibus program announcement, the NIA releases targeted Funding Opportunity Announcements (FOAs) throughout the year. These FOAs are listed to inform potential applicants about other funding opportunities to which they can apply; applications submitted in response to this Omnibus program announcement are not limited to research and development areas described in the following targeted FOAs. FOAs may specify specific budget caps that are above the caps listed for Omnibus applications. Applicants are encouraged to visit the following webpage for an up to date list of NIA SBIR/STTR funding opportunities:

<https://www.nia.nih.gov/research/nia-small-business-funding-opportunities>

For projects that aim to address Alzheimer's Disease and Related Dementias, applicants are encouraged to consider the following funding opportunity which allows Phase I budgets up to \$450,000 and Phase II budgets up to \$2.5M (for topics covered by the approved waiver from SBA):

- Advanced Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R43/R44 Clinical Trial Optional): Accepts Phase I, Phase II, Direct-to-Phase II and fast-track applications. Details can be found here: <https://grants.nih.gov/grants/guide/pa-files/PAS-18-187.html>

- Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R41/R42 Clinical Trial Optional): Accepts Phase I, Phase II, and fast-track applications. Details can be found here: <https://grants.nih.gov/grants/guide/pa-files/PAS-18-188.html>

Phase IIB Competing Renewal Awards

NIA welcomes submission of Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing a wide range of aging-focused products, including digital-mobile/cyber-health technology, pharmaceutical compounds, and medical devices. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to realize further progress in commercialization, including stimulating interest in and investment by third parties.

Prospective Phase IIB Competing Renewal applicants are strongly encouraged to contact NIA's SBIR-STTR program coordinator prior to consideration and preparation of a Phase IIB application--& well in advance of the SBIR-STTR submission due dates.

For questions about potential NIA SBIR/STTR grant applications and NIA's participation in the Phase IIB program, please contact:

Michael-David ARR Kerns, M.M., M.S., Ph.D.
 Program Contact, NIA Small Business R & D Programs
 Telephone: 301-402-7713
 Email: kernsmd@mail.nih.gov
 Bio: <https://www.nia.nih.gov/about/staff/kerns-michael-david>

Research Topics of Interest to NIA

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		https://grants.nih.gov/grants/guide/pa-files/PAS-18-188.html https://grants.nih.gov/grants/guide/pa-files/PAS-18-187.html https://grants.nih.gov/grants/guide/pa-files/PAR-18-186.html https://grants.nih.gov/grants/guide/pa-files/PAR-18-185.html https://grants.nih.gov/grants/guide/pa-files/PAR-18-184.html https://grants.nih.gov/grants/guide/pa-files/PAR-18-183.html
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

The below topics are for both non-clinical trial and clinical trial applications.

Division of Neuroscience (DN)

The Division of Neuroscience (DN) fosters and supports extramural research and training to further the understanding of the dementias of old age, as well as neural and behavioral processes associated with the normally aging brain. An area of special emphasis is brain-behavior relationships. An important component of this Division is the support of basic, clinical, and epidemiological studies of AD and related dementias of aging.

- A. Development of new and/or validation of existing sensitive, specific, and standardized tests for diagnostic screening and the development of biomarkers.
- B. Target discovery and validation through the application of systems biology and systems pharmacology approaches of MCI, AD, ADRD, or other dysfunctions of the central nervous system.
- C. Preclinical and/or clinical discovery, development, and/or evaluation of drug, nutritional, behavioral, cognitive, sensory, environmental, or other types of interventions to remediate age-related cognitive decline and/or other dysfunctions of the central nervous system.

- D. Development of new technologies for in-home use or for coordination or delivery of services to sustain in-home living for individuals with MCI, AD, ADRD, or that may prolong functional independence when there are dysfunctions of the central nervous system.
- E. Development of biosensors and prosthetic devices, technologies, and related software development to aid in the assessment, diagnosis, and remediation of age-related cognitive decline and/or other dysfunctions of the central nervous system.
- F. Development of technology and analysis tools to examine genetic, epigenetic, transcriptomic, proteomic, metabolomic, and cell stress pathways in neurons and glia of the aging and AD/ADRD brain.
- G. Improvement of technology to analyze structural and functional brain connectivity at the cell, neural circuitry, and global-network levels to define the normal trajectory of brain structure and function over the adult lifespan.
- H. Development of technology, including non-invasive methods and novel probes, to monitor and manipulate the plasticity of neural circuits in the adult and aged nervous system.
- I. Development of novel markers of neural stem cell function and novel approaches for analysis of next-generation sequence data.

Division of Aging Biology (DAB)

The Division of Aging Biology promotes and supports research and training on the molecular, cellular, genetic, and physiological mechanisms underlying normal aging and age-related pathologies. The objective of DAB-funded research is to elucidate the basic biochemical, genetic, and physiological mechanisms underlying the process of aging and age-related changes in humans and in animal models of human aging. This includes investigations of the gradual or programmed alterations of structure and function that characterize normal aging and investigations of how these adverse changes become risk factors for, or accompany, age-related conditions and disease states.

- A. Development of interventions to 1) reduce oxidative or other stresses and aging-related diseases; 2) improve the immune response to foreign molecules or reduce the response to self or suppress age-induced inflammation; 3) enhance longevity or slow aging and may affect other age-related conditions or diseases; 4) reduce the level of damage to nucleic acids, proteins and lipids and the macromolecular complexes formed from these molecules, and improve the damage surveillance and repair potential of cells.
- B. Development of minimally-perturbing techniques for collecting blood old non-human animals and the development of non-invasive research and test methods for use in non-human animals.
- C. Development of novel strategies for treating age-related renal, pulmonary, urology, reproductive disorders, and age-related changes in hormone production and function.
- D. Development of novel methodology for treating osteoarthritis, including devices, processes and pharmacological agents with the potential to: (1) slow the rate of joint deterioration, (2) promote the remodeling of damaged joints, (3) reduce the likelihood of progression to osteoarthritis, and/or (4) improve outcomes for patients with active osteoarthritis.
- E. Development of tools and resources in genetics and genomics to study molecular mechanisms of normal aging or aging-related diseases.
- F. Development of novel methodology for treating chronic wound healing, including devices, processes and pharmacological agents with the potential to: (1) improve the rate and or quality of wound healing, and/or (2) improve outcomes for patients with chronic wounds.

- G. Development of biomarkers for prognosis, diagnosis, or treatment monitoring of aging or aging-related diseases; and analysis or integration of large data sets for developing biomarkers or biomarker signatures of aging or age-related diseases.

Division of Behavioral and Social Research (DBSR)

DBSR areas of research that may be of interest to small businesses include, but are not limited to:

- A. Behavioral economics approaches (incentives or disincentives) to motivate sustainable behavior change to improve health and well-being.
- B. Technology-based applications (including robotics and sensors) to aid elderly, including maintaining or improving cognitive function and detecting cognitive impairment.
- C. Innovative statistical methods (e.g., machine learning, development of artificial intelligence algorithms) for analysis of “big data” (i.e., time intensive, multisource data) to inform a deeper understanding of mechanisms underlying aging, in both clinical (e.g. using EHR data for early diagnosis of aging related disease such as dementia, and co-morbidities) and naturalistic settings (e.g. home assessment using technology to predict age-related diseases).
- D. Social, behavioral, environmental interventions for individuals, institutions, families, or communities to maintain older adult independence, increase well-being and prevent disease and/or disability, including within workplace settings.
- E. Sampling and data-collection methodologies for large population-based studies, including genetics and Genome Wide Association approaches, behavioral interventions and blood-spot technology for biological data collection in large-scale studies.
- F. Survey development, archiving and database tools, including infrastructure to integrate big data, such as use of artificial intelligence and machine learning, for deeper understanding of aging-related phenomena.

Division of Geriatrics and Clinical Gerontology (DGCG)

The Division of Geriatrics and Clinical Gerontology (DGCG) supports clinical and translational research on health and disease in the aged, and research on aging over the human life span, including its relationships to health outcomes. DGCG foci include translational research for the development of new interventions for age-related conditions, prevention and treatment of multiple chronic conditions in the elderly, and studies that help to promote evidenced based geriatric care and inform policies affecting older adults.

- A. Development and validation of human aging mechanistic markers predictive for various age-related conditions or responses to interventions. Products of interest include the development and validation of commercial assays which could be used in clinical/epidemiologic research to assess mechanisms of aging (e.g., cell senescence, autophagy, DNA damage and repair) in human blood, tissues or cells. This may involve refinement of existing assays (e.g., conversion of lab assay to high-throughput screening) and/or de novo assay development for use in clinical research. Novel molecular imaging techniques (in vitro and in vivo) to study aging mechanisms in humans are also encouraged.
- B. Potential new therapeutics and/or interventions targeting fundamental mechanisms of aging. This may include identification of new therapeutic targets or repurposing of existing FDA-approved medications.

- C. Development of bioinformatic tools for big data integration, visualization and in-depth analysis of “omics” data for predictive markers of aging, molecular pathways associated with aging and age related diseases, and omic targets for therapeutic translation.
- D. Development of high throughput drug screening platforms to identify small molecules for enhancing the functions of protective genetic/metabolic factors associated with exceptional longevity or health span in humans.
- E. Development of clinical decision-support tools able to broadly integrate into the electronic health record.
- F. Development of assistive technologies/robotics, improved instrumentation/imaging and sensor technology, and new therapeutic interventions.
- G. Development and validation of improved approaches for evaluation, monitoring or treatment of diastolic dysfunction in older adults.
- H. Development of methods and technology to accurately determine the renal glomerular filtration rate (GFR) in older persons and patients with chronic kidney disease.
- I. Development and validation of non-invasive methods of examining bone quality (density, architecture, and strength of bone).
- J. Development and validation of instruments and/or methods to evaluate fatigability, innovative approaches to pain control, and new technology.
- K. Development of vaccines and other agents for preventing and treating infections in older persons.
- L. Development of devices and/or techniques for preventing or treating urinary incontinence.
- M. Development and effectiveness testing of innovative, practical, cost-effective technologies, data collection and extraction systems.
- N. Development and validation of novel, practical, cost-effective and reliable assays, imaging, and/or sensing technologies of physiologic changes with age and multiple markers of age-related chronic inflammation. Of particular interest are unobtrusive sensing and wearable technologies which will facilitate the collection of data on a variety of physiological parameters in longitudinal studies such as monitoring caloric intake and/or energy expenditure.
- O. Development of new diagnostic tests to predict adverse and/or costly, or favorable, health outcomes with aging or in the setting of chronic diseases, injuries, surgery, hospitalization, or other health-related conditions.

For more information on research topics, contact:

Program Contact, NIA Small Business R & D Programs:

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National Institute on Aging (NIA)

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Bio: <https://www.nia.nih.gov/about/staff/dea/kerns-michael-david>

Division of Aging Biology:

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Division of Behavioral and Social Research:

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Division of Geriatrics and Clinical Gerontology:

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Division of Neuroscience:

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Bio: <https://www.nia.nih.gov/about/staff/martin-jones-zane>

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

NIAAA supports research on the causes, prevention, control, and treatment of the major health problems associated with alcohol use. Through its extramural research programs, NIAAA funds a wide range of basic and applied research to develop new and/or improved technologies and approaches for increasing the effectiveness of diagnosis, treatment, and prevention. NIAAA also is concerned with strengthening research dissemination, scientific communications, public education, and data collection activities in the areas of its research programs.

Limited Amount of Award

NIAAA will make awards compliant with all statutory guidelines as outlined above. Total funding support (direct costs, indirect costs, fees) normally may not exceed \$168,087 for Phase I awards and \$1,120,586 for the duration of the Phase II awards. With appropriate justification from the applicant, NIAAA may consider awards that exceed these amounts by up to 50%. NIAAA has received a budgetary guideline waiver from the Small Business Administration for applications relating to the limited list of scientific topics (Appendix A). Applicants considering a requested budget greater than the standard limits are strongly encouraged to contact program staff before submitting an application. For budgetary, administrative, or programmatic reasons, NIAAA may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application.

Phase IIB Competing Renewal Awards

NIAAA will accept SBIR/STTR Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing products that require approval of a Federal regulatory agency (e.g., FDA, FCC). Such products include, but are not limited to, medical implants, drugs, vaccines, biologicals, and new treatment or diagnostic tools that require FDA approval. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. To be eligible for Phase IIB consideration, the project must retain high significance in the light of current market conditions.

Prospective applicants are strongly encouraged to contact NIH staff well in advance of submitting a Phase IIB Competing Renewal application by submitting to Ms. Megan Ryan (contact information below) a letter of intent that includes the following information:

- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Grant number and title
- Progress of the Phase II award
- Goals and justification for the Phase IIB request

It is expected that only a portion of NIAAA SBIR/STTR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

NIAAA supports Investigational New Drug (IND)-enabling studies for therapeutic candidates under separate FOAs (<https://niaaa.nih.gov/grant-funding/funding-opportunities>).

Commercialization Assistance Programs

NIAAA Phase I grantees may consider applying for the Niche Assessment Program or the I-Corps at NIH pilot program. NIAAA Phase II grantees are eligible to apply for the Commercialization Accelerator Program (CAP).

Research Topics of Interest to NIAAA

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		https://niaaa.nih.gov/grant-funding/funding-opportunities
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		https://niaaa.nih.gov/grant-funding/funding-opportunities

NIAAA Non-Clinical Trials Topics:

Medications Development

Pharmacotherapy offers a promising means for treating AUD. Currently, there are four Food and Drug Administration (FDA)-approved pharmacotherapies for the treatment of AUD: disulfiram (Antabuse®), oral naltrexone (Revia®), acamprosate (Campral®), and the injectable suspension formulation of naltrexone (Vivitrol®). Another medication, nalmefene (Selincro®), has recently been approved by the European Medicines Agency (EMA). However, given the heterogeneous nature of AUD, many patients have limited or no response to the aforementioned medications. Because of this, developing and evaluating new, more efficacious medications remains a high priority.

During the past five decades, alcohol research has enriched our understanding of the biological mechanisms underlying AUD. Various neurotransmitter systems, neuromodulators, and intracellular signaling pathways have a role in AUD. To date, more than 35 promising targets have been shown to alter alcohol drinking behavior. Some of the new promising targets include, but are not limited to, corticotrophin-releasing factor1 (CRF-1), adrenergic α 1 and α 2, vasopressin 1B, orexin 1 and 2, opioid receptor-like (NOP), opioid kappa, 5-HT₂, GABA-A and GABA-B, metabotropic glutamate (mGluR), glutamate transporter (GLT), nicotinic acetylcholine (nAChR), phosphodiesterase (PDE), glial derived neurotrophic factor (GDNF), and neuroimmune and epigenetic modulators. New medications that bind to these and additional targets are needed.

Candidate medications may include novel and re-purposed compounds. However, grant applications that propose to study compounds already extensively investigated or currently being studied patients with AUD will not be accepted. Thus, applications proposing the use of naltrexone, acamprosate, disulfiram, topiramate, ondansetron, varenicline, gabapentin, and baclofen are not responsive to this topic.

Specific areas of interest include medications that target one or more domains of the addiction cycle, including reward, stress and negative affect, incentive salience, executive function, habituation, and impulsivity/compulsivity.

For questions, contact:

Raye Z. Litten, Ph.D.

Telephone: 301-443-0636

Email: Raye.Litten@nih.gov

Additional targets for pharmaceutical development include, but are not limited to agents that attenuate excessive alcohol use and other symptoms of AUD, e.g., craving, sleep problems, and negative affect as well as those that hold promise for the treatment of alcoholic hepatitis, liver fibrosis, cirrhosis, pancreatitis, cardiomyopathy, or other alcohol-induced tissue damage.

For pre-clinical questions, contact:

Mark Egli, Ph.D. (Neuroscience and behavior)

Telephone: 301-594-6382

Email: Mark.Egli@nih.gov

Svetlana Radaeva, Ph.D. (Organ damage)

Telephone: 301-433-1189

Email: Svetlana.Radaeva@nih.gov

Technological Methods for the Treatment of Hazardous Drinking and Alcohol Use Disorder

- Develop, improve, and validate ecological momentary assessment (EMA) methods for capturing real-time data for use in alcohol clinical trials and treatment paradigms.
- Use technology (e.g. EMA, brain imaging) and innovative statistical methods (e.g., machine learning, systems science dynamic models) appropriate for analysis of “big data” (i.e., time intensive, multisource data) to inform our understanding of mechanisms underlying the initiation, maintenance, and recovery from problematic drinking in both treatment and naturalistic settings.

Leverage unique features of mobile technologies to provide personalized monitoring and just-in-time interventions including but not limited to a variety of racial/ethnic and linguistic populations.

- Optimize existing technologies to increase their utilization and effectiveness in specific treatment contexts (e.g., primary care) and improve patient-provider communication to decrease harmful drinking including across racial, ethnic and linguistic groups.
- Develop and test computerized versions of empirically-supported treatments, including but not limited to in languages other than English.
- Develop and test novel computerized interventions which capitalize on hypothesized brain-based or behavioral mechanisms underlying drinking
- Develop software to train potential treatment professionals on how to provide evidence-based treatments
- Devise novel methods (e.g., Web-mining software of social networking sites) that capture social network information among groups at risk for alcohol use disorder and high-risk drinking, including but not limited to racial and ethnic minority populations.
- Develop and test the efficacy of neurophysiological treatment approaches such as transcranial magnetic stimulation, neurofeedback, and deep brain stimulation.

Anita Bechtholt, Ph.D.

Telephone: 301-443-9334

Email: anita.bechtholt@nih.gov

Prevention

This area of interest focuses on the development and evaluation of innovative prevention and intervention programs, or specific materials for integration into existing programs, which utilize state-of-the-art technology and are based on currently accepted clinical and behavioral strategies. Applicants are strongly encouraged to consult with research methodologists and statisticians to ensure that state-of-the-art approaches to design, analysis, and interpretation of studies under this topic are used. Areas that may be of interest to small businesses include, but are not limited to:

- Development and evaluation of innovative prevention/intervention programs, or specific materials for integration into existing programs, which utilize state-of-the-art technology and are based on currently accepted clinical and behavioral strategies. Special emphasis should be placed on the needs of high-risk groups, ethnic and minority populations, youth, children of individuals with alcohol use disorder, women, the handicapped, sexual and gender minority populations, and the elderly. Examples of such materials include school-based curricula, interactive videos, computer-based multimedia programs, training manuals for teachers or parents, and community-based programs.
- Development and evaluation of educational materials designed to intervene with the elderly around specific age-related risks for alcohol problems. Particular attention should be given to age-related reductions in alcohol tolerance, interactions between alcohol and prescription and over-the-counter medications, possible exacerbation of some medical conditions common among the elderly, potential biomedical and behavioral consequences of excessive alcohol use, and the role of alcohol in falls, fires, burns, pedestrian and traffic injuries, and other unintentional injuries.
- Development and evaluation of statistical analysis programs tailored to the design and analysis of alcohol prevention-relevant research. Programs could focus on a variety of areas including: imputation of missing data under varying design assumptions; development and application of statistical models suited to small sample sizes common in racial and ethnic minority research; simulation of distributions of outcomes based on varying mixtures of sample populations; application of chronic or infectious disease models to targeted communities; and models of the potential effect of various policy-based interventions, such as increased taxation or reduction of outlet density by license revocation and control.

Robert C. Freeman, Ph.D.
Telephone: 301-443-8820
Email: Robert.Freeman@nih.gov

Improving the Delivery of Alcohol Treatment Services

NIAAA's treatment services research program studies the organization, management, and financing of alcohol treatment services, and how these affect service availability, access, utilization, cost, and quality. Needed innovations in this area include the development of state-of-the-art technologies, software, and protocols to expand and improve the delivery of evidence-based treatment for alcohol use disorder.

Areas that may be of interest to small businesses include, but are not limited to, the development and assessment of software or tools to:

- assist clinicians in selecting and delivering evidence-based treatments consistent with patient needs and available staff and program resources across racially, ethnically and linguistically diverse populations. Special attention should be paid to promoting fidelity of treatment delivery in real-world contexts. For example: software to enable the creation or use of clinical decision support systems, screening protocols, or patient registries; prescription medication management tools; scripts or guides for delivery of brief interventions; and interactive training resources.
- support long-term recovery, by facilitating patients' continued engagement in recovery support services as an adjunct to or after treatment. For example: software to assist patients in self-management and self-monitoring of drinking behaviors, cues, or triggers, and/or in locating treatment resources or recovery support services.
- assist treatment programs and service agencies in measuring clinically relevant performance indicators or improvements in quality of service provision.
- promote engagement and mitigate burnout among counselors and others engaged in direct treatment service delivery. Tools are needed to reinforce training on therapeutic techniques; provide minimally-obtrusive methods for monitoring and enhancing fidelity of service delivery; engage counselors in mindfulness or other strategies to manage job stress and reduce burnout; and provide front-line counselors with supports essential to maintaining productive therapeutic relationships with patients.

Lori Ducharme, Ph.D.
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Email: Lori.Ducharme@nih.gov

Fetal Alcohol Spectrum Disorders (FASD) and Alcohol-Related Birth Defects

FASD is the collective term for the broad array of adverse effects resulting from in utero alcohol exposure. Fetal alcohol syndrome (FAS), the first form of FASD discovered and the most well-known, is characterized by craniofacial abnormalities, growth retardation, and nervous system impairments that often include intellectual disabilities. Other diagnostic categories include partial FAS, alcohol-related neurodevelopmental disorder (ARND), and alcohol-related birth defects (ARBD). Children and adults with FASD may exhibit multiple cognitive, behavioral, and emotional deficits that impair daily functioning in many domains. The NIAAA supports research leading to improved diagnosis and assessment of prenatal alcohol exposure and related impairment and disability, as well as the development of therapeutic interventions, including tools to enhance academic and daily living skills across diverse racial, ethnic and linguistic populations. Areas that may be of interest to small businesses include, but are not limited to:

- Development and assessment of diagnostic and/or screening methods, tools, or technologies to improve earlier identification of individuals affected by prenatal exposure.
- Development and validation of biomarkers that can be used to verify prenatal alcohol exposure in neonates or predict those individuals with neurobehavioral deficits later in life.

- Development and validation of assessment methods to provide more accurate clinical diagnosis of FASD at all life stages.
- Development and testing of skill-building, therapeutic, and education program products that enhance the social, cognitive, adaptive and motor abilities of individuals with FASD.
- Development of neurobehavioral tools or instruments to assess responsiveness of individuals with FASD to medications and/or cognitive/behavioral therapies.
- Development of accurate measures of the responsiveness of children affected by prenatal alcohol exposure to stress and predictors of vulnerability to alcohol-drinking or other psychopathology during adolescence and adulthood.
- Development and evaluation of educational and training programs designed to enhance the skills of non-professional caregivers in dealing with the problems associated with FASD.
- Development and validation of innovative methods, tools or technology to prevent harmful drinking during pregnancy.

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Development of Clinical Biomarkers of Alcohol Exposure and Alcohol-Induced Organ Damage

There is a well-recognized need for prognostic and diagnostic biomarkers of alcohol exposure, for biomarkers of the response to clinical treatment, and for biomarkers to monitor abstinence in high-risk individuals. Quantitative and qualitative markers of high-risk drinking behavior and alcohol-induced tissue damage would greatly improve medical efforts to recognize and treat alcohol-related disorders. Currently, no clinically available laboratory test can reliably diagnose duration of alcohol use or predict the progression of alcohol-induced organ damage. Traditional alcohol biomarkers fail to provide long-term information. More recently developed alcohol biomarkers (ethanol metabolites phosphatidylethanol (PEth), ethyl glucuronide (EtG) and ethyl sulfate (EtS)) display improved sensitivity, specificity, and accuracy over classical biomarkers. Their useful range of a few days (EtG) to 2-4 weeks (PEth) addresses many, but not all, clinical needs.

Effective biomarkers are essential to early detection of alcohol use disorder (AUD) or early stages of organ damage. Early detection will make it possible for patients to consider intervention to prevent long-term medical, psychological, and social consequences of alcohol use.

Several separate, distinct diagnostic settings and circumstances are in need of reliable specific biomarkers. Alcohol biomarkers that address the following are needed:

- Biomarkers that detect cumulative intake of alcohol over a period of months or more; thus, a biomarker that is stable over months, reflecting duration and amount of alcohol exposure.
- Biomarkers that detect failure of compliance after withdrawal; thus, a biomarker with a short half-life.

- Biomarker signatures of alcohol-induced organ damage, which are likely to be organ-specific.
- Biomarker signatures of familial risk factors for AUD. Early identification of subjects predisposed to AUD will allow for early intervention, possible prevention, and allow the subjects to make informed personal decisions.

Characteristics of useful biomarkers are:

- Sensitivity, specificity, accuracy, and reliability
- Ease of use and acceptability to patient and provider
- Found in easily obtained specimens, such as serum or plasma, urine, saliva, or hair.
- Validity, reproducibility, affordability, and transportability to a variety of settings, including AUD treatment centers, hospitals, primary care offices, or the workplace.

Pattern-based molecular signatures —as opposed to single component biomarkers — may be predicted to provide greater sensitivity, specificity, accuracy, and reliability than single component biomarkers. Thus, high throughput discovery approaches using genomics, epigenomics, transcriptomics, proteomics, metabolomics, lipomics, or glycomics are encouraged.

Also of interest:

- Improvement of turn-around time and cost efficiency of current assays for PEth, EtS, EtG and other alcohol biomarkers.
- Design and development of point of care devices, for use in rural or remote primary care and hospital settings.

Small business efforts for improvements at any stage in the biomarker pipeline are of interest, including discovery, validation, development, and implementation to real world settings.

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Alcohol Biosensors

Small business applications proposing to design and produce a wearable device to monitor blood alcohol levels in real time are sought. The device should be able to quantitate blood alcohol level, and interpret and store the data or transmit it to a smartphone or other device by wireless transmission. The device should have the ability to verify standardization at regular intervals and to indicate loss of functionality. The power source should be dependable and rechargeable. Data storage and transmission must be completely secure in order to protect the privacy of the individual. A form of subject identification would be an added benefit. The device can be removable.

The alcohol biosensor device should be unobtrusive, passive in action, appealing to the wearer, and can take the form of clothing, bracelet, jewelry, or any other format located in contact with the human body. A non-invasive technology is preferred. Novel and innovative approaches to detecting blood alcohol, rather than alcohol that has exuded across the skin, are especially encouraged.

Alcohol detection technology for personal alcohol monitoring will serve useful purposes in research, clinical and treatment settings; will play a role in public safety; and will be of interest to individuals interested in keeping track of personal health parameters.

This topic also includes the opportunity to develop appropriate data analysis systems for individual level evaluation as well as for assessment of trends in research populations.

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Alcohol Use and HIV Infection, and HIV Co-infection with HCV, HBV, or TB

Alcohol consumption is widely recognized as a co-factor in the sexual transmission, susceptibility to infection, and progression of infectious diseases, including HIV and HIV co-infection with HCV, HBV, or TB. However, detailed relationships between alcohol use and viral infections, disease progression, anti-viral (or anti-TB) therapy and adverse outcomes, notably in liver disease progression, are less recognized or understood particularly across different racial and ethnic groups. Recent research indicates that inflammatory pathways predominate in liver disease including alcoholic hepatitis whereas adaptive immunity plays a primary role in viral hepatitis, offering multiple targets for novel preventive and therapeutic interventions. Comprehensive studies to improve understanding of the factors underlying alcohol and viral etiologies in liver disease and the impact of anti-viral drugs on liver disease progression are needed. A better understanding of alcohol's effects on liver disease in patients with HIV and co-infections may improve diagnosis and treatment outcomes. NIAAA supports research leading to improved diagnosis and treatment of alcohol-induced disorders in people infected with HIV, and HIV co-infection with HCV, HBV, or TB including but not limited to racial, ethnic and gender identity minorities.

Areas that may be of interest to small businesses include, but are not limited to:

- New preventive and therapeutic approaches designed to protect the liver from alcohol and antiretroviral drug-induced liver injury in patients infected with HIV, and HIV co-infection with HCV, HBV, or TB
- Development of therapies aimed at molecular targets that play a role in the development of alcohol-associated and viral liver and/or lung diseases.
- Development and evaluation of drugs that mitigate the effects of oxidative stress on mitochondrial function thereby preventing liver disease progression.
- Development of biomarkers for individuals who are most prone to alcohol-induced damage in those patients with HIV alone or HIV co-infection.

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Electronic Diagnostic Clinical Assessment of Frailty among HIV+ Individuals with Past and/or Current Alcohol Use Disorder: Severity and Patterns

Innovative self-report, biological, and/or common clinical measures for the identification and diagnosis of frailty related to alcohol use among alcohol-using HIV patients and those with related comorbidities are

sought. Measurement of frailty should be calibrated for severity of alcohol use and be both clinically useful and predictive of morbidity and mortality. Applications proposing the development of medical decision-making algorithms to inform clinical care of HIV+ individuals who drink and include frailty index(es) through an internet site are sought. The primary goal of this site will be to provide normative and educational information for providers and patients related to medical care to reduce frailty index(es) related to morbidity and mortality as primarily a useful tool for clinicians who encounter HIV patients who continue to drink and may or may not be compliant with antiretroviral treatment for suppression of viral replication and restoration of immune function.

- Development of this site should be tested in the widest range of individuals, including but not limited to racial, ethnic and gender identity minorities, at various trajectories of progression of HIV disease and patterns of alcohol use. In particular, information from measures should be able to accurately identify individuals who are “sick quitters” and/or have high degree of frailty due to either past and/ or current alcohol use.
- This clinical decision-making tool should be of greatest value to diagnostic assessment and interventions within clinical settings and may include the development of audio, visual, and/or training modules to support the use of appropriate diagnostic index(es) across linguistic groups.
- Support of an electronic internet site for scoring and collection of information on HIV disease characteristics, frailty and patterns of alcohol use in clinical populations, and to provide information on a range of options for assessment of alcohol use severity in HIV+ populations (e.g. brief assessment instruments, calendar methods, biological markers, etc.).
- Identify current and emerging methods for behavioral and/or biological intervention to reduce alcohol use in the context of HIV and improve clinical outcomes.

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Monitoring Alcohol Use among HIV+ Patients

Of particular importance is the measurement of patterns of alcohol use among HIV+ individuals. Wearable alcohol biosensors (see related topic) should be developed to maximize acceptability and minimize stigmatization among the widest range of users. It is expected that the most effective devices will be unobtrusive devices (perhaps wrist-worn) that assess a variety of physiological measures in addition to alcohol use and that interact with smart phone technologies for additional assessment or data management features (e.g., momentary ecological assessment) related to medication adherence for HIV and related comorbidities.

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Stem Cell Research for Alcohol-induced Disorders

Recent advances in stem cell research provide opportunities to enhance understanding of alcohol-related conditions, including alcohol use disorder (AUD), and to develop novel medications for these conditions. The NIAAA encourages SBIR/STTR research on the use of stem cells in elucidating the pathophysiology of alcohol-related conditions and identifying novel targets for treatment. Areas that may be of interest to small businesses include, but are not limited to:

- Generate and disseminate induced pluripotent stem cells (iPS) from adult human cells to resemble diverse individual variations in alcohol metabolism. Use these genetic variant models to study AUD and pharmacotherapy development. Examples of these genetic variations include alcohol dehydrogenase (ADH), aldehyde dehydrogenase (ALDH), cytochrome P450 isozyme CYP2E1, and glutathione S-transferase (GST).

- Generate and disseminate disease-specific iPS cell lines for studies on the biology and signaling pathways that contribute to alcohol-related disease pathology.
- Models derived from human iPS cells to study biological and pathological effects of alcohol and its metabolites *in vivo*.
- Using CRISPR (clustered regularly interspaced short palindromic repeats) gene editing technology on iPS cells to study alcohol-related disease

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Role of Non-coding RNAs in the Neuroadaptation to Alcohol Use Disorder

Gene expression changes after alcohol exposure are well documented. In particular, a vast network of expression changes is found in the brain (and other tissues) following both acute and chronic alcohol exposure. These neuroadaptations are thought to underlie alcohol tolerance and alcohol and alcohol use disorder as well as mediating the toxic effects of alcohol on neurodevelopment. The discovery of gene expression regulation mediated by RNA molecules that are transcribed from DNA, but do not code for protein, has set into motion a revolution in molecular biology. These novel RNAs are classified broadly as non-coding RNAs (ncRNAs) and include both small (microRNAs or miRNAs) and large classes (long non-coding RNAs or lncRNAs) that function to alter the expression of genes to which they bind and modify chromatin states. Because it is estimated that the majority of the genome consists of non-protein coding regions, of which ncRNAs make up a substantial portion, understanding how alcohol alters the expression of ncRNAs and their targets has significant potential for understanding the mechanisms of alcohol neuroadaptation. However, because of their diverse role in cellular functions and combinatorial mechanisms of action, many challenges still exist in gaining a full appreciation of the role of ncRNAs in alcohol neuroadaptation.

NIAAA seeks the development of novel technologies to both measure and interpret ncRNA gene expression signatures in the brain and/or primary neuronal cultures following alcohol exposure. These technologies could include, but are not limited to: novel methods to tag and measure ncRNAs, new imaging techniques to monitor changes in ncRNAs, and novel bioinformatic algorithms to interpret alcohol-induced alterations in ncRNAs and predict and validate target genes.

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In vivo Detection of Neuromodulators in Behaving Animals

Neuromodulators, such as neuroimmune factors, modulate a wide range of brain functions and play an important role in neurodevelopment and synaptic function. To understand how activities of neuromodulators contribute to alcohol use disorders and how changes at the molecular level link to behavior, effective tools are needed to detect changes of neuromodulators in real time in the brain of behaving animals. Currently available methods that measure neuromodulator levels in the CSF fluid would not allow the analysis of dynamic changes of neuromodulators with spatial and temporal precision. To facilitate the understanding of how neuromodulators shape neuronal activity and contribute to alcohol use disorders, more accurate methods of detection are needed.

Recent advances in a variety of *in vivo* neurotechniques provide a great opportunity to achieve this goal. For example, cell-based fluorescent reporters, which detect the activity of G protein-coupled receptors through a fluorescent Ca²⁺ sensor, can be developed to detect neuromodulators that activate G protein-coupled receptors, such as chemokines. In addition, *in vivo* fluorescence imaging using target-activated

small-molecule fluorochromes coupled with nanotechnology may also provide a powerful tool to visualize neuromodulator changes in the intact brain.

With this SBIR/STTR solicitation, NIAAA seeks the development and application of techniques that can detect neuromodulator changes in real time with spatial and temporal precision in behaving animals. Techniques that allow the *in vivo* detection of neuromodulators over an extended time period, such as implantable cell- or probe-based biosensors, will be particularly encouraged.

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Ex vivo Screens to Identify Pharmacotherapies for Alcohol Use Disorder

High throughput screening efforts have identified many small molecules acting at biological targets thought to be important modulators of excessive alcohol drinking and other alcohol use disorder (AUD) phenotypes. Concurrently, *in vivo* animal models of alcohol drinking and related behavioral measures are currently used to assess potential therapeutic efficacy of medications under development. *Ex vivo* efficacy screens are an important link between these two activities. In contrast to many behavioral models, *ex vivo* tissue- and cell-based assays are desirable for their simplicity, speed, and capacity to test small drug quantities. To date, little attention has been devoted toward developing and validating neuronal tissue- and cell-based screening platforms that can be used to inform go/no go decisions for subsequent *in vivo* preclinical efficacy testing.

With this SBIR/STTR grant solicitation, NIAAA seeks the development and validation of *ex vivo* screens capable of predicting efficacy test results in preclinical behavioral models of AUD. Such assays should include array of parameters that model aspect/aspects of AUD. They should also be able to discriminate positive and negative control drugs found in the AUD pharmacotherapy literature and be sensitive to drugs with diverse mechanisms of action. In addition, the assays developed under this solicitation should be relatively rapid, simple and capable of generate readily reproducible results.

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Develop Network Pharmacology Strategy for Preclinical Medication Development

The frequent failure of using highly selective drugs for disease treatment has challenged the concept of “one gene, one drug and one disease” and led to the emergence of a new paradigm, network pharmacology, as a drug development and treatment strategy. This strategy combines the knowledge of biological networks with multiple drug targets to simultaneously regulate multiple pathways perturbed by disease conditions. Given the multi-target nature of alcohol action, alcohol use disorder (AUD) arises from brain network perturbation. The network pharmacology/combined pharmacological approach, either using drug combinations or multi-target drugs, may serve as an effective strategy for the treatment of alcohol-induced brain dysfunction and behavior disorders.

NIAAA seeks preclinical development of combined pharmacological approaches to synergistically regulate multiple drug targets for AUD. Areas that may be of interest to small businesses include, but are not limited to:

Objective 1: Develop and validate new target combinations using cellular and animal models.

Objective 2: Prioritize multi-drug targets and identify the effective drug combinations or multi-target drugs for the medication development.

Objective 3: Use high-throughput screening of compound libraries to identify multi-target drugs.

Objective 4: Encourage adaption of low throughput assays to high throughput screening, development of lead compounds, and identification of drug candidate(s) with proper pharmaceutical properties for medication development.

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Novel Tools and Technologies to Detect the Effects of Alcohol on the CNS Structure and Activities

Alcohol affects virtually all of the major neurotransmission systems in the brain by interacting with membrane ion channels, neurotransmitter release machineries and receptors, signal transduction pathways, genes and epigenetic factors. In order to better understand the acute and chronic effects of alcohol and mechanisms of alcohol intoxication and alcohol use disorder, it is important to be able to simultaneously detect the structure and activities of large numbers of neurons with intact connections to facilitate the analysis of neurocircuits. Equally important, structure and activities in different subcellular domains (soma, dendrites, spines, axon, etc.) of CNS neurons need to be monitored with high temporal resolution. Additionally, recent developments indicate that glial cells play more important roles in the normal function of the brain and may be important alcohol targets. There is a need to monitor glia-neuron interactions.

There have been great advances in recent years in chemical and optogenetic methodologies, enabling improved ability to monitor CNS structure and activities in larger numbers and at much higher spatial and temporal resolution. Building upon these advances, NIAAA seeks SBIR/STTR research to develop the novel tools and technologies to detect the effects of alcohol on activities of specific cell types, neuron-glia interactions, and the structure and activities of large numbers of neurons in alcohol-drinking/exposure settings, preferentially with intact neural network. These include, but are not limited to, the following:

- Improving chemical or genetic sensors to detect dynamic changes in calcium, voltage, cAMP etc.
- Developing tools and sensors to monitor structure and activities of neurons and glial cells, and their interactions
- Developing tools and sensors to monitor synaptic activities
- Defining cell types in the neurocircuits
- Developing miniature and nanoscale apparatus and sensors, or miniaturizing and optimizing detection apparatus for the study of alcohol effects
- Developing computational methods for the acquisition and analysis of large scale data

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Research Tools

The NIAAA supports the development of new or improved tools to enhance the ability to conduct alcohol-related laboratory studies on humans and animals and to more effectively analyze data from large databases. Areas that may be of interest to small businesses include, but are not limited to:

- A. Development of novel animal models, including transgenic animals, possessing specific traits of significance for the study of alcohol use disorder (AUD), or for the study of specific pathologic disease states which arise from excessive alcohol consumption.

- B. Development of a hepatocyte cell line capable of maintaining viability and metabolic functions in culture systems for an indefinite period.
- C. Development of specialized cell culture chambers to provide controlled administration of ethanol to *in vitro* cell systems.
- D. Development of experimental systems that mimic organ function, including, but not limited to, co-culture and novel approaches to three dimensional culture.
- E. Development of new methods of ethanol administration to animals that produce precise dose control or that closely mimic types of alcohol exposure occurring in humans, including, but not limited to, binge drinking, acute consumption, moderate consumption and chronic consumption.
- F. Development of ligands which will enhance the potential usefulness of PET and SPECT neuroimaging technologies for the study of the etiology of AUD and related brain pathology.
- G. Development of computational, statistical or bioinformatics tools to organize and manage high throughput data obtained by genomic, functional genomic or other 'omic strategies.
- H. Development of databases, methods for integration of databases, or data analysis systems for alcohol research.

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Data science tools for integrating alcohol research

NIAAA-supported studies in genomics, imaging, electrophysiology and optogenetics, electronic health records, and personal wearable devices presents new challenges in analyses and interpretations and opportunities for discovery. Starting with applications submitted in 2019, all human subject data from NIAAA supported funding is expected to be deposited in publicly accessible archives. This influx of new data, along with publicly available databases and future results, can be analyzed using data science approaches. However, many of the tools needed to answer questions in alcohol research require specific applications, algorithms or toolkits that are not currently available. Data science includes and extends beyond bioinformatics and computational neuroscience to discover new relationships and pathways for complex systems of normal human function and during adaptations due to disorders or disease.

The goal is to develop data science analysis algorithms, mathematical models, and software tools in alcohol research, integrating data across disciplines and clinical and basic sciences realms.

NIAAA seeks

- New algorithms for integrative analysis of current NIAAA and public 'big data' sets, including machine learning, deep learning, artificial intelligence, data mining and other model based and model-free approaches.
- Software applications for data interfaces for aggregation, imputation, harmonization, or visualization of data from multiple sources, including current and future NIH data systems (i.e. NCBI (National Center for Biotechnology Information), dbGaP (database of Genotypes and Phenotypes), National Institute of Mental Health Data Archive), or other studies of alcohol research.
- Algorithms and/or software tools for improving data collection, i.e. smart phone apps, extraction of specific alcohol research parameters from existing large databases and established public health studies, biological sensors or wearable devices.
- Generation and validation of computational and/or systems biology models of alcohol exposure and use on cellular, organ, network, or organism scales. Multiscale models are appropriate, along with models that include data from clinical and basic science research and longitudinal perspectives from initial alcohol exposure and extending through abuse, treatment, recovery and relapse.

Activities and deliverables are expected to use currently available data sets and databases. The generation of new primary data is not supported by this topic.

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Development of novel tools to measure potentially toxic alcohol metabolites and advanced glycation end products in body fluids & other organs

Chronic and binge alcohol intake can cause multiple negative effects on many organs, including the brain, leading to changes in behavior and executive functions. Neuronal dysfunction and brain damage are frequently observed in alcoholics and the lack of objective tools for early detection of alcohol use disorders (AUD) and subsequently the long-time lag, usually in years, between the neurotoxic alcohol exposure and the clinical diagnosis of AUD with mental dysfunction need to be improved. The roles of acetaldehyde (AA), one of the main metabolites of alcohol, in alcohol-induced neurotoxicity in the brain are poorly understood. However, it is known that AA does not cross the blood brain barrier and AA produced in the brain seems to be important in causing neurotoxicity. After prolonged consumption of alcohol, if AA concentration increases in brain, it could potentially react with many cellular proteins and nucleophilic biomolecules to covalent AA-protein or DNA adducts. In addition, early glycation products resulting from excessive alcohol intake, or elevated amounts of glucose or fructose can undergo progressive modifications over time to generate irreversible cross-linked products, called advanced glycation end products (AGEs). AGEs usually alter the functions target proteins and thereby change their physical and properties. Consequently, accumulation of AGEs that have been implicated in the development of many of the pathological sequelae including neurodegenerative diseases such as Alzheimer disease, Parkinson disease, Creutzfeldt-Jakob disease, and amyotrophic lateral sclerosis. Therefore, development of novel techniques to measure potentially toxic alcohol metabolites and its adducts and/ or AGEs would be important early detection of AUD. In this connection, areas of interest include, but are not limited to:

- Develop tools/kits for early detection and to measure AA-adducts and AGEs in serum, CSF, brain and other organs of AUDs in animal models and in pre-clinical settings and their relationship to the biomarkers of neuro-inflammation.
- Develop tools/kits to measure AA-adducts and AGEs, like other oxidative and carbonyl stress end products; advanced lipoperoxidation end products (ALE) and advanced oxidation protein products (AOPP).
- Develop tools to study interaction of AA-adducts and AGEs with RAGE (Receptor for AGEs) and measurement of structural damage to the extracellular matrix and other components.
- Measure AGE–RAGE mediated activation of nuclear factor NF-B, cytokines and growth factors genes and increased expression of neuro-inflammatory molecules.

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Single Cell Genomics (RNA Sequencing): Application to Develop Molecular Markers of Alcohol Use Disorder

Due to advancements in DNA biotechnology, single cell genomics (RNA Sequencing (RNA-Seq)) has become an attractive technique to conduct systematic and unbiased discovery of gene expression profiles. The RNA-Seq approach will reveal the molecular fingerprint of cell states and their predicted signaling circuits in tissues across development and disease. The objective of this SBIR concept is to measure RNA-Seq of human blood cells to identify gene profiles and use them as biomarkers to monitor different stages of alcohol use disorders.

Some examples of the topics could be to:

- Develop rapid and cost-effective RNA seq methods/technologies in human blood cells
- Characterize the gene expression profile in human blood cells of AUD subjects.
- Identify and validate specific gene profile signature as biomarkers in AUD subjects.
- Develop technology/device for rapid screening different stages of alcohol use and AUD

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NIAAA Clinical Trials Topics:

Medications Development

Pharmacotherapy offers a promising means for treating AUD. Currently, there are four Food and Drug Administration (FDA)-approved pharmacotherapies for the treatment of AUD: disulfiram (Antabuse®), oral naltrexone (Revia®), acamprosate (Campral®), and the injectable suspension formulation of naltrexone (Vivitrol®). Another medication, nalmefene (Selincro®), has recently been approved by the European Medicines Agency (EMA). However, given the heterogeneous nature of AUD, many patients have limited or no response to the aforementioned medications. Because of this, developing and evaluating new, more efficacious medications remains a high priority.

During the past five decades, alcohol research has enriched our understanding of the biological mechanisms underlying AUD. Various neurotransmitter systems, neuromodulators, and intracellular signaling pathways have a role in AUD. To date, more than 35 promising targets have been shown to alter alcohol drinking behavior. Some of the new promising targets include, but are not limited to, corticotrophin-releasing factor1 (CRF-1), adrenergic α 1 and α 2, vasopressin 1B, orexin 1 and 2, opioid receptor-like (NOP), opioid kappa, 5-HT₂, GABA-A and GABA-B, metabotropic glutamate (mGluR), glutamate transporter (GLT), nicotinic acetylcholine (nAChR), phosphodiesterase (PDE), glial derived neurotrophic factor (GDNF), and neuroimmune and epigenetic modulators. New medications that bind to these and additional targets are needed.

Candidate medications may include novel and re-purposed compounds. However, grant applications that propose to study compounds already extensively investigated or currently being studied patients with AUD will not be accepted. Thus, applications proposing the use of naltrexone, acamprosate, disulfiram, topiramate, ondansetron, varenicline, gabapentin, and baclofen are not responsive to this topic.

Specific areas of interest include medications that target one or more domains of the addiction cycle, including reward, stress and negative affect, incentive salience, executive function, habituation, and impulsivity/compulsivity.

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Additional targets for pharmaceutical development include, but are not limited to agents that attenuate excessive alcohol use and other symptoms of AUD, e.g., craving, sleep problems, and negative affect as well as those that hold promise for the treatment of alcoholic hepatitis, liver fibrosis, cirrhosis, pancreatitis, cardiomyopathy, or other alcohol-induced tissue damage.

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Technological Methods for the Treatment of Hazardous Drinking and Alcohol Use Disorder

- Develop, improve, and validate ecological momentary assessment (EMA) methods for capturing real-time data for use in alcohol clinical trials and treatment paradigms.
- Use technology (e.g. EMA, brain imaging) and innovative statistical methods (e.g., machine learning, systems science dynamic models) appropriate for analysis of “big data” (i.e., time intensive, multisource data) to inform our understanding of mechanisms underlying the initiation, maintenance, and recovery from problematic drinking in both treatment and naturalistic settings. Leverage unique features of mobile technologies to provide personalized monitoring and just-in-time interventions including but not limited to a variety of racial/ethnic and linguistic populations.
- Optimize existing technologies to increase their utilization and effectiveness in specific treatment contexts (e.g., primary care) and improve patient-provider communication to decrease harmful drinking including across racial, ethnic and linguistic groups.
- Develop and test computerized versions of empirically-supported treatments, including but not limited to in languages other than English.
- Develop and test novel computerized interventions which capitalize on hypothesized brain-based or behavioral mechanisms underlying drinking
- Develop software to train potential treatment professionals on how to provide evidence-based treatments
- Devise novel methods (e.g., Web-mining software of social networking sites) that capture social network information among groups at risk for alcohol use disorder and high-risk drinking, including but not limited to racial and ethnic minority populations.
- Develop and test the efficacy of neurophysiological treatment approaches such as transcranial magnetic stimulation, neurofeedback, and deep brain stimulation.

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Prevention

This area of interest focuses on the development and evaluation of innovative prevention and intervention programs, or specific materials for integration into existing programs, which utilize state-of-the-art technology and are based on currently accepted clinical and behavioral strategies. Applicants are strongly encouraged to consult with research methodologists and statisticians to ensure that state-of-the-art approaches to design, analysis, and interpretation of studies under this topic are used. Areas that may be of interest to small businesses include, but are not limited to:

- Development and evaluation of innovative prevention/intervention programs, or specific materials for integration into existing programs, which utilize state-of-the-art technology and are based on currently accepted clinical and behavioral strategies. Special emphasis should be placed on the needs of high-risk groups, ethnic and minority populations, youth, children of individuals with alcohol use disorder, women, the handicapped, sexual and gender minority populations, and the elderly. Examples of such materials include school-based curricula, interactive videos, computer-based multimedia programs, training manuals for teachers or parents, and community-based programs.
- Development and evaluation of educational materials designed to intervene with the elderly around specific age-related risks for alcohol problems. Particular attention should be given to age-related reductions in alcohol tolerance, interactions between alcohol and prescription and over-the-counter medications, possible exacerbation of some medical conditions common among the elderly, potential biomedical and behavioral consequences of excessive alcohol use, and the role of alcohol in falls, fires, burns, pedestrian and traffic injuries, and other unintentional injuries.

- Development and evaluation of statistical analysis programs tailored to the design and analysis of alcohol prevention-relevant research. Programs could focus on a variety of areas including: imputation of missing data under varying design assumptions; development and application of statistical models suited to small sample sizes common in racial and ethnic minority research; simulation of distributions of outcomes based on varying mixtures of sample populations; application of chronic or infectious disease models to targeted communities; and models of the potential effect of various policy-based interventions, such as increased taxation or reduction of outlet density by license revocation and control.

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Improving the Delivery of Alcohol Treatment Services

NIAAA's treatment services research program studies the organization, management, and financing of alcohol treatment services, and how these affect service availability, access, utilization, cost, and quality. Needed innovations in this area include the development of state-of-the-art technologies, software, and protocols to expand and improve the delivery of evidence-based treatment for alcohol use disorders.

Areas that may be of interest to small businesses include, but are not limited to, the development and assessment of software or tools to:

- assist clinicians in selecting and delivering evidence-based treatments consistent with patient needs and available staff and program resources across racially, ethnically and linguistically diverse populations. Special attention should be paid to promoting fidelity of treatment delivery in real-world contexts. For example: software to enable the creation or use of clinical decision support systems, screening protocols, or patient registries; prescription medication management tools; scripts or guides for delivery of brief interventions; and interactive training resources.
- support long-term recovery, by facilitating patients' continued engagement in recovery support services as an adjunct to or after treatment. For example: software to assist patients in self-management and self-monitoring of drinking behaviors, cues, or triggers, and/or in locating treatment resources or recovery support services.
- assist treatment programs and service agencies in measuring clinically relevant performance indicators or improvements in quality of service provision.
- promote engagement and mitigate burnout among counselors and others engaged in direct treatment service delivery. Tools are needed to reinforce training on therapeutic techniques; provide minimally-obtrusive methods for monitoring and enhancing fidelity of service delivery; engage counselors in mindfulness or other strategies to manage job stress and reduce burnout; and provide front-line counselors with supports essential to maintaining productive therapeutic relationships with patients.

Lori Ducharme, Ph.D.

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Fetal Alcohol Spectrum Disorder (FASD) and Alcohol-Related Birth Defects

FASD is the collective term for the broad array of adverse effects resulting from in utero alcohol exposure. Fetal Alcohol Syndrome (FAS), the first form of FASD discovered and most well-known, is characterized by craniofacial abnormalities, growth retardation, and nervous system impairments that often include mental retardation. Other diagnostic categories include partial FAS, alcohol-related neurodevelopmental disorder (ARND), and alcohol-related birth defects (ARBD). Children and adults with FASD may exhibit multiple cognitive, behavioral, and emotional deficits that impair daily functioning in many domains. The NIAAA supports research leading to improved diagnosis and assessment of prenatal exposure,

impairment and disability, as well as the development of therapeutic interventions, including tools to enhance academic and daily living skills across diverse racial, ethnic and linguistic populations. Areas that may be of interest to small businesses include, but are not limited to:

- Development and assessment of diagnostic and/or screening methods, tools, or technologies to improve earlier identification of fetuses and/or children affected by prenatal alcohol exposure.
- Development and validation of biomarkers that can be used to verify prenatal alcohol exposure in neonates or predict those individuals with neurobehavioral deficits later in life.
- Development and validation of assessment methods to provide more accurate clinical diagnosis of FASD at all life stages.
- Development and testing of skill-building, therapeutic, and education program products that enhance the social, cognitive, adaptive and motor abilities of individuals with FASD.
- Development of neurobehavioral tools or instruments to assess responsiveness of individuals with FASD to medications and/or cognitive/behavioral therapies.
- Development of accurate measures of the responsiveness of children affected by prenatal exposure to alcohol to stress and predictors of vulnerability to alcohol-drinking or other psychopathology during adolescence and adulthood.

- Development and evaluation of educational and training programs designed to enhance the skills of non-professional caregivers in dealing with the problems associated with FAS.
- Development and validation of innovative methods, tools or technology to prevent harmful drinking during pregnancy.

For basic research questions, contact:

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Development of Clinical Biomarkers of Alcohol Exposure and Alcohol-Induced Organ Damage

There is a well-recognized need for prognostic and diagnostic biomarkers of alcohol exposure, for biomarkers of the response to clinical treatment, and for biomarkers to monitor abstinence in high-risk individuals. Quantitative and qualitative markers of high-risk drinking behavior and alcohol-induced tissue damage would greatly improve medical efforts to recognize and treat alcohol-related disorders. Currently, no clinically available laboratory test can reliably diagnose duration of alcohol use or predict the progression of alcohol-induced organ damage. Traditional alcohol biomarkers fail to provide long-term information. More recently developed alcohol biomarkers (ethanol metabolites phosphatidylethanol (PEth), ethyl glucuronide (EtG) and ethyl sulfate (EtS)) display improved sensitivity, specificity, and accuracy over classical biomarkers. Their useful range of a few days (EtG) to 2-4 weeks (PEth) addresses many, but not all, clinical needs.

Effective biomarkers are essential to early detection of alcohol use disorder (AUD) or early stages of organ damage. Early detection will make it possible for patients to consider intervention to prevent long-term medical, psychological, and social consequences of alcohol use.

Several separate, distinct diagnostic settings and circumstances are in need of reliable specific biomarkers. Alcohol biomarkers that address the following are needed:

- Biomarkers that detect cumulative intake of alcohol over a period of months or more; thus a biomarker that is stable over months, reflecting duration and amount of alcohol exposure.
- Biomarkers that detect failure of compliance after withdrawal; thus a biomarker with a short half-life.
- Biomarker signatures of alcohol-induced organ damage, which are likely to be organ-specific.
- Biomarker signatures of familial risk factors for AUD. Early identification of subjects predisposed to AUD will allow for early intervention, possible prevention, and allow the subjects to make informed personal decisions.

Characteristics of useful biomarkers are:

- Sensitivity, specificity, accuracy, and reliability
- Ease of use and acceptability to patient and provider
- Found in easily obtained specimens, such as serum or plasma, urine, saliva, or hair.
- Validity, reproducibility, affordability, and transportability to a variety of settings, including AUD treatment centers, hospitals, primary care offices, or the workplace.

Pattern-based molecular signatures —as opposed to single component biomarkers --may be predicted to provide greater sensitivity, specificity, accuracy, and reliability than single component biomarkers. Thus, high throughput discovery approaches using genomics, epigenomics, transcriptomics, proteomics, metabolomics, lipomics, or glycomics are encouraged.

Also of interest:

- Improvement of turn-around time and cost efficiency of current assays for PEth, EtS, EtG and other alcohol biomarkers
- Design and development of point of care devices, for use in rural or remote primary care and hospital settings.

Small business efforts for improvements at any stage in the biomarker pipeline are of interest, including discovery, validation, development, and implementation to real world settings.

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Alcohol Biosensors

Small business applications proposing to design and produce a wearable device to monitor blood alcohol levels in real time are sought. The device should be able to quantitate blood alcohol level, and interpret and store the data or transmit it to a smartphone or other device by wireless transmission. The device should have the ability to verify standardization at regular intervals and to indicate loss of functionality. The power source should be dependable and rechargeable. Data storage and transmission must be completely secure in order to protect the privacy of the individual. A form of subject identification would be an added benefit. The device can be removable.

The alcohol biosensor device should be unobtrusive, passive in action, appealing to the wearer, and can take the form of clothing, bracelet, jewelry, or any other format located in contact with the human body. A non-invasive technology is preferred. Novel and innovative approaches to detecting blood alcohol, rather than alcohol that has exuded across the skin, are especially encouraged.

Alcohol detection technology for personal alcohol monitoring will serve useful purposes in research, clinical and treatment settings; will play a role in public safety; and will be of interest to individuals interested in keeping track of personal health parameters.

This topic also includes the opportunity to develop appropriate data analysis systems for individual level evaluation as well as for assessment of trends in research populations.

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Alcohol Use and HIV Infection, and HIV Co-infection with HCV, HBV, or TB

Alcohol consumption is widely recognized as a co-factor in the sexual transmission, susceptibility to infection, and progression of infectious diseases, including HIV and HIV co-infection with HCV, HBV, or TB. However, detailed relationships between alcohol use and viral infections, disease progression, anti-viral (or anti-TB) therapy and adverse outcomes, notably in liver disease progression, are less recognized or understood particularly across different racial and ethnic groups. Recent research indicates that inflammatory pathways predominate in liver disease including alcoholic hepatitis whereas adaptive immunity plays a primary role in viral hepatitis, offering multiple targets for novel preventive and therapeutic interventions. Comprehensive studies to improve understanding of the factors underlying alcohol and viral etiologies in liver disease and the impact of anti-viral drugs on liver disease progression are needed. A better understanding of alcohol's effects on liver disease in patients with HIV and co-infections may improve diagnosis and treatment outcomes. NIAAA supports research leading to improved diagnosis and treatment of alcohol-induced disorders in people infected with HIV, and HIV co-infection with HCV, HBV, or TB including but not limited to racial, ethnic and gender identity minorities.

Areas that may be of interest to small businesses include, but are not limited to:

- New preventive and therapeutic approaches designed to protect the liver from alcohol and antiretroviral drug-induced liver injury in patients infected with HIV, and HIV co-infection with HCV, HBV, or TB
- Development of therapies aimed at molecular targets that play a role in the development of alcohol-associated and viral liver and/or lung diseases.
- Development and evaluation of drugs that mitigate the effects of oxidative stress on mitochondrial function thereby preventing liver disease progression.
- Development of biomarkers for individuals who are most prone to alcohol-induced damage in those patients with HIV alone or HIV co-infection.

For basic research questions on alcohol and HIV, and HIV co-infection, contact:

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For clinical or epidemiological questions on HIV, contact:
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Electronic Diagnostic Clinical Assessment of Frailty among HIV+ Individuals with Past and/or Current Alcohol Use Disorder: Severity and Patterns

Innovative self-report, biological, and/or common clinical measures for the identification and diagnosis of frailty related to alcohol use among alcohol-using HIV patients and those with related comorbidities are sought. Measurement of frailty should be calibrated for severity of alcohol use and be both clinically useful and predictive of morbidity and mortality. Applications proposing the development of medical decision-making algorithms to inform clinical care of HIV+ individuals who drink and include frailty index(es) through an internet site are sought. The primary goal of this site will be to provide normative and educational information for providers and patients related to medical care to reduce frailty index(es) related to morbidity and mortality as primarily a useful tool for clinicians who encounter HIV patients who continue to drink and may or may not be compliant with antiretroviral treatment for suppression of viral replication and restoration of immune function.

- Development of this site should be tested in the widest range of individuals, including but not limited to racial, ethnic and gender identity minorities, at various trajectories of progression of HIV disease and patterns of alcohol use. In particular, information from measures should be able to accurately identify individuals who are “sick quitters” and/or have high degree of frailty due to either past and/ or current alcohol use.
- This clinical decision-making tool should be of greatest value to diagnostic assessment and interventions within clinical settings and may include the development of audio, visual, and/or training modules to support the use of appropriate diagnostic index(es) across linguistic groups.
- Support of an electronic internet site for scoring and collection of information on HIV disease characteristics, frailty and patterns of alcohol use in clinical populations, and to provide information on a range of options for assessment of alcohol use severity in HIV+ populations (e.g. brief assessment instruments, calendar methods, biological markers, etc.).
- Identify current and emerging methods for behavioral and/or biological intervention to reduce alcohol use in the context of HIV and improve clinical outcomes.

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Monitoring Alcohol Use among HIV+ Patients

Of particular importance is the measurement of patterns of alcohol use among HIV+ individuals. Wearable alcohol biosensors (see related topic) should be developed to maximize acceptability and minimize stigmatization among the widest range of users. It is expected that the most effective devices will be unobtrusive devices (perhaps wrist-worn) that assess a variety of physiological measures in addition to alcohol use and that interact with smart phone technologies for additional assessment or data management features (e.g. momentary ecological assessment) related to medication adherence for HIV and related comorbidities.

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Data science tools for integrating alcohol research

NIAAA-supported studies in genomics, imaging, electrophysiology and optogenetics, electronic health records, and personal wearable devices presents new challenges in analyses and interpretations and opportunities for discovery. Starting with applications submitted in 2019, all human subject data from NIAAA supported funding is expected to be deposited in publicly accessible archives. This influx of new data, along with publicly available databases and future results, can be analyzed using data science approaches. However, many of the tools needed to answer questions in alcohol research require specific applications, algorithms or toolkits that are not currently available. Data science includes and extends beyond bioinformatics and computational neuroscience to discover new relationships and pathways for complex systems of normal human function and during adaptations due to disorders or disease.

The goal is to develop data science analysis algorithms, mathematical models, and software tools in alcohol research, integrating data across disciplines and clinical and basic sciences realms.

NIAAA seeks

- New algorithms for integrative analysis of current NIAAA and public 'big data' sets, including machine learning, deep learning, artificial intelligence, data mining and other model based and model-free approaches.
- Software applications for data interfaces for aggregation, imputation, harmonization, or visualization of data from multiple sources, including current and future NIH data systems (i.e. NCBI (National Center for Biotechnology Information), dbGaP (database of Genotypes and Phenotypes), National Institute of Mental Health Data Archive), or other studies of alcohol research.
- Algorithms and/or software tools for improving data collection, i.e. smart phone apps, extraction of specific alcohol research parameters from existing large databases and established public health studies, biological sensors or wearable devices.
- Generation and validation of computational and/or systems biology models of alcohol exposure and use on cellular, organ, network, or organism scales. Multiscale models are appropriate, along with models that include data from clinical and basic science research and longitudinal perspectives from initial alcohol exposure and extending through abuse, treatment, recovery and relapse.

Activities and deliverables are expected to use currently available data sets and databases. The generation of new primary data is not supported by this topic.

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Development of novel tools to measure potentially toxic alcohol metabolites and advanced glycation end products in body fluids & other organs

Chronic and binge alcohol intake can cause multiple negative effects on many organs, including the brain, leading to changes in behavior and executive functions. Neuronal dysfunction and brain damage are frequently observed in alcoholics and the lack of objective tools for early detection of alcohol use disorders (AUD) and subsequently the long-time lag, usually in years, between the neurotoxic alcohol exposure and the clinical diagnosis of AUD with mental dysfunction need to be improved. The roles of acetaldehyde (AA), one of the main metabolites of alcohol, in alcohol-induced neurotoxicity in the brain are poorly understood. However, it is known that AA does not cross the blood brain barrier and AA produced in the brain seems to be important in causing neurotoxicity. After prolonged consumption of alcohol, if AA concentration increases in brain, it could potentially react with many cellular proteins and nucleophilic biomolecules to covalent AA-

protein or DNA adducts. In addition, early glycation products resulting from excessive alcohol intake, or elevated amounts of glucose or fructose can undergo progressive modifications over time to generate irreversible cross-linked products, called advanced glycation end products (AGEs). AGEs usually alter the functions target proteins and thereby change their physical and properties. Consequently, accumulation of AGEs that have been implicated in the development of many of the pathological sequelae including neurodegenerative diseases such as Alzheimer disease, Parkinson disease, Creutzfeldt-Jakob disease, and amyotrophic lateral sclerosis. Therefore, development of novel techniques to measure potentially toxic alcohol metabolites and its adducts and/ or AGEs would be important early detection of AUD. In this connection, areas of interest include, but are not limited to:

- Develop tools/kits for early detection and to measure AA-adducts and AGEs in serum, CSF, brain and other organs of AUDs in animal models and in pre-clinical settings and their relationship to the biomarkers of neuro-inflammation.
- Develop tools/kits to measure AA-adducts and AGEs, like other oxidative and carbonyl stress end products; advanced lipoperoxidation end products (ALE) and advanced oxidation protein products (AOPP).
- Develop tools to study interaction of AA-adducts and AGEs with RAGE (Receptor for AGEs) and measurement of structural damage to the extracellular matrix and other components.
- Measure AGE–RAGE mediated activation of nuclear factor NF- κ B, cytokines and growth factors genes and increased expression of neuro-inflammatory molecules.

Contact information:

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Single Cell Genomics (RNA Sequencing): Application to Develop Molecular Markers of Alcohol Use Disorder

Due to advancements in DNA biotechnology, single cell genomics (RNA Sequencing (RNA-Seq)) has become an attractive technique to conduct systematic and unbiased discovery of gene expression profiles. The RNA-Seq approach will reveal the molecular fingerprint of cell states and their predicted signaling circuits in tissues across development and disease. The objective of this SBIR concept is to measure RNA-Seq of human blood cells to identify gene profiles and use them as biomarkers to monitor different stages of alcohol use disorders.

Some examples of the topics could be to:

- Develop rapid and cost-effective RNA seq methods/technologies in human blood cells
- Characterize the gene expression profile in human blood cells of AUD subjects.
- Identify and validate specific gene profile signature as biomarkers in AUD subjects.
- Develop technology/device for rapid screening different stages of alcohol use and AUD

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Direct your general questions about the SBIR/STTR program or scientific/research issues to:

Megan Ryan, M.B.A.
National Institute on Alcohol Abuse and Alcoholism
6700B Rockledge Dr.
Rockville, MD 20852-1705

For administrative and business management questions, contact:

Mr. Jeff Thurston
Grants Management Specialist
National Institute on Alcohol Abuse and Alcoholism
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Email: jeffrey.thurston@nih.gov

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.

NIAID's Division of AIDS (**DAIDS**), Division of Allergy, Immunology, and Transplantation (**DAIT**), and Division of Microbiology and Infectious Diseases (**DMID**) encourage SBIR/STTR applications related to their mission and activities as described below. Questions regarding specific research areas may be addressed to the NIAID Program Officials listed below. General questions about the NIAID SBIR and STTR programs or administrative and business management concerns may be directed to the NIAID Small Business Program Team (<https://www.niaid.nih.gov/grants-contracts/small-business-program-team>).

When possible, *applicants are encouraged to use email* for communication.

For information about NIAID's Small Business Programs, please visit <https://www.niaid.nih.gov/grants-contracts/small-businesses>.

Limited Total Amounts for Phase I and Phase II Awards

Total funding support (direct costs, indirect costs, fee) normally may not exceed \$252,131 for Phase I awards and \$1,680,879 for Phase II awards. Budget requests at or near these hard caps should be well justified. Phase II/IIB applicants should note that NIAID **will not** generally allow awards (of any duration) that exceed \$1,000,000 total costs per year.

NIH has received a waiver from SBA, as authorized by statute, to exceed total award amount hard caps for specific topics. The current list of approved topics can be found in Appendix A of this document or at <https://sbir.nih.gov/funding#omni-sbir>. Approved topics that align with NIAID's priority research areas are listed for each Division; however, a listed topic from any IC is sufficient to consider budget requests that exceed the hard caps. Budget requests exceeding the hard caps must be very well justified in the "Budget Justification" attachment to the Research and Related Budget form and be clearly consistent with the scope of the proposal.

NIAID will allow Phase I applications with budgets of up to \$300,000 total costs per year for up to 2 years; and Phase II or Phase IIB applications with budgets of up to \$1,000,000 total costs per year for up to 3 years. Requests for these budget levels must be very well-justified. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

Applicants are strongly encouraged to contact the NIAID SBIR/STTR Program Team prior to submitting any application in excess of the hard caps. NIAID staff cannot provide prior approval to exceed hard caps. Compliance with a pre-approved topic will be confirmed at time of award by the applicant's Grants Management Specialist and Program Officer.

NIAID will generally not fund applications at budget levels exceeding these budget guidelines. For budgetary, administrative, or programmatic reasons, NIAID may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

Phase IIB Competing Renewal Awards

NIAID welcomes Phase IIB Competing Renewal Applications (**SBIR only**) for NIAID Phase II awards via the Omnibus Solicitation for SBIR Grant Applications and other NIAID SBIR Funding Opportunity Announcements that explicitly allow Phase IIB Applications. NIAID Phase II funding limits (as described above) apply unless otherwise stated in the funding opportunity announcement (FOA).

Research Topics of Interest to NIAID

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s		X	
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44): https://grants.nih.gov/grants/guide/pa-files/PAR-18-632.html
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		NIAID Clinical Trial Implementation Cooperative Agreement (U01): https://grants.nih.gov/grants/guide/pa-files/PAR-18-633.html NIH Research Project Grant (Parent R01 Clinical Trial Required): https://grants.nih.gov/grants/guide/pa-files/PA-19-955.html (low risk clinical trial proposals, only)

NIAID Non-Clinical Trials Topics:

Division of AIDS

The Division of AIDS (DAIDS) supports a global research portfolio to advance biological knowledge of HIV/AIDS, its related co-infections, and co-morbidities. With the ultimate goal of creating an “AIDS-Free Generation,” the division develops and supports the infrastructure and biomedical research needed to: 1) halt the spread of HIV through the development of an effective vaccine and biomedical prevention strategies that are safe and desirable; 2) develop novel approaches for the treatment and cure of HIV infection; 3) treat and/or prevent HIV co-infections and co-morbidities of greatest significance; and 4) partner with scientific and community stakeholders to efficiently implement effective interventions.

Director: Dr. Carl Dieffenbach

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Basic Sciences Program

Supports basic and applied research on the causes, diagnosis, treatment, and prevention of HIV and AIDS.

Director: Dr. Diana Finzi

Telephone: 301-451-2598

Email: Dfinzi@niaid.nih.gov

- A. ***Epidemiology Branch.*** Population-based research, modeling, and comparative effectiveness studies (not including clinical trials) that assess the natural history, biologic, and clinical course of HIV/AIDS, and related outcomes, and could advance treatment and prevention of HIV. Specific interests include phylodynamics and other factors related to HIV transmission and associated biological and behavioral factors, basic research on immunology, virology, and antiretroviral therapy, issues surrounding care for HIV and other co-morbidities, interactions and impact on clinical outcomes. Development of novel electronic tools, including devices and computer programs to enhance behaviors, such as treatment adherence or uptake of treatment guidelines, is also of interest.

Contact: Lori Zimand

Telephone: 240-627-3212

Email: lzimand@niaid.nih.gov

- B. ***Basic Research Branch.*** Innovative technologies for detection of acute HIV infection or HIV rebound following long-term suppression of viremia. Identification and validation of new targets for discovery or design of strategies to prevent HIV transmission, inhibit replication, control viremia in the absence of antiretroviral drugs, or eradicate reservoirs of HIV that persist despite long-term antiretroviral therapy. Innovative approaches for monitoring changes in the size of the persistent HIV reservoir.

Contact: Dr. Karl Salzwedel

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Email: salzwedelkd@niaid.nih.gov

- C. ***Targeted Interventions Branch.*** Discovery and development of small molecule inhibitors with novel or underexplored mechanisms of action using standard and high-throughput technologies; cell-based and gene therapies; RNA-based therapeutics; next-generation biologics; novel targeting and delivery vehicles for agents active against HIV; therapeutic vaccines and monoclonal antibodies; protein chemistry-based anti-HIV approaches; assays to quantitate latent virus; animal models to facilitate evaluation of agents to treat or cure HIV infection.

Contact: Dr. Brigitte Sanders
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Vaccine Research Program

Supports the discovery, development and clinical evaluation of an HIV/AIDS vaccine.

Director: Dr. Mary Marovich
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- A. **Vaccine Clinical Research Branch (VCRB).** Research areas: (1) phase I, II, and III domestic and international clinical trials of candidate AIDS vaccines; (2) evaluation and characterization of immune responses in HIV-infected and uninfected immunized volunteers, using micro and macro assays; and (3) studies to identify, validate, and standardize immunologic and virologic markers for monitoring response of participants in vaccine clinical trials.

Contact: Dr. Jim Lane
Telephone: 240-627-3033
Email: laneji@mail.nih.gov

- B. **Preclinical Research and Development Branch (PRDB).** Preclinical research and development of candidate AIDS vaccines, delivery methods, novel vaccine vectors, and adjuvants for the prevention of AIDS; promotion and evaluation of safety and efficacy of the prevention modalities, especially novel vaccine concepts identified in preclinical models including studies using non-human primates, humanized mouse, and other animal models; genetic and immunologic variation studies in relation to AIDS vaccine development; and mucosal and innate immunity in SIV, HIV, and SHIV models.

Contact: Dr. Anjali Singh
Telephone: 240-627-3030
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- C. **Vaccine Translational Research Branch (VTRB).** VTRB enables, facilitates, and operationalizes HIV vaccine translational research by advancing innovative vaccine concepts and scalable unit operations into the development of cGMP manufactured, vialled products for clinical testing. VTRB's efforts to accelerate the development of preventive HIV-1 vaccines involves identifying, supporting and advancing: (a) cell line development to increase Env expression, production, quality, and yield; (b) evaluation of phase-appropriate upstream and downstream manufacturing processes; (c) scalable and prototype process development and purification platforms for viral vectors and HIV-1 Env proteins; (d) cGMP manufacturing of broad portfolio of vaccine products ranging from complex HIV Env protein immunogens, nanoparticle-based vaccines, viral vectors, virus-like particles (VLP), DNA and mRNA vaccines, monoclonal antibodies (neutralizing and non-neutralizing) for testing in early phase human clinical trials; (e) procuring and manufacturing new and/or alternative adjuvant analogs with similar agonist functions as those currently available for optimal immune response; (f) novel and emerging nanoparticle antigen and adjuvant delivery modalities and dosage forms, coformulation technologies and platforms for immunization; (g) antigen-adjuvant formulation development, analytics development to support product characterization, in-process operations, release, and stability testing; and (h) preclinical safety and toxicology testing.

Contact: Dr. Michael Pensiero
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Email: mpensiero@niaid.nih.gov

Therapeutics Research Program

Develops and oversees research and development of therapies for HIV disease, including complications, co-infections and co-morbidities, in adults.

Director: Dr. Peter Kim
Telephone: 301-451-2761
Email: peter.kim2@nih.gov

- A. ***Drug Development and Clinical Sciences Branch.*** Preclinical development of experimental therapies for HIV, TB and other HIV/AIDS-related infectious diseases; including long-acting/extended release approaches; maintenance of a database of potential anti-HIV and anti-opportunistic infection compounds; immunologic, virologic, and pharmacologic research related to the design and conduct of clinical trials; development and evaluation of practical and affordable tests to measure viral load, drug toxicities, and drug resistance to monitor populations in resource-poor settings; development of tests to detect early infection in seropositive HIV-infected adult and pediatric individuals.

Contact: Dr. Joe Fitzgibbon
Telephone: 240-627-3088
Email: jfitzgibbon@niaid.nih.gov

- B. ***HIV Research Branch.*** Clinical research of treatments for acute and chronic HIV infection and approaches to achieve sustained remission or cure; strategies to augment HIV-specific immune responses, general host immunity to control or clear HIV infection, and prevention of HIV disease-associated end organ disease.

Contact: Tia Morton
Telephone: 240-627-3073
Email: frazierti@niaid.nih.gov

- C. ***Complications & Co-Infections Research Branch.*** Preclinical and clinical research to evaluate new or improved therapies for the treatment and prevention of HIV-related serious infectious and non-infectious complications in HIV-infected adults.

Contact: Dr. Chris Lambros
Telephone: 240-627-3093
Email: clambros@niaid.nih.gov

- D. ***For evaluation of therapeutic agents or diagnostics for hepatitis B in HIV infected in adults.***

Contact: Dr. Chris Lambros
Telephone: 240-627-3093
Email: clambros@niaid.nih.gov

- E. ***Tuberculosis Clinical Research Branch.*** Translational and clinical research for tuberculosis, with and without HIV co-infection, to facilitate the development of biomarkers/diagnostics, therapies, and prevention/vaccines.

Contact: Dr. Lakshmi Jayashankar
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Prevention Science Program

Supports basic research on mechanisms of HIV transmission supportive of new biomedical strategies for interrupting transmission. Supports domestic and international phase I, II, and III clinical trials to evaluate HIV/AIDS prevention strategies, including microbicides, chemoprophylactic agents, and other biomedical and behavioral risk reduction interventions.

Director: Dr. Sheryl Zwierski
Telephone: 301-402-4032
Email: szwerski@niaid.nih.gov

- A. **Preclinical Microbicides and Prevention Research Branch.** Preclinical development of non-vaccine biomedical HIV prevention products including topical microbicides, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and multipurpose prevention technologies (MPT). Emphasis on drug delivery systems (DDS) designed to achieve systemic protection for ≥ 1 month. Development of shorter duration products, which address a compelling specific public health need. Key populations are adolescents, cisgender women, men who have sex with men (MSM), and transgender people.

Chief: Dr. Jim Turpin
Telephone: 301-451-2732
Email: jturpin@niaid.nih.gov

- B. **Clinical Microbicide Research Branch.** Clinical development of promising microbicides to prevent HIV infection with the ultimate goal to advance safe, effective, and acceptable microbicide products toward licensure.

Chief: Dr. Roberta Black
Telephone: 301-496-8199
Email: rblack@niaid.nih.gov

- C. **Clinical Prevention Research Branch.** Development of safe and effective non-vaccine biomedical and integrated HIV prevention interventions to reduce the number of new HIV infections in adults and adolescents. Support the development of HIV incidence assays, biomarkers of adherence, mathematical modeling, and other tools needed to accomplish these objectives.

Chief: Dr. David Burns
Telephone: 301-435-8896
Email: burnsda@niaid.nih.gov

- D. **Maternal, Adolescent and Pediatric Medicine Branch.** Therapies for cure, management, treatment and prevention of HIV and HIV-associated complications in pregnant women, infants, children, and adolescents. Strategies to reduce transmission of HIV and HIV co-infections from mother to child.

Contact: Judi Miller, R.N.
Telephone: 240-292-4801
Email: jmillera@niaid.nih.gov

Division of Allergy, Immunology, and Transplantation

The Division of Allergy, Immunology, and Transplantation (DAIT) supports studies of the immune system in health and the cause, pathogenesis, diagnosis, prevention, and treatment of disease caused by immune dysfunction.

Director: Daniel Rotrosen, M.D.
Telephone: 301-496-1886
Email: drotrosen@niaid.nih.gov

- A. **Allergy, Asthma and Airway Biology Branch.** Conditions of interest: asthma, food allergy, eosinophilic esophagitis and gastroenteritis in relation to food allergy, atopic dermatitis, urticaria, rhinitis, rhinosinusitis, drug allergy, sepsis. The Branch supports basic and clinical studies investigating mechanisms of disease and new approaches to diagnose, treat or

prevent these conditions. Special interest for SBIR/STTR includes a) the development of biomarkers as diagnostic markers, markers of disease severity and predictive markers for treatment effectiveness, particularly of immunologic interventions such as allergen immunotherapy for food and respiratory allergy; b) the development of new forms of allergen immunotherapy aiming at increased tolerogenic immune responses and decreased allergenicity.

Chief: Alkis Togias, M.D.

Telephone: 301-496-8973

Email: togiasa@niaid.nih.gov

- B. **Basic Immunology Branch.** The Branch supports basic and clinical research in the following areas: adjuvant discovery and development; origin, maturation, and interactions of immune cells; immune cell receptors, and ligands; cytokine biology; molecular basis of immune activation, antigen recognition, and immune tolerance; immune response regulation; hematopoiesis and stem cell biology; computational immunology; immunologic mechanisms associated with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome; enhancement of vaccine effectiveness in neonates and adults, and basic immunology of vaccines and immunotherapeutics as medical countermeasures for biodefense. Special interests for SBIRs include: adjuvant discovery and/or development; bioinformatics tools for immune epitope predictions/visualization, and/or for the analysis of multi-parameter or systems immunology data; development of immunologic reagents for analysis of immunity in non-mammalian (e.g., frogs, fish, *C. elegans*) and under-represented mammalian (e.g., pig, ferret) models, and development of novel/improved methods to analyze human immune responses from limited amounts of human sample (tissue, cells, serum, etc.).

Chief: Dr. Alison Deckhut-Augustine

Telephone: 301-496-7551, Fax: 301-480-2381

Email: augustine@niaid.nih.gov

- C. **Autoimmunity and Mucosal Immunology Branch.** Preclinical and clinical research to develop and improve therapies for the treatment of autoimmune diseases and primary immune deficiencies (not HIV); basic research of autoimmune disease mechanisms and biomarkers; immunotherapy of disease processes; disorders mediated by lymphocyte products; and mucosal immunity.

Chief: Dr. James McNamara

Telephone: 301-451-3121, Fax: 301-480-1450

Email: jmcnamara@niaid.nih.gov

- D. **Transplantation Branch.** Preclinical and clinical research in organ, vascularized composite tissue and cellular transplantation: acute and chronic graft rejection, allogeneic and xenogeneic transplantation, development of immunomodulatory agents to prevent and treat graft rejection and to promote acute and long term graft acceptance and immunologic tolerance, genomics of the alloimmune response, graft versus host disease for hematopoietic stem cell transplantation, minor histocompatibility antigens, complications of immunosuppression in transplantation, and major histocompatibility complex (MHC) region genomics, technologies for MHC typing, and clinical applications of high-resolution HLA typing.

Chief: Nancy D. Bridges

Telephone: 301-496-5598

Email: nbridges@niaid.nih.gov

- E. **Radiation Countermeasures Program.** The Radiation and Nuclear Countermeasures Program will consider preclinical research on the identification and evaluation of medical countermeasures (MCMs) for public health emergencies involving ionizing radiation, through: 1) development of mitigators and therapeutics for acute radiation syndrome, delayed effects of acute radiation exposure, and/or radiation combined injury; 2) advancement of radionuclide-specific therapies, including chelating, blocking, or other novel decorporation agents; 3) improvement of methods for accurate, high-throughput radiation biodosimetry; 4) identification of biomarkers of organ-specific radiation

injury; and 5) assessment of biomarkers of radiation injury in special populations and formulation of MCMs for administration to these affected groups.

Acting Chief: Charles Hackett, Ph.D., Associate Director

Telephone: 301-496-1886

Email: CHackett@niaid.nih.gov

Division of Microbiology and Infectious Diseases

The Division of Microbiology and Infectious Diseases (DMID) supports research to better understand, treat, and ultimately prevent infectious diseases caused by virtually all infectious agents, except HIV. DMID supports a broad spectrum of research from basic molecular structure, microbial physiology and pathogenesis, to the development of new and improved vaccines and therapeutics. DMID also supports medical diagnostics research, which is defined as research to improve the quality of patient assessment and care that would result in the implementation of appropriate therapeutic or preventive measures. DMID does not support research directed at decontamination or the development of environmentally oriented detectors, whose primary purpose is the identification of specific agents in the environment. Note that some of the organisms and toxins listed below are considered NIAID priority pathogens or toxins for biodefense and emerging infectious disease research.

Division Small Business Representative: Dr. Barbara Mulach

Telephone: 240-627-3322

Email: bmulach@niaid.nih.gov

Division Small Business Representative: Dr. Alyssa Werner

Telephone: 301-761-7525

Email: alyssa.werner@nih.gov

A. *Bacteriology and Mycology Branch.*

The branch oversees research and product development related to:

- Bacterial infections with emphasis on hospital-related infections, including *Acinetobacter*, *Klebsiella*, *Serratia*, *Legionella*, *Pseudomonas*, *Aeromonas*, *Enterobacter*, *Proteus*, non-enteric *E. coli*, staphylococci, enterococci, actinomycetes among others;
- Bacterial zoonoses, including plague, anthrax, tularemia, glanders, melioidosis, Lyme disease, rickettsial diseases, anaplasmosis, ehrlichiosis and Q fever, and leptospirosis;
- Fungal infections including *Candida*, *Aspergillus*, *Cryptococcus*, *Coccidioides*, *Histoplasma*, *Blastomyces*, *Pneumocystis*, *Microsporidia*, and other pathogenic fungi.

Research is encouraged in the following general areas: (1) vaccines, adjuvants, therapeutics and diagnostics (including target identification and characterization, device or apparatus development, novel delivery, and preclinical evaluation); (2) strategies to combat antibacterial and antifungal drug resistance; (3) applied proteomics and genomics; (4) host-pathogen interactions, including pathogenesis and host response; (5) genetics, molecular, and cell biology; and (6) microbial structure and function.

Research on all of the above is welcome, but the following areas are of particular interest to the branch:

- Vaccines, therapeutics, and medical diagnostics for hospital infections
- Adjunctive therapies and non-traditional approaches to combat and treat antimicrobial resistance
- Diagnostics for invasive fungal diseases
- Novel approaches for the diagnosis of Lyme disease

- Vaccines against Coccidioidomycosis

Contact: Dr. Alec Ritchie
Telephone: 240-627-3356
Email: aritchie@niaid.nih.gov

B. ***Enteric and Sexually Transmitted Infections Branch.***

Enterics Section:

Research portfolios focus on enteric bacterial pathogens such *Campylobacter* spp., *Clostridia* spp., pathogenic *Escherichia coli*, *Helicobacter* spp., *Listeria* spp., *Vibrio* spp., *Salmonella* serovars, *Shigella* spp., enteric *Yersinia* spp., and *Bacteroides* spp. (enterotoxins only). Also within the branch portfolio are toxins such as ricin toxin, *Staphylococcus* enterotoxin B, and botulinum neurotoxins; gastrointestinal diseases associated with diarrhea, dysbiosis; and the gastrointestinal microbiota and microbiome.

Special emphasis areas include:

- Development of pediatric vaccines to prevent the major worldwide causes of diarrhea; vaccines against neurotoxins and enterotoxins, and vaccines for enteric diseases where waning immunity is an issue (i.e., *C. difficile* and *Salmonella* infection).
- Development of antimicrobials and antivirals that focus on novel targets such as host-pathogen interactions to combat the development of resistance; therapies that target toxins once they enter cells; and therapies to treat recurrent diseases.
- Development of simple, rapid point-of-care diagnostic tools for the simultaneous identification of multiple pathogens that includes their antimicrobial resistance profiles; diagnostics for use in low-resource settings, especially for typhoid; and novel diagnostics that differentiate *C. difficile* colonization from infection.

Sexually Transmitted Infections Section:

Areas of emphasis include the development of medical diagnostics including better and more rapid multiplex point of care tests, ability to rapidly determine antibiotic sensitivity, and novel technologies enabling testing in low resource settings while maintaining high sensitivity/specificity; development of new classes of antimicrobials and non-antimicrobial treatment approaches, particularly those focused on reducing the development of antibiotic resistance; novel delivery systems for multipurpose prevention technologies, vaccines and therapeutics for Sexually Transmitted Infections (STIs) and other reproductive tract syndromes such as bacterial vaginosis and pelvic inflammatory disease; understanding vaginal ecology and immunology and approaches to developing synthetic microbiota for use as biotherapeutics or as adjunct therapy to antibiotic treatment; development of epidemiologic and behavioral strategies to reduce transmission of STIs; developing and evaluating interventions and products to better serve adolescents, medically underserved populations, and minority groups who are disproportionately affected by STIs; development of multipurpose prevention technologies to prevent STIs, HIV, and unintended pregnancies; better understanding of the role of STIs in infertility, premature birth, and adverse outcomes of pregnancy and how to improve outcomes; and better understanding of the role of STIs in HIV transmission and the role of HIV in altering the natural history of STIs.

Contact: Dr. Tom Hiltke
Telephone: 240-627-3275
Email: thiltke@niaid.nih.gov

C. ***Parasitology and International Programs Branch.***

Research areas: (1) protozoan infections, including amebiasis, cryptosporidiosis, cyclosporiasis, giardiasis, leishmaniasis, malaria, trypanosomiasis, toxoplasmosis; helminth infections, including cysticercosis, echinococcosis, lymphatic filariasis, schistosomiasis, onchocerciasis, others (e.g., roundworms, tapeworms, and flukes); invertebrate vectors/ectoparasites, black flies, sandflies, tsetse flies, mosquitoes, ticks, snails, and mites; (2) parasite biology (genetics, genomics, physiology, molecular biology, and biochemistry); (3) protective immunity, immunopathogenesis, and evasion of host defense; (4) clinical, epidemiological, and natural history studies of parasitic diseases; (5) research and development of vaccines, drugs, immunotherapeutics and immunoprophylaxis, and medical diagnostics; and (6) vector biology and management, mechanisms of pathogen transmissions.

Research on the above is welcome, but research on the following is of particular interest to the branch:

- New drug discovery or re-purposing of existing drugs to treat parasitic diseases
- Highly sensitive diagnostics tools for parasitic diseases
- Vaccines, monoclonal antibodies, and vaccine technologies applicable to prevention or elimination of parasitic diseases
- Technologies or approaches that address arthropod vector monitoring, management, and control, to prevent transmission of vector-borne pathogens to humans

Contact: Dr. Annie Mo

Telephone: 240-627-3320

Email: moa@niaid.nih.gov

D. **Respiratory Diseases Branch.**

Research areas include: (1) **viral respiratory diseases** caused by influenza viruses, human coronaviruses including SARS, MERS, and novel emerging coronaviruses, rhinoviruses, respiratory syncytial virus and other related paramyxoviruses; (2) **mycobacterial diseases**, including tuberculosis (TB) caused by bacteria of the *Mycobacterium tuberculosis* complex, leprosy, Buruli ulcer and non-tuberculous mycobacterial (NTM) diseases, particularly pulmonary infections in persons not afflicted with HIV/AIDS; (3) **other bacterial respiratory diseases** including bacterial pneumonia, pertussis, Group A and B streptococcal diseases, meningitis, upper respiratory infections, acute exacerbations of chronic obstructive pulmonary disease cystic fibrosis; and (4) **mixed viral/bacterial respiratory infections.**

Special emphasis areas include:

- Development of new or improved antimicrobials (especially for antimicrobial-resistant pathogens) and antivirals, including immunotherapeutics, immunomodulators, and host-directed therapies to augment anti-infectives;
- Methodologies for rapid, point-of-care evaluation of drug levels in TB patients to facilitate therapeutic drug monitoring;
- New or improved vaccines (with and without adjuvants);
- Improved delivery systems and formulations for drugs/vaccines;
- Microbial and host biomarkers and biosignatures suitable for diagnostic tests;
- Rapid multiplex diagnostic tests, including low cost point-of-care, or other tools to detect infection prior to active disease and to identify drug resistance;
- Diagnostics to distinguish viral from bacterial infections.

There is particular need for preventive and treatment countermeasures for influenza, including universal vaccine platforms and broad-spectrum antivirals; for diagnostics (including drug

susceptibility tests), novel therapeutics, and vaccines (including adjuvants) against *Mycobacterium tuberculosis* (TB); for novel TB diagnostics; particularly diagnostics suitable for diagnosis in pediatric populations and rapid drug susceptibility testing; for relevant diagnostics, preventive and curative interventions against non-HIV associated pulmonary Non-tuberculous mycobacteria (NTM); and for the prevention, diagnosis, and treatment of *Bordetella pertussis*, *Group A streptococcus*, and *Streptococcus pneumoniae* infections and other antibacterial resistant infections.

Contact: Dr. Xin-Xing Gu
Telephone: 240-627-3265
Email: guxx@niaid.nih.gov

E. **Virology Branch.**

The Virology Branch focuses on:

- a. Acute viral infections: arthropod-borne (ex.: tick-borne) and rodent-borne viral diseases (including Dengue, Zika, West Nile, Japanese encephalitis, Chikungunya, yellow fever, hantavirus, Crimean-Congo Hemorrhagic fever, severe fever with thrombocytopenia syndrome (SFTS), Heartland virus, Bourbon virus, Tick-borne Encephalitis virus (TBE), Powassan virus, LaCrosse, Rift Valley Fever virus, etc.), viral hemorrhagic fevers (Ebola, Lassa fever, etc.), Nipah, Hendra, measles, polio, coxsackie virus, enteroviruses, poxviruses, rabies, rubella, Astroviruses, Caliciviruses, Rotavirus;
- b. Persistent viral infections: adenoviruses, BK virus, bornaviruses, coronaviruses, herpesviruses, human T-lymphotrophic virus, JC virus, human papillomaviruses, parvoviruses, emerging human polyomaviruses;
- c. Acute infections with hepatitis viruses A, B, C, D and E (HAV, HBV, HCV, HDV, and HEV); chronic infections with hepatitis viruses, B, C, D and E;
- d. Transmissible Spongiform Encephalopathies (TSE).

Areas of emphasis for SBIR/STTR applications include:

- Development of vaccines;
- Development of techniques to improve vaccine stability;
- Approaches to identify antiviral targets and agents;
- Chemical design and synthesis of novel antiviral agents;
- Development of therapeutic interventions;
- Development and validation of point of care assays for disease diagnosis and to measure response to therapy;
- Development of new preclinical animal model systems that predict clinical efficacy of vaccines, therapeutics and diagnostics.

The Virology Branch does not support applications covering environmental detection and decontamination.

Contact: Dr. Mindy Davis
Telephone: 301-761-6689
Email: mindy.davis@nih.gov

NIAID Clinical Trials Topics:

NIAID will generally consider clinical trial proposals consistent with the topics listed above. However, applicants are strongly encouraged to consult with NIAID Program Staff at least 10 weeks before the receipt date.

For further information, please consult NIAID's Investigator-Initiated Clinical Trial Resources page:
<https://www.niaid.nih.gov/grants-contracts/investigator-initiated-clinical-trial-resources>

For more information on NIAID's SBIR/STTR research topics, program policy or to identify NIAID Subject Matter Experts for a specific topic, please contact:

Dr. Natalia Kruchinin
SBIR/STTR Program Coordinator
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Phone: 240-669-2919
Email: kruchinn@niaid.nih.gov

General Inquiries and subscription requests for NIAID's SBIR/STTR List-Serv: NIAIDSBIR@mail.nih.gov

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

The mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases.

For additional information about areas of interest to the NIAMS, please visit NIAMS Long Range Plan at http://www.niams.nih.gov/About_Us/Mission_and_Purpose/long_range.asp.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NIAMS may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Generally, NIAMS does not fund Phase I applications with a total cost greater than \$252,131 or a project period greater than 2 years and Phase II applications with a total cost greater than \$1,680,879 or a project period greater than 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application. It is not the intent of NIAMS to support clinical trials through the SBIR/STTR mechanism. Applicants who wish to submit clinical trials applications to the NIAMS are encouraged to utilize one of the NIAMS FOAs listed [HERE](#).

Research Topics of Interest to NIAMS

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?	X	

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s		X	
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		https://www.niams.nih.gov/grants-funding/conducting-clinical-research/investigator-clinical-trial-policies .

NIAMS Non-Clinical Trials Topics:

The NIAMS small business program supports research and development of products and services for prevention, diagnosis and treatment of rheumatic, musculoskeletal and skin diseases. The research topics include, but are not limited to, the following:

- A. ***Rheumatic Diseases.*** The NIAMS supports research on rheumatic and related diseases including rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), Lyme arthritis, viral arthritis, gout, calcium pyrophosphate deposition disease (CPDD), spondyloarthropathies, and systemic autoimmune diseases such as systemic lupus erythematosus (SLE), systemic scleroderma (SSc), and autoimmune myositis.
- B. ***Musculoskeletal Diseases.*** The musculoskeletal system is composed of the skeleton, the muscles, and connective tissues such as cartilage, tendon, and ligament. The NIAMS supports research aimed at improving the diagnosis, treatment, and prevention of diseases and injuries of the musculoskeletal system and its component tissues. The topics in this area include research on musculoskeletal diseases such as osteoporosis, osteoarthritis, muscular dystrophy, and osteogenesis imperfecta, tissue engineered products, orthopedic devices and implants, and sports medicine and fitness.
- C. ***Skin Diseases.*** The NIAMS supports research on a wide range of skin diseases and conditions including chronic inflammatory skin diseases such as psoriasis, rosacea, acne vulgaris, and atopic dermatitis and autoimmune diseases such as pemphigus, vitiligo, and alopecia areata. The NIAMS also supports research on skin repair and regeneration in treatment of chronic wounds and reducing scar formation. Skin cancer is an area of overlap with the National Cancer Institute (NCI), with the NIAMS focus on the response of keratinocytes to UV light and early stages in the development of non-melanoma skin cancer and products for prevention of melanocyte tumorigenesis.

This is not an inclusive list of all research topics covered by the NIAMS. To learn more, please visit the NIAMS supported scientific areas at <https://www.niams.nih.gov/grants-funding/funding-opportunities/supported-scientific-areas>

Special Emphasis Areas of Interest to Small Businesses:

NIAMS supports all Research and Development activities within its mission, Particular areas of programmatic interest relative to small business initiatives include, but are not limited to:

- A. Innovation research on rare musculoskeletal, rheumatic and skin diseases
- B. Multiplex assay development for arthritis and musculoskeletal and skin diseases
- C. Lab to marketplace: translation of scientific discoveries in NIAMS mission areas from labs into products on the market
- D. Test and/or validation of novel, state-of-the-art candidate biomarker platforms for predicting the onset and progression of inflammatory diseases of interest to the NIAMS and for determining the pharmacodynamics, safety and/or efficacy of therapeutic agents targeting those diseases.

NIAMS Clinical Trials Topics:

NIAMS does not participate in the SBIR/STTR clinical trial funding opportunities. NIAMS NON-SBIR/STTR clinical trial funding opportunities support all research within the NIAMS mission areas.

For general SBIR/STTR program information, contact:

Dr. Xibin Wang, NIAMS SBIR/STTR Coordinator
Telephone: 301-451-3884, Fax: 301-480-1284
Email: wangx1@mail.nih.gov

For administrative and business management questions, contact:

Ms. Aleisha S. James
Telephone: 301-594-3968, Fax: 301-480-5450
Email: jamesaleisha@mail.nih.gov

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to improve health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and medical care. This is achieved through: research and development of new biomedical imaging and bioengineering techniques and devices to fundamentally improve the detection, treatment, and prevention of disease; enhancing existing imaging and bioengineering modalities; supporting related research in the physical and mathematical sciences; encouraging research and development in multidisciplinary areas; supporting studies to assess the effectiveness and outcomes of new biologics, materials, processes, devices, and procedures; developing technologies for early disease detection and assessment of health status; and developing advanced imaging and engineering techniques for conducting biomedical research at multiple scales.

Research Topics of Interest to NIBIB

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s		X	

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		https://www.nibib.nih.gov/research-funding/funding-opportunities
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		https://www.nibib.nih.gov/research-funding/funding-opportunities

NIBIB Non-Clinical Trials Topics:

- A. **Artificial Intelligence, Machine Learning, and Deep Learning.** Design and development of intelligent and innovative algorithms, software, methods, and computational tools to enhance analysis of complex medical images and data. Relevant technologies include those that facilitate organization, representation, retrieval, analysis, recognition, and classification of biomedical and biological data and images. Unsupervised and semi-supervised techniques and methodologies are of particular interest.
- B. **Bio-Electromagnetic Technologies.** Development of technologies that use static or dynamic electromagnetic fields for sensing, imaging, or therapeutic effects. The emphasis is on increasing the sensitivity, spatial/temporal resolution, efficacy, or safety of bioelectromagnetic devices through the development of novel hardware, method of operation, or pre-/post-processing techniques for single modalities or the combination of multiple modalities. This program may support the development of magnetic particle imaging, electrical impedance tomography, electroencephalography, magnetoencephalography, electromagnetic-field-induced hyperthermia/ablation, and microwave/terahertz imaging, for example.
- C. **Biomaterials and Biomolecular Constructs.** Development of biomaterials and biomolecular constructs that can be used for a broad spectrum of biomedical applications across a spectrum of diagnostic, therapeutic, imaging, and interventional applications. Research that is supported includes the design, synthesis, characterization, processing and manufacturing of these materials as well as the design and development of devices constructed of these materials and their clinical performance.
- D. **Biomedical Informatics.** Development of structures and algorithms to improve the collection, annotation, aggregation, anonymization, classification, retrieval, integration, analysis, and dissemination of quantitative and qualitative biomedical data. Examples of informatics tools and resources supported by this program are: biostatistics methods for bioinformatics, meta databases and integrative services, digital biomarkers, information-driven computer-aided diagnosis and decision support systems, digital atlases, data mining, large scale biomedical image/information databases, data fusion, and hyperspectral data analysis and -omics. This program is intended to support NIBIB's other program areas in biomedical imaging and bioengineering researchers.
- E. **Biosensors and Physiological Detectors.** Development of sensor technologies for the detection and quantitation of clinically relevant analytes in complex matrices. Application areas include (among

others) diagnostic, therapeutic, imaging, and other biomedical applications. Technologies encompassed include microfluids for cell sorting, DNA sensors for liquid biopsy, small molecule detectors for implantable devices, haptic feedback touch sensors, and optical detectors for in vitro tissue monitoring, among others.

- F. **Connected Health-Mobile Health and Telehealth.** Development of enabling technologies that emphasize the integration of wireless technologies with human and biological interfaces. This program includes the development of software and hardware for telehealth and mobile health studies. This program includes the input and delivery of healthcare information digitally for the analysis or monitoring of health or disease status. The emphasis is on developing mobile health technologies driven by clinical needs and integrating these technologies in healthcare delivery, wellness, and daily living.
- G. **Engineered Cells.** Development of engineered cells to elicit a broadly applied biomedically relevant effect across a spectrum of diagnostic, therapeutic, imaging, and interventional applications. Emphasis is on engineering functionality and issues surrounding biocompatibility of engineered cells. Functionality could be derived from controlling natural or artificial attributes of an engineered cell and based on biochemical, optical, and/or mechanical properties, for example.
- H. **Engineered Tissues.** Development of technologies to enable the *in vivo* and *in vitro* engineering of human tissue constructs for biomedical applications. Emphasis is on the design and construction of tools for analyzing and controlling the function of engineered human tissues. Outcomes include but are not limited to: real-time, non-invasive monitoring of tissue function and cell-environment interactions; control of spatiotemporal tissue growth through cell viability, guiding, differentiation, and migration; design, 3D printing, and assembly of human tissues for and biomedical applications; preservation of biological specimens, from protein solutions and cell suspensions to tissues and organs, for a variety of biomedical applications, including transplantation.
- I. **Image-Guided Interventions.** Development of novel image-directed technologies for guidance, navigation, tissue differentiation, and disease identification for reaching specified targets during therapeutic procedures, which may range along the continuum from non-invasive to minimally invasive to open surgical interventions. These technologies may range from molecular to macroscopic scale levels. In addition, emphasis includes technologies that expand needed procedural access for individuals otherwise excluded by disease characteristics, co-morbidities, and other parameters.
- J. **Image Processing, Visual Perception, and Display.** Design and development of algorithms for post-acquisition image processing and analysis. These algorithms include methods for image segmentation, image registration, atlas generation, morphometry measurement, and the determination of function and structure from medical images. Also supported by this program is the development of theoretical models and analysis tools to evaluate and improve the perception of medical images. This may include diagnostic-performance evaluation, assessment of computer-aided diagnosis technologies, statistical models for evaluation of observer performance, and assessment of observer variability. Finally, this program supports the development of visualization tools for improved detection.
- K. **Magnetic Resonance Imaging.** Development of *in vivo* MR imaging and MR spectroscopy, for both animal and human research and potential clinical applications. The emphasis is on the development of MRI hardware and methodologies, including image acquisition and reconstruction techniques, that would improve the speed, spatial resolution, information content, efficiency, robustness, quality, patient experience, and safety. The emphasis should be on technological development rather than detailed applications to specific diseases or organs.
- L. **Mathematical Modeling, Simulation and Analysis.** Development of novel mathematical modeling, simulation and analysis tools that can be broadly applied across a wide spectrum of diagnostic, therapeutic, imaging, and interventional applications. Emphasis is on engineering solutions for theory-driven, physics-based, physiologically realistic, virtual representations of biomedical systems, with a

particular weight on multiscale modeling. Interests include, but are not limited to: multiscale modeling, predictive modeling frameworks, non-standard methodologies, and methods to address model credibility, reproducibility, and reuse.

- M. ***Molecular Probes and Imaging Agents.*** Development and biomedical application of molecular probes and imaging agents across all imaging modalities for the visualization, characterization and quantification of normal biological and pathophysiological processes and anatomy in living organisms at the molecular, cellular and organ levels. The emphasis is on engineering of targeting and responsive molecular probes of high sensitivity and specificity for PET and SPECT (radiotracers), MR (T1, T2, CEST, hyperpolarized agents), EPR, CT, optical (fluorescent and bioluminescent probes), ultrasound (microbubbles) and photoacoustic imaging.
- N. ***Nuclear Medicine.*** Research and development of technologies that create images out of the gamma-ray or positron emissions from radioactive agents that are injected, inhaled, or ingested into the body. The emphasis is on: simulation and development of new detectors, collimators, and readout methods that enhance the signal quality of detecting isotope emissions; designs of novel camera geometries; and correction methods that compensate for the radiation physics properties to improve the clinical reliability of the image. Of interest are improvements and corrections for interaction events in PET detectors and enhancement to time of flight (TOF) image generation methods (reconstructions algorithms); as well as new collimator and camera designs for SPECT.
- O. ***Optical Imaging and Spectroscopy.*** Development and application of optical imaging, microscopy, and spectroscopy techniques for improving disease prevention, diagnosis, and treatment in the medical office, at the bedside, or in the operating room. Examples of research areas include fluorescence imaging, bioluminescence imaging, OCT, SHG, IR imaging, diffuse optical tomography, optical microscopy and spectroscopy, confocal microscopy, and multiphoton microscopy. The emphasis is on development of cost effective, portable, safe, and non-invasive or minimally invasive devices, systems, and technologies.
- P. ***Point of Care Technologies-Diagnostics.*** Development of rapid in-vitro diagnostic technologies and monitoring platforms that provide real time medical evaluation and analysis of the disease status or condition at the time and place of patient care. Technology development area examples within the program include but are not limited to disposable lateral flow assays, nucleic acid testing platforms, glucose monitoring devices, etc. The program includes the delivery of healthcare that is safe, effective, timely, patient centered, efficient, and available in centralized and decentralized locations.
- Q. ***Surgical Tools.*** Design, development, and initial validation of tools to improve the outcomes of surgical interventions across a spectrum of indications. Emphasis is on engineering tools for surgical interventions directed toward improved patient outcomes, decreased patient burden, affordability, and expanded procedural access for patients.
- R. ***Synthetic Biology for Technology Development.*** Design and wholesale construction of new biological parts and systems and the re-design of existing, natural biological systems for tailored purposes. This program may include, but is not limited to: synthetic biological circuits for control and decision-making, design and evolution systems to construct biomolecules and biological systems, or advanced genome editing machinery for DNA manipulation.
- S. ***Technologies for Immunoengineering.*** Manipulating the human immune system through the design, construction, and initial validation of platform technologies. Interests include but are not limited to: nanomaterials for artificial antigen presenting cells, immunomodulatory; T-cells for immunotherapies; and smart bandages to control wound healing. Examples of other tools for analyzing and controlling the function of the engineered immune system include but are not limited to: microfluidics to fabricate artificial antigen presenting cells or bioreactors to produce engineered immune cells at scale.
- T. ***Technologies for Tissue Chips.*** Development of technologies to enable the engineering of tissue chips/microphysiological systems for biomedical applications. Emphasis is on the design and construction of in vitro tools for analyzing and controlling the function of engineered human tissues.

Examples include but are not limited to: microfluidics to control spatiotemporal tissue growth, 3D bioprinting systems for tissue assembly, high-throughput assays and instruments to reduce the cost, time, and complexity of tissue engineering, and bioreactors to produce tissues at scale.

- U. **Therapeutic Medical Devices.** Design and development of non-imaging devices intended for therapeutic interventions. Emphasis is on engineering non-imaging devices, components, and control systems for in vivo therapeutic interventions directed toward overcoming a technological challenge that limits biomedical application. Devices may be, but are not limited to: rehabilitative or curative; assistive; or preventative.
- V. **Ultrasound: Diagnostic and Interventional.** Improvement of technologies for diagnostic, interventional and therapeutic uses of ultrasound. The diagnostic ultrasound program includes, but is not limited to the design, development and construction of transducers, transducer arrays, and transducer materials, innovative image acquisition and display methods, innovative signal processing methods and devices, and optoacoustic and thermoacoustic technology. It also includes the development of image-enhancement devices and methods, such as contrast agents, image and data presentation and mapping methods, such as functional imaging and image fusion. The therapeutic ultrasound program includes, but is not limited to the design, development, and construction of transducers, transducer arrays, interventional technologies, adjunct enhancement of non-ultrasound therapy applications, high-intensity focused ultrasound (HIFU), or hyperthermia applications. It also includes non-invasive or minimally invasive interventional surgical or therapy tools, ultrasound contrast agents for therapy, targeted drug delivery, neuromodulation, and biopsy.
- W. **X-ray, Electron, and Ion Beam.** Simulation, design and development of new detector systems; new readout methods that enhance the signal quality for x-ray image generation; designs of novel imaging geometries; algorithms that compensate for the physical properties of the detection system to improve the clinical reliability of the image (reconstruction algorithms); and approaches to radiation dose reduction, especially in CT. Of interest are diagnostic image enhancements via photon counting, dual energy, and new applications of cone-beam tomography.

NIBIB Clinical Trials Topics:

NIBIB will accept clinical trials in any area listed above in the non-clinical trials topics.

For additional information on research topics, contact:

Mr. Todd Merchak
National Institute of Biomedical Imaging and Bioengineering
Telephone: 301-496-8592, Fax: 301-480-1614
Email: todd.merchak@nih.gov

For administrative and business management questions, contact:

Mr. James Huff
National Institute of Biomedical Imaging and Bioengineering
Telephone: 301-451-4786, Fax: 301-451-5735
Email: huffj@mail.nih.gov

NATIONAL CANCER INSTITUTE (NCI)

The National Cancer Institute's SBIR Development Center program is one of the nation's largest sources of financing for small businesses engaged in technology innovation. Its funding, mentoring and networking assistance is offered to small businesses demonstrating promising next-generation cancer cure technologies, with the ultimate goal being successful commercialization and life-changing public benefit. NCI's SBIR/STTR Programs offer funding for therapeutic agents and devices; in vitro and in vivo diagnostics, including companion diagnostics and imaging agents; agents and technologies for cancer prevention; tools for research in cancer biology, cancer control, and epidemiology; digital health, including health information technology and bioinformatics; and many more areas of interest to the NCI.

The goal of NCI's SBIR/STTR program is to increase small business participation and private-sector commercialization of novel technologies that can prevent, diagnose and treat cancer. The major NCI SBIR/STTR portfolio areas are listed below as a guide to general technology areas funded through the program. However, NCI will accept any applications outside these topic areas and proposing innovative cancer-related technologies with strong commercial potential.

Major NCI SBIR/STTR Portfolio Areas:

- Therapeutics (e.g., Small Molecules, Biologics, Radiomodulators, and Cell-based Therapies)
- *In Vitro* and *In Vivo* Diagnostics (e.g., Companion Diagnostics and Prognostic Technologies)
- Imaging Technologies (e.g., Agents, Devices, and Image-Guided Interventions)
- Devices for Cancer Therapy (e.g., Interventional Devices, Surgical, and Radiation and Ablative Therapies, Hospital Devices)
- Agents and Technologies for Cancer Prevention
- Technologies for Cancer Control (e.g., Behavioral Health Interventions, Tools for Genetic, Epidemiologic, Behavioral, Social, and/or Surveillance Cancer Research)
- Tools for Cancer Biology Research

NCI is committed to lessening the impact of cancer by propelling technological innovation. The NCI SBIR/STTR Programs are aligned with recommendations laid out by the Cancer Moonshot Blue Ribbon Panel Report: <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel>

For more information on NCI SBIR/STTR high priority areas, please visit the NCI SBIR Development Center's Research Topics of Interest page: <http://sbir.cancer.gov/funding/researchtopicsinterest>

For up-to-date information on high priority technology areas, and to learn about programmatic initiatives and upcoming events, visit the NCI SBIR Development Center homepage: <http://sbir.cancer.gov/>.

In addition, please see the contact list at the end of the NCI section to identify the NCI SBIR/STTR Program Director(s) that specializes in your technology area.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NCI may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Generally, NCI will fund Phase I applications with budgets up to \$252,131 total costs and project periods up to 2 years; Phase II applications with budgets up to \$1,680,879 total costs combined over all years and with project periods up to 3 years will be considered. However, for certain research topic, the U.S. Small Business Administration has approved an NIH SBIR/STTR Topic Waiver list for which the NCI generally will fund Phase I applications with higher budgets up to \$400,000 total costs combined over all years, and project periods up to 2 years; similarly, for certain research topics NCI will consider Phase II applications

with higher budgets up to \$2,000,000 total costs combined over all years, and project periods up to 3 years. These NCI SBIR/STTR Waiver Topic areas can be found in the NCI Section of Appendix A below. Applicants considering a requested budget greater than these waiver limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards

The NCI does not accept applications for Phase IIB SBIR competing renewal awards through this Omnibus solicitation. However, the NCI offers Phase IIB opportunities in the form of the NCI SBIR Phase IIB Bridge Award, which is announced via a separate funding solicitation: <https://sbir.cancer.gov/bridge>. The NCI Phase IIB Bridge Award is designed to support the next stage of development for cancer-related technologies previously funded under SBIR or STTR Phase II awards from any Federal agency. The purpose of this award is to address the funding gap known as the "Valley of Death" between the end of the SBIR Phase II award and the subsequent round of financing needed to advance a product or service toward commercialization. To achieve this goal, the Bridge Award funding opportunity is specifically designed to incentivize partnerships between Federally-funded SBIR Phase II awardees and third-party investors and/or strategic partners. Competitive preference and funding priority will be given to applicants that demonstrate the ability to secure substantial independent third-party investor funds (i.e., third-party funds that equal or exceed the requested NCI funds).

To ensure that you will be notified upon the release of the NCI SBIR Phase IIB Bridge Award solicitation, please sign up for the NCI SBIR mailing list: <https://sbir.cancer.gov/emailsignup>. If you have any questions regarding the NCI SBIR Phase IIB Bridge Award, please contact your Phase II program director.

Research Topics of Interest to NCI

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		https://sbir.nih.gov/funding/individual-announcements
Clinical Trials NON- SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		R21, R01, P01, K08 https://www.cancer.gov/grants-training/grants-funding/funding-opportunities

NCI Non-Clinical Trials Topics:

- A. Therapeutics (e.g., Small Molecules, Biologics, Radiomodulators, and Cell-based Therapies)
- B. In Vitro and In Vivo Diagnostics (e.g., Companion Diagnostics and Prognostic Technologies)
- C. Imaging Technologies (e.g., Agents, Devices, and Image-Guided Interventions)
- D. Devices for Cancer Therapy (e.g., Interventional Devices, Surgical, and Radiation and Ablative Therapies, Hospital Devices)
- E. Agents and Technologies for Cancer Prevention
- F. Technologies for Cancer Control (e.g., Behavioral Health Interventions, Tools for Genetic, Epidemiologic, Behavioral, Social, and/or Surveillance Cancer Research)
- G. Digital health tools and software platforms for cancer control, prevention and care.
- H. Tools for Cancer Biology Research
- I. Research Tools (e.g., Animal Models, Cell Lines)
- J. Low-cost prevention/diagnostic/therapeutic products for low-resource settings (cancer global health)

NCI Clinical Trials Topics:

- A. Therapeutics (e.g., Small Molecules, Biologics, Radiomodulators, and Cell-based Therapies)
- B. In Vitro and In Vivo Diagnostics (e.g., Companion Diagnostics and Prognostic Technologies)
- C. Imaging Technologies (e.g., Agents, Devices, and Image-Guided Interventions)
- D. Devices for Cancer Therapy (e.g., Interventional Devices, Surgical, and Radiation and Ablative Therapies, Hospital Devices)
- E. Agents and Technologies for Cancer Prevention

- F. Technologies for Cancer Control (e.g., Behavioral Health Interventions, Tools for Genetic, Epidemiologic, Behavioral, Social, and/or Surveillance Cancer Research)
- G. Digital health tools and software platforms for cancer control, prevention and care.
- H. Low-cost prevention/diagnostic/therapeutic products for low-resource settings (cancer global health)

For additional information about the NCI SBIR/STTR programs, please contact the NCI SBIR Development Center:

Small Business Innovation Research (SBIR) Development Center National Cancer Institute
9609 Medical Center Drive
Rockville, MD 20850
Website: <http://sbir.cancer.gov>
Email: NCISbir@mail.nih.gov
Phone: 240-276-5300

For additional information on research topics, please contact a Program Officer with the relevant area of expertise:

Michael Weingarten, MA
Director, NCI SBIR Development Center
Email: weingartenm@mail.nih.gov

Gregory Evans, PhD
Program Director and Team Leader
Email: evansgl@mail.nih.gov
Areas of expertise: Therapeutics (Immunotherapy, Gene Therapy), Cancer Imaging, Cancer Control, Tools for Cancer Biology Research, and Digital Health

Andrew Kurtz, PhD
Program Director and Team Leader
Email: kurtza@mail.nih.gov
Areas of expertise: Therapeutics (Small Molecules, Biologics, Nanotherapeutics), and Molecular Diagnostics

Patricia Weber, DrPH
Program Director
Email: weberpa@mail.nih.gov
Areas of expertise: Digital Health and Therapeutics (Small Molecules, Biologics, Immunotherapy)

Xing-Jian Lou, PhD
Program Director
Email: loux@mail.nih.gov
Areas of expertise: In Vitro Diagnostics and Therapeutics (Gene Therapy, Biologics, Small Molecules)

Deepa Narayanan, MS, CCDM
Program Director
Email: narayanand@mail.nih.gov
Areas of expertise: Radiation Therapy, Cancer Imaging, Medical Devices, and Clinical Trials

Amir Rahbar, PhD, MBA
Program Director
Email: amir.rahbar@nih.gov
Areas of expertise: In Vitro Diagnostics, Proteomics, and Therapeutics (Biologics, Small Molecules)

Ming Zhao, PhD

Program Director

Email: zhaoming3@mail.nih.gov

Areas of expertise: In Vitro Diagnostics, Cancer Stem Cells, Molecular Imaging, Bioinformatics, Therapeutics (Small Molecules, Biologics, Immunotherapy), and Cancer Control (Community-Based Participatory Research)

Jonathan Franca-Koh PhD, MBA

Program Director

Email: jonathan.franca-koh@nih.gov

Areas of expertise: Cancer Biology, Biologics, Small Molecules, and Cell Based Therapies

Christie Canaria, PhD

Program Director

Email: Christie.canaria@nih.gov

Areas of Expertise: Cancer/Biological Imaging, Research Tools and Devices

Kory Hallett, PhD

Program Director

Email: kory.hallett@nih.gov

Areas of expertise: Immunology, Immunotherapy/Immuno-Oncology, Monoclonal Antibodies, Hematopoietic Stem Cell Transplantation, and Cell-Based Therapies

Ashim Subedee, PhD

Program Director

Email: ashim.subedee@mail.nih.gov

Areas of Expertise: Therapeutics and Theranostics, Cancer Imaging, Radiation Therapy, Cancer Prevention, and Digital Health

For administrative and grants management questions, please contact:

Jaime Montes

Grants Management Specialist

Office of Grants Administration

National Cancer Institute

9609 Medical Center Drive

West Tower, 2W536

Rockville MD 20850

Telephone: 240-276-6288

Fax: (240) 276-7913

Email: montesj@mail.nih.gov

For NCI-related SBIR Information, visit: <http://sbir.cancer.gov>.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

The mission of the NICHD is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation.

The NICHD has a broad and diverse research portfolio, including biological, behavioral, and clinical research related to conception and pregnancy, normal and abnormal development in childhood, reproductive health, rehabilitation, and population dynamics across the lifespan.

For up-to-date information on priority research areas of scientific interest to the NICHD, please visit our home page at <http://www.nichd.nih.gov>.

Pre-submission Resources & Commercialization Assistance

There are several resources and programs available throughout the SBIR/STTR process. For more information, please visit our [Commercialization Resources & Programs webpage](#).

Limited Amount of Award

The NICHD will accept SBIR/STTR applications up to \$252K total costs for Phase I for a time period no greater than 2 years and \$1.6M for Phase II for a time period no greater than 3 years. It is strongly encouraged to contact program staff prior to applying.

The NICHD received a budgetary guideline waiver from the Small Business Administration for applications relating to a limited list of scientific topics in Appendix A. For these the NICHD will accept applications up to \$300K total costs for Phase I and \$2M for Phase II. Applicants should propose a budget that is reasonable and appropriate for completion of the research project and requests for these budget levels must be very well justified. Applicants are strongly encouraged to contact the listed NICHD Branch Contact Program Officer for scientific-related questions about a project's eligibility for a budgetary waiver.

For general budgetary questions, applicants are encouraged to contact NICHD's SBIR/STTR Grants Management Coordinator. **For budgetary, administrative or programmatic reasons the NICHD may decrease the budget or length of an award or decide not to fund an application recommended by scientific review.**

Phase IIB Competing Renewal Awards

The NICHD accepts Phase IIB SBIR Competing Renewal applications to support additional R&D necessary for approval of a federal regulatory agency (e.g., FDA, FCC). Such products may include medical implants, pediatric devices, drugs, vaccines, and new treatment or diagnostic tools. Applicants who received NICHD SBIR Phase I or Phase II support and who are currently Phase II awardees are eligible. If the project meets the criteria for a budgetary waiver (Appendix A), the Phase IIB should not exceed \$3M total costs for three years. The amount of award may vary year to year depending on the research proposed. **Funding priority will be given to those small business concerns that show the ability to develop innovative products and demonstrate growth towards independence from the SBIR/STTR programs.**

NICHD Supported Funding Opportunity Announcements (FOAs)

In addition to the Omnibus program announcement, for up-to-date NICHD releases on targeted **funding announcements and programmatic initiatives** visit: <https://sbir.nih.gov/funding/individual-announcements> or https://www.nichd.nih.gov/grants-funding/SBIR_STTR/Pages/default.aspx.

Research Topics of Interest to NICHD

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		RFAs https://sbir.nih.gov/funding/individual-announcements

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		Check the NICHD website for active FOAs: https://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/active-foa/Pages/default.aspx

NICHD Non-Clinical Trials Topics:

The major NICHD research priority areas for each Branch are listed below. Investigator initiated applications that have commercial potential that fall outside these topic areas but fall within the research mission of the NICHD are also considered through this Omnibus solicitation.

A. Child Development and Behavior Branch

The CDBB encourages innovative developmentally-sensitive theoretically-grounded evidence-based small business initiatives that develop technology and products addressing the psychological, social and emotional, psychobiological, language, numerical, literacy, cognitive and intellectual development and health of persons from infancy to maturity recognizing the important role others have in contributing to the healthy development of an individual. Products that target at-risk populations and/or exploit new technologies that can expand the effective reach or inclusion of underserved populations in order to encourage healthy development and/or our understanding of the influences of context and/or behavior on development are especially encouraged.

Foci of specific interest include, but are not limited to (please also see the [CDBB description for research priorities](#)):

- **Enhancing Bilingual and Biliteracy Development:** Adaptive learning technology to enhance bilingual and/or biliteracy development in English-language learning children and youth.
- **Measures of Neurodevelopment:** Develop easy to administer neurodevelopmental measures from evidence-based neurocognitive research specific to typically developing infants and toddlers that are shown to correlate with development of brain connectivity and activation.
- **Pediatric Primary Care Behavioral and Health Promotion Interventions:** Facilitate research on the impact of behavioral and health promotion interventions in pediatric primary care and related clinical settings with a focus on end result child and adolescent health outcomes.
- **Psychosocial Adjustment for Individuals in High-Risk Environments:** Develop measures to identify and tools to stimulate developmental factors and mechanisms which promote short- and long-term psychosocial adjustment for children and adolescents exposed to high-risk family and neighborhood environments.
- **School Readiness Skills in Economically and Socially Disadvantaged Children:** Develop mobile device apps and/or hand-held devices that promote the development of school readiness skills and abilities in diverse populations of children as well as

measures of home, child care and preschool environments and practices that are related to child learning and development.

- **Reading, Writing, and Mathematics Struggling Learners:** Develop assistive technology to enhance learner outcomes for individuals that struggle to acquire literacy and numeracy skills.
- **Assessment and Enhancement of Reasoning Development:** Develop validated and specific assessment tools that are sensitive to contributing factors (e.g., biobehavioral, environmental, cultural, academic, and cognitive factors) to facilitate research on and the promotion of neurocognitive development of reasoning (e.g., quantitative, deductive, inductive, causal) in typically developing populations.

Kathy Mann Koepke, PhD

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Email: KMK@nih.gov

B. Contraceptive Reproductive Branch

The [CRB](#) supports research with an emphasis on developing new and improved methods of fertility regulation as well as research on the benefits and risks of contraceptive drugs, devices and surgical procedures.

Areas of interest include, but are not limited to:

- Development of new and improved methods of fertility regulation, for men and women, that are safe, effective, inexpensive, reversible and acceptable
- Synthesis and testing of novel chemical compounds that are potential contraceptives
- Multipurpose technologies designed to prevent sexually transmitted infections, such as HIV, as well as pregnancy

Steven C. Kaufman, MD

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Email: kaufmans@exchange.nih.gov

C. Developmental Biology and Structural Variation Branch

The [DBSVB](#) supports biomedical research on the cellular, molecular, and genetic aspects of normal and aberrant embryonic and fetal development including early embryogenesis, organogenesis, causative factors in teratogenesis, and topics in regenerative biology.

Areas of interest include but are not limited to:

- Development of new animal model systems to understand developmental mechanisms and causes of structural birth defects
- Innovative technologies for *in vivo* imaging of developmental processes (cell and tissue dynamics) and gene expression
- Development of antibodies, novel ligands and other probes to facilitate our understanding of normal and abnormal embryonic development in model organisms
- Technologies for quantitative measurement of physical properties of cells/tissues *in vivo*
- Innovative and high throughput genomic and proteomic techniques
- Technologies to facilitate and advance systems biology approaches to the study of embryonic development and structural birth defects
- Innovative technologies to facilitate and advance high throughput chemical screening (including small molecules) for advancing structural birth defects research
- Software development to facilitate the collection and analyses of data generated using high throughput screening platforms in model organisms

- Technologies/methodologies to generate and software to mine data related to wound healing and regenerative responses across animal species
- Novel reagents for activation and mobilization of endogenous/adult stem cells to promote *in vivo* tissue regeneration
- High throughput screening technologies of small molecules in human Embryonic Stem (ES) Cells or Induced Pluripotent Stem Cells (iPSCs) and disease specific iPSCs for targeted modification of signaling pathways affected in structural birth defects
- Technologies for iPSC-based regenerative medicine in the context of structural birth defect
- Innovative technologies for studying metabolomics in developing vertebrate embryos

Mahua Mukhopadhyay, PhD
Phone: 301-435-6886
Email: mukhopam@mail.nih.gov

D. Fertility and Infertility Branch

The [FIB](#) supports research on the reproductive processes of men and women and of animals with similar reproductive systems related to developing safer and more effective means of regulating, preserving or achieving fertility.

Areas of interest include but are not limited to:

- Development of reagents to facilitate study of reproductive and developmental processes
- Development of improved methods of growing and differentiating stem cell lines *in vitro*, including feeder cell-free approaches
- Development of novel assays, kits, and devices to monitor fertility and treat infertility and gynecological disorders
- Use of genomics and proteomics to develop novel diagnostics and treatments for reproductive diseases and disorders
- Development of high-resolution technologies to provide invasive or noninvasive assessments of reproductive and developmental competence
- Development of experimental animal models that would be useful for studying the physiology and pathophysiology of reproductive processes
- Development of techniques and identification of novel biomarkers to produce, identify, and use healthy gametes
- Development of improved and novel technologies for the preservation of human gametes
- Development of improved technologies for preimplantation genetic diagnosis
- Development of *in vitro* model systems that are useful for understanding human embryo implantation.
- Development of improved technologies for the reprogramming of cells, including embryonic stem cells or adult cells, into eggs and sperm
- Development of innovative technologies for point-of-care testing for infertility and reproductive diseases and disorders
- Development of new methods to alter the function of trophoblast cells so that the embryo/fetus can be protected from ill effects of maternal viral infection
- Development of genomic, epigenomic or proteomic technologies to diagnose impairments in sperm function, fertilization, ovulation, implantation, decidualization and other aspects of reproductive processes

Ravi Ravindranath, DVM, PhD
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Email: ravindr@mailto.nih.gov

E. Gynecologic Health and Disease Branch

The [GHDB](#) supports biomedical research related to gynecologic health throughout the reproductive lifespan, beginning at puberty and extending through early menopause.

Areas of interest include, but are not limited to:

- Development of new diagnostic approaches and treatments for female pelvic floor disorders, including drugs, and devices used for treatment of pelvic organ prolapse, urinary incontinence, fecal incontinence and other female pelvic floor disorders
- Development of new diagnostic methods and novel surgical and non-surgical treatments for uterine fibroids, endometriosis, adenomyosis, and benign ovarian cysts
- Production of marketable novel or improved methods, devices, and technologies for the diagnosis, monitoring and therapy of gynecologic pain disorders including chronic pelvic pain, vulvodynia, and dysmenorrhea
- Generation of new approaches for the diagnosis, monitoring and treatment of abnormal menstrual cyclicity
- Surgical and non-surgical treatments for girls and women with reproductive tract abnormalities, including congenital structural abnormalities and complications from female genital cutting.
- Devices and/or technologies designed to address surgical challenges in gynecologic surgeries, including hysterectomy.
- Technologies designed to apply omics platforms (genomics, proteomics, metabolomics etc.) to questions of gynecologic health and disease.

Candace M. Tingen, PhD
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F. Intellectual and Developmental Disease Branch

The [IDDB](#) sponsors research aimed at preventing, diagnosing, and ameliorating intellectual and developmental disabilities (IDD). Emphasis is on studies related IDD, including common and rare neuromuscular and neurodevelopmental disorders, such as Down, Fragile X, and Rett syndromes, mitochondrial conditions, inborn errors of metabolism, autism spectrum disorders, and others.

Areas of interest include, but are not limited to:

- Innovative tools, including molecular, imaging, statistical or behavioral tools, to characterize the etiology and pathophysiology of abnormal nervous system development.
- Methods and devices to delineate genetic, genomic, and epigenetic causes of IDD and develop gene-based treatments.
- Methods or devices designed to screen for and diagnose IDD and other conditions, particularly those identified or identifiable by newborn screening.
- Assessment tools for use in the clinic or community settings to enable the accurate measurement of change in response to interventions.
- Development of early interventions leading toward the prevention, diagnosis and treatment of IDD.
- Methods or devices to develop or apply smart technologies to enhance screening, diagnosis, prevention, treatment or management of IDD conditions.
- Development of assessment measures or treatments for co-morbid symptoms in IDD including disordered sleep, self-injurious behaviors, obesity, gastrointestinal dysfunction, seizures/epilepsy, ADHD and other mental health disorders.

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Email: krotoskd@mail.nih.gov

G. Maternal and Pediatric Infection Disease Branch

The [MPIDB](#) supports domestic and international research on human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) and related infections (such as tuberculosis, hepatitis and malaria) in women of child bearing age, pregnant women, mothers, fetuses, infants, children and adolescents. Specific areas of interest include but are not limited to epidemiology, clinical manifestations, pathogenesis, transmission, treatment and prevention (including vaccines and other biomedical modalities) of HIV infection, Zika infection and other infectious diseases in children, adolescents and pregnant women, including prevention of mother to child transmission of HIV and other congenital infections, and HIV-related and other infectious-disease related complications in these populations.

Additional areas of interest include:

- New technologies relevant to resource-limited countries for:
 - Screening, diagnosis, and management of infectious diseases in pregnant women, infants and children, including but not limited to HIV (e.g. congenital CMV, Zika virus)
 - Rapid assays to monitor disease activity and response to therapy for as well as immune response to vaccinations against relevant infections in infants and children (e.g. malaria, tuberculosis), which can be used at the individual level and/or as part of public health campaigns (e.g. eradication of outbreaks and prevention of spread)
 - Diagnosis and treatment of HIV-related co-morbidities (e.g., diagnosis of tuberculosis in children)
 - Diagnosis and treatment of Zika-related outcomes in mothers and infants
 - Simple and less technologically demanding point of care assays to monitor CD4 cell percentage/count, HIV viral load, or other surrogate markers of HIV disease progression in children
 - Interventions designed to promote or optimize medication adherence
- Child-friendly formulations (preferably not liquid preparations) -of drugs- used to treat or prevent HIV infection, complications of HIV infection, and/or other high-priority infections such as tuberculosis, hepatitis, and malaria relevant to children, particularly in resource-limited countries; Fixed-dose drug formulations and innovative methodologies for development of solid heat stable formulations capable of being administered to young children (e.g., sustained release beads, etc.) and/or improve pill or volume burden
- Innovative long-lasting drug formulations for antiretroviral and other anti-infective drugs that would allow less frequent drug administration (e.g., once daily, weekly or monthly)
- Simple, standardized, validated tools to evaluate neurodevelopmental outcomes in children in resource-limited settings
- Innovative data collection approaches to leverage and link electronic medical records and/or other health information systems to better understand HIV treatment and prevention, and related infections, among infants, children, adolescents and women of child bearing age.
- Biomedical modalities, including vaccines, to prevent acquisition of HIV and other infectious diseases in children, adolescents and women.
- Topical microbicide agents, alone or as part of multipurpose prevention technologies (MPTs), to prevent sexual acquisition of HIV and other sexually transmitted infections in adolescents, adult women, and pregnant or postpartum women.
- New, non-invasive technologies to evaluate complications of antiretroviral drugs (e.g., mitochondrial toxicity, bone toxicity) in HIV-infected infants, children, adolescents, pregnant women, and their fetuses.

- New technologies for measuring the HIV latent reservoir, including high-throughput, reliable and sensitive assays.

Sonia Lee, PhD
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H. **Obstetric and Pediatric Pharmacology and Therapeutics Branch**

The [OPPTB](#) promotes research to improve the safety and efficacy of pharmaceuticals and to ensure centralization and coordination of research, clinical trials, and drug development activities for obstetric and pediatric populations. This includes developing and supporting a comprehensive national effort to increase the knowledge base for understanding how to appropriately treat disease during pregnancy, infancy, and childhood using pharmaceuticals that are appropriately tested within their target populations.

Applications to advance the study of obstetric and pediatric pharmacology include:

- Development of artificial intelligence (AI) pharmacokinetic/pharmacodynamic modeling to improve therapeutic approaches during pregnancy, infancy, childhood, and adolescences.
- Development of artificial intelligence (AI) drug delivery system to better characterize the impact of physiological and developmental changes on pharmacokinetics, pharmacodynamics, drug disposition and response
- Development of drug delivery robot to target and assess the state of various organ systems during therapy in pregnancy or infancy
- Development of robust controls, and autonomic specimen sampling for limited blood volumes
- Development of artificial intelligence (AI) models for drug assay development that can be utilized across therapeutic areas
- Development of non-invasive devices for evaluating adherence to chronic therapy in life-threatening conditions (e.g., HIV, diabetes, asthma, and liver and kidney transplantation)
- Development of novel approaches for oral mucosal, transdermal, nasal, ocular and pulmonary drug delivery systems and device technologies
- Use of a materials science approach to overcome solubility limitations of pediatric drugs, increase bioavailability, decrease excipient exposure, and provide effective taste masking.
- Development of nanosized formulations to optimize efficacy and minimize toxicity of pediatric drugs
- Artificial intelligence (AI) drug discovery – master algorithms for pregnancy associated/induced diseases that can lead to the development of new targeted therapeutics for diseases like pre-eclampsia, gestational diabetes, and preterm labor

June Lee, MD, PhD
Phone: 301-435-6987

I. **Pediatric Growth and Nutrition Branch**

The [PGNB](#) supports research designed to support short and long-term health so that children can achieve their full potential through an expanded understanding of those factors that influence metabolism, growth (body composition and linear growth) and neurodevelopment. An additional focus is on those biological (e.g., genetic, nutritional, endocrinological) factors that contribute the early life origins of non-communicable disease (e.g., obesity, diabetes, cardiovascular disease, osteoporosis). The PGNB encourages research that focuses on detecting the biological antecedents of these conditions during pregnancy, infancy and childhood.

Areas of interest include, but are not limited to:

New research tools, improved measurement methods, and technologies that enhance our understanding of:

- Growth:
 - Physical growth, body composition, bone health, nutrition, and obesity
 - Determinants of normal bone mineral accretion and peak bone mass. Interactions of muscle and bone during infancy and childhood
 - Neuroendocrinology of puberty, linear growth, body composition
 - Mechanisms of hormone action during linear growth, pubertal maturation, and other aspects of physical development
- Biological antecedents of childhood obesity and its short and long-term consequences:
 - Genetic and molecular mechanisms of obesity, psychosocial risks of obesity, and therapeutic interventions for obesity in children and adolescents
 - Impact of early life exposures including infant feeding practices on short and long-term health and development
- Biology of nutrition as it pertains to health and development (physical and neurological function) during pregnancy, infancy and childhood including discovery, development and deployment of biomarkers for early detection of:
 - Mal-(over-/under) nutrition; including biomarkers of exposure, status, function and effect (i.e., impact on early life development including neurodevelopment)
 - Enhanced understanding of the role of human milk in child health and development.
 - Maternal nutrition (pre-pregnancy, pregnancy, and lactation)
 - Novel approaches to enhanced infant feeding practices in term and pre-term infants
- Developmental origins of adult disease including:
 - Ascertain biomarkers early in life that predict the onset of chronic diseases such as diabetes, osteoporosis, and the metabolic syndrome later in life. The PGN Branch emphasizes the life course model to develop primary preventive approaches to these chronic diseases.
 - Develop platforms for implementation of biomarkers of disease status, nutritional status, and biological function from infancy through adolescence

Andrew A. Bremer, MD, PhD

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J. **Pediatric Trauma and Critical Illness Branch**

The **PTCIB** supports research and research training in pediatric trauma, injury prevention, and critical illness across the continuum of care. These efforts include:

Research on the prevention, treatment, and management of physical and psychological trauma and the surgical, medical, psychosocial, and systems interventions needed to improve outcomes for critically ill and injured children and youth.

Studies of the continuum of psychosocial, behavioral, biological, and physiological influences that affect child health outcomes in trauma, injury, and critical care.

Basic, clinical, and translational studies that explore short- and long-term consequences of such traumatic experiences as exposure to natural or man-made disasters, all forms of violence against children, as well as experiences of bereavement, grief and loss.

Research linking the science of pediatric emergency and critical care medicine to the epidemiology, prevention, and treatment of trauma and injury in infants, children and adolescents.

Applications of interest include, but are not limited to:

- Research and development of pediatric-specific technologies, devices and equipment used by emergency and trauma care as well as pediatric critical care personnel.
- Research and development of novel strategies or approaches in caring for injured children prior to and during transport to treatment settings.
- Development of tools and technologies for screening and determination of the nature and extent of injuries related to forms of child maltreatment.
- Research and development of devices and innovative therapeutic technologies for management of medical conditions and related problems stemming from critical illness and serious or life-threatening injuries.
- Development and testing of preventive intervention tools, materials, and technologies designed to improve clinical practice, parenting and social system support for injured or traumatized children.
- Development and testing of preventive intervention tools, materials, and technologies designed to reduce pediatric trauma exposure and the number and severity of pediatric injuries and deaths.
- Research and development of effective tools and technologies to improve the environment of pediatric intensive care including resources to promote patient safety and to enhance clinical education and training of critical care personnel.
- Development of tools and technologies that support the diagnoses and treatment of critical illness in children, including nosocomial infections and iatrogenic injury.

Valerie Maholmes, PhD, CAS

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K. Population Dynamics Branch

The [PDB](#) supports research and research training in demography, reproductive health, and population health. In demography, the Branch supports research on the scientific study of human populations, including fertility, mortality and morbidity, migration, population distribution, nuptiality, family demography, population growth and decline, and the causes and consequences of demographic change. In reproductive health, the Branch supports behavioral and social science research on sexually transmitted diseases, HIV/AIDS, family planning, and infertility. In population health, the Branch supports data collection and research on human health, productivity, behavior, and development at the population level, using such methods as inferential statistics, natural experiments, policy experiments, statistical modeling, and gene/environment interaction studies.

Applications are encouraged, but are not limited to these areas:

- Technological innovations or inventions to improve collection of biomarker and anthropometric data in large population-representative surveys
- Hardware or software to improve collection of accurate cause of death information or health diagnosis in large population-representative surveys or in administrative data sets
- Methods for integrating geographical information systems (GIS), spatial network analysis, and/or simulation methods for demographic research
- Methods for improving collection, documentation, archiving, and dissemination of population representative data sets, especially data sets that are complex, multilevel or multimodal

- Methods for protecting and assuring confidentiality for human subjects when collecting, archiving, or disseminating population-representative data sets, especially data sets that are longitudinal or that include both spatial and individual-level data
- Methods for reducing cost of collecting and disseminating large-population-representative data sets
- Development of effective tools for prevention research and intervention programs related to STD/HIV, pregnancy, contraceptive use, child health, at risk youth, adolescent and young adult mortality, and other health-related topics, and to the dissemination of such tools
- Innovative approaches to teaching population studies and other behavioral and social sciences at the undergraduate and graduate level
- Innovative approaches for research design, data collection techniques, measurement, and data analysis techniques in the social and behavioral sciences, with particular attention to methodology and measurement issues in studying diverse populations, sensitive behaviors, confidential behaviors; in issues related to the protection of research subjects; and in issues related to the archiving and disseminating complex datasets

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L. **Pregnancy and Perinatology Branch**

The [PPB](#) supports research in the following areas: the physiology of pregnancy and labor; high-risk pregnancies, including those with hypertensive disorders, diabetes or seizure disorders; fetal pathophysiology; premature labor and birth; diagnostic, monitoring, and therapeutic devices and instruments for newborn infants in the nursery and in Neonatal ICU setting; improving the existing products or developing new products that would improve the routine and extended care of the newborn infants; products and agents related to breastfeeding; hospital supplies specifically related to use in the care of newborn infants; nanotechnology and its application for the care of newborn infants; instruments and devices for assessing and monitoring the nursery environment (noise, lighting, and odor); disorders of the newborn; sudden infant death syndrome; and biological and behavioral antecedents of low birth weight.

The following topic areas are of high priority:

- Non-invasive (or minimally invasive) methods to assess preeclampsia; gestational diabetes; fetal well-being; spontaneous preterm birth; and stillbirth
- Methods to characterize the bioactive components of human milk
- Methods to longitudinally assess the structure and functions of the human placenta
- Devices, instruments, and tools to minimize bacterial colonization, reduce proclivity for thrombus formation, and reduce healthcare associated infection risks
- Lab-on-a-chip; specifically, non- or minimally-invasive approaches for assessing: metabolic profiles (e.g., glucose and lactate/pyruvate), ketone bodies, bilirubin (unconjugated, free, indirect, and total), and other major analytes (Na⁺ Ca⁺ Cl⁺ K⁺ etc.); serum levels of administered medications; and fetal and neonatal kidney function
- Rapid methods for diagnosis of bacterial infections and the assessment of antibiotic sensitivity
- Improved syringes, needles, and injection set ups to help administer small doses of medications over prolonged periods (e.g., insulin for treating hyperglycemia)
- Methods to assess pain in the newborn, analgesia, and the evaluation of neonatal opioid withdrawal syndrome
- Non-invasive measures to assess brain energy utilization in the newborn, especially glucose, oxygen, lactate, ketones, and other energy substrates

- Improved devices and instruments for assisted ventilators for use in neonatal ICU

Andrew A. Bremer, MD, PhD
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M. National Center for Medical Rehabilitation Research

This Center supports innovative research on the restoration, replacement, enhancement or adaptation of function for people with chronic physical disabilities. This includes rehabilitative approaches across etiologies and the lifespan, as well as the environmental and policy factors that promote full participation. We encourage studies that integrate biomedical, engineering and/or psychosocial approaches to develop practical and creative solutions to the daily functioning of people with disabilities and their families. The mission of the NCMRR is to increase the effectiveness of medical rehabilitation practices through research. Information about specific program areas within NCMRR can be found [here](#).

Examples may include but are not limited to:

- **Adaptation and Plasticity:** Develop non-invasive and surrogate measures of plasticity that would be appropriate for use in a clinical setting to target rehabilitation therapies and monitor treatment effectiveness (e.g., biomarkers, imaging)
- **Novel Technology:** Orthotics, prosthetics, and robotics devices and interfaces; Assistive technologies; Invasive and non-invasive biological sensors, prosthetic systems or implants to improve function; New control methods and improved sensory feedback; Strategies for controlling and adapting to the environment; Advanced wheelchair designs and enhancements and other mobility devices; Biomaterials and tissue interfaces, nanotechnology, bionics
- **Rehabilitation Interventions:** Development and use of robotics; Gaming applications; Virtual and Augmented Reality; Simulations; M-health and other approaches to promote participation, understand and support healthy behaviors, reduce health disparities and enhance clinical compliance, especially in children with physical disabilities.
- **Chronic Symptom Management:** Methods to increase screening for chronic conditions or preventable secondary conditions in individuals with physical disability; Prevention and treatment strategies for mitigating symptoms associated with multiple chronic conditions in individuals with physical impairments, including persistent pain, symptoms of obesity, diabetes, cardiovascular deconditioning, fatigue, symptoms of overuse injuries, pressure ulcers, sleep disturbances, and depressive symptoms; Improving muscle capacity in chronic physical disability to include therapeutic or adaptive exercise and muscle stimulation; muscle-disuse syndromes and contractures; Rehabilitation interventions for improvement of physical disability and comorbid cognitive, sensory, or somatic consequences of impairment, disease or injury; Autonomic function in the context of injury or specific conditions.
- **Rehabilitation in the Community:** Strategies to build or modify community and/or environmental resources that provide effective rehabilitation and health promotion services within the individual's own community. Development of engineering, crowdsourcing, and social science approaches to promote, monitor, and sustain outcomes in real world settings.

Investigators proposing budgets exceeding the guidelines are encouraged to contact program staff six weeks prior to submitting the application.

For additional information on research topics, contact:

Dr. Louis A. Quatrano, PhD

Phone: 301-402-4221
Email: quatrano@mail.nih.gov

NICHD Clinical Trials Topics:

The NICHD will generally consider clinical trial proposals consistent with the topics listed above with the following exception:

A. Developmental Biology and Structural Variation Branch

The [DBSVB](#) does not support clinical trials through the SBIR/STTR program.

Dr. Mahua Mukhopadhyay, PhD
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Email: mukhopam@mail.nih.gov

For additional SBIR/STTR program administrative information and research topics contact:

Louis Quatrano, PhD
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Phone: 301-402-4221
Email: quatrano@mail.nih.gov

For additional financial/business management questions contact:

Mindy Bixby
Grants Management Specialist
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Contractor
Phone: 301-402-3204
Email: mindy.bixby@nih.gov

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

NIDA is the lead federal agency supporting scientific research on drug use and its consequences. Our mission is to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health through: 1) Strategically supporting and conducting basic and clinical research on drug use (including nicotine), its consequences, and the underlying neurobiological, behavioral, and social mechanisms involved and 2) Ensuring the effective translation, implementation, and dissemination of scientific research findings to improve the prevention and treatment of substance use disorders and enhance public awareness of addiction as a brain disorder. For additional information about areas of interest to the NIDA, please visit our home page at <https://sbir.nih.gov/nida/divisions>.

SBIR and STTR programs at NIH are primarily intended to encourage private-sector commercialization of technology and to increase small business participation in federally funded research and development (R&D). The goal of NIDA SBIR/STTR program is to increase small business participation and private-sector commercialization of novel technologies that can prevent, diagnose and treat SUD.

Both the SBIR and STTR programs consist of the three phases. During Phase I, NIDA supports the projects which establish the technical merit and feasibility of proposed research / R&D efforts and determines the quality of performance of the applicant (small business concern or SBC) before providing further Federal support in Phase II. Provided that the feasibility is established, during Phase II, NIDA supports research or R&D efforts initiated in Phase I. During Phase III, SBC is to pursue commercialization with non-SBIR/STTR funds (either Federal or non-Federal). Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant. Phase III funding may be from any of a number of different sources including, but not limited to: private, venture capital firms, investment companies, joint ventures, R&D limited partnerships, strategic alliances, research contracts, sales of prototypes (built as part of this and/or other project), public offering, state finance programs, non SBIR-funded R&D or production commitments from a Federal agency for use by the United States government or other industrial firms. NIDA monitors SBC efforts to pursue, with non-SBIR/STTR funds, the commercialization of the results of the research or R&D funded in Phases I and II of the SBIR/STTR Program.

NIDA funding decisions will be based on combination of factors:

- Potential for commercialization and public health impact;
- Whether the similar projects have already been funded (for reference, search [NIH RePORTER](#));
- The results of Phase I and the commercial potential and scientific/technical merit of the Phase II application (for Phase II applications);
- The quality of performance of the applicant, with emphasis on prior applicant success in Phase III;
- The peer review scores and critique;
- Availability of funds

SPECIAL FEATURES OF NIDA SBIR PROGRAM

Limited Amount of Award

According to the statutory guidelines, total funding support levels (including direct costs, indirect costs, and fee) are \$168,087 for Phase I awards and \$1,120,586 for Phase II awards. In certain cases, the US Congress allows awards to exceed these amounts by up to 50% (\$252,131 for Phase I and \$1,680,879 for Phase II- hard cap). Budgets that exceed the hard caps (more than \$252,131 for Phase I and more than \$1,680,879 for Phase II) must receive a waiver from US Small Business Administration (SBA). NIH - not the applicant - must apply for this waiver. The list of NIDA waivers can be found in the Program

Descriptions and Research Topics and APPENDIX A. If adequate justification is provided and research focus is within NIDA's SBA approved waiver, applicants may request up to \$350,000 in total costs with the project period up to 1.5 years; or up to \$3,000,000 in total costs with the project period up to 3 years for Phase II.

Applicants are strongly encouraged to contact NIDA SBIR and STTR Representatives prior to submitting any application in excess of the guidelines. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project. For programmatic, budgetary or administrative reasons, NIDA may decrease the length of an award and/or the budget, or not fund an application. If applicants choose to request funds above the approved hard caps, they are strongly advised to contact NIDA SBIR/STTR Program Staff prior to application submission.

Fast-Track Applications

Important consideration for NIDA Fast-Track Mechanism:

- Preliminary data that clearly supports the project feasibility;
- Clear, measurable, achievable milestones. Milestones for Phase I must be written with the goal of addressing all significant questions of technical feasibility. Phase I milestones must be quantitative, not qualitative (e.g., "an affinity of x nM," rather than "twice as potent as Y" or the "twice as potent as the best analog". Milestones should also be written utilizing the appropriate controls. Phase I Milestones must be written to allow the claim that their completion fully demonstrates the establishment of the product/service feasibility;
- Well-conceived Commercialization Plan;
- Letters of Phase III support/interest, of additional funding commitments, and/or resources from the private sector or non-SBIR/STTR funding sources;
- Track record/previous success in commercializing product or services;
- Discussion with NIH Program Staff strongly encouraged

The NIH Fast-Track mechanism expedites the decision and award of SBIR and STTR Phase II funding by incorporating a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together. The Fast-Track application will receive a single rating for the entire proposed project (i.e., it will receive a numerical score or it will receive an "unscored" designation). To be eligible for the Fast-Track option, the Phase I Research Plan must include well-defined, quantifiable milestones that should be achieved as Go/No-Go requirements prior to initiating Phase II work. In addition, as is required for all Phase II applications, the Phase II portion of a Fast-Track application must present a well-defined Commercialization Plan. NIDA encourages Fast-Track mechanism for scientifically meritorious applications that have expressly high potential for near term commercialization. Applicants considering a Fast-Track application are strongly encouraged to contact program staff at NIDASBIR@mail.nih.gov BEFORE applying. NIDA staff will assist the applicant in determining whether the proposed project addresses NIDA's programmatic priorities, and whether the proposed project satisfies NIDA's criteria for Fast Track mechanism. Potential Fast-Track applicants are encouraged and expected to discuss with the NIDA program staff the following:

- **Value of the SBIR/STTR Project** - the public/market need addressed, specifying weaknesses in the current approaches to meet this need; the commercial applications of the research and the innovation inherent in this application.
- **Justification** of the pertinence of the Fast Track mechanism to the proposed research.
- **Expected Outcomes and Impact** - the proposed project and its key technology objectives; the product, process, or service to be developed in Phase III; the potential societal, educational, and scientific benefits of this work; the non-commercial impacts to the overall significance of the project.
- **Market, Customer, and Competition** - the market and/or market segments targeted, a brief profile of the potential customer, significant advantages SBC's innovation will bring to the market

(e.g., commercial viability, better performance, lower cost, faster, more efficient or effective, new capability; the hurdles to overcome in order to gain market/customer acceptance of the proposed innovation; any strategic alliances, partnerships, or licensing agreements already in place to market and sell the product, FDA approval (if required), marketing and sales strategy, overview of the current competitive landscape and any potential competitors over the next several years, etc).

Research Topics of Interest to NIDA

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

The major NIDA SBIR/STTR portfolio areas are listed below as a guide to general technology areas funded through the program. Applications proposing innovative SUD-related technologies with strong commercial potential that fall outside these topic areas are also encouraged through this Omnibus solicitation.

For up-to-date information about NIDA SBIR/STTR Program, and to learn about programmatic initiatives and upcoming events, visit the homepage: <https://sbir.nih.gov/nida/index>

NIDA Non-Clinical Trials Topics:

- Research Tools (e.g., Animal Models, Cell Lines)
 - Innovative in vitro, in situ, or in vivo tools for the analysis of the central nervous system, normal and/or diseased;
 - Tools for Addiction Biology Research;
 - Technologies, including molecular imaging, gene expression profiling, and genotyping and sequencing approaches designed to better inform SUD diagnosis and treatment;
 - Tools to simplify the design and preclinical development of medications for SUDs;
 - Discovery of SUD-related biomarkers and/or related biomarker assay development with emphasis on peripheral measures
- Therapeutics (e.g., Small Molecules, Biologics Therapies)
 - Assay development (e.g., biochemical, functional) and validation, especially, hiPSC-based assays, human organoid, or 3-D culture systems with the intention of developing medium to high-throughput assays
 - Early therapeutic discovery activities ranging from Target ID and validation through lead development
- In Vitro and In Vivo Diagnostics

NIDA Clinical Trials Topics:

- Clinical drug development
- Technologies or formulations to improve medication delivery
- Predictors of clinical outcomes in SUDs, e.g. physiological, electroencephalographic, cognitive tests, and biochemical, epigenetic, and genetic assays.
- Point of care monitoring systems to improve quantitative assessment of subject adherence to clinical trial protocols
- Development of portable, efficacious neuromodulatory devices
- Digital health tools and software platforms for SUD control, prevention and care.
- Technologies for SUD Control (e.g., Behavioral Health Interventions, Tools for Genetic, Epidemiologic, Behavioral, Social, and/or Surveillance Research)

In addition, please see the contact list at the end of the NIDA section to identify the NIDA SBIR/STTR Program staff that specializes in your technology area to discuss other innovative SUD-related technologies and approaches.

Prior to Submission

Applicants are strongly encouraged to request a technical assistance meeting with NIDA SBIR/STTR staff prior to submitting any application. To schedule a meeting, please email NIDASBIR@mail.nih.gov with brief answers to the following:

- What problem are you trying to solve?
- How is this problem solved now? What is the current gold standard to treat/to solve this problem?
- What is your product and how is it different from the current standard?
- Is your solution a consumer or regulated product? What is the FDA regulatory path?
- Who is the end-user of your product? Who is the purchaser?

For additional information on research topics, please contact a Program Officer with the relevant area of expertise:

Elena Koustova, PhD, MBA

Director, Office of Translational Initiatives and Program Innovations

Email: elena.koustova@nih.gov

Areas of expertise: Biomedical Product Development and Commercialization, Drug Discovery and non-clinical R&D

Leonardo Angelone, PhD

Program Officer

Email: leonardo.angelone@nih.gov

Areas of expertise: FDA-regulated Medical Devices, including Neuroimaging medical devices, Software as Medical Device (SAMd), Neuromodulation Devices, Software

Ramachandran Arudchandran, PhD

Program Officer

Email: ramachandran.arudchandran@nih.gov

Areas of expertise: Therapeutics (Small Molecules, Biologics, Nanotherapeutics, Immunotherapy, Cell & Gene Based Therapies), Biomarker Development and Validation

Irina Sazonova, PhD

Program Officer

Email: irina.sazonova@nih.gov

Areas of expertise: Biomedical Research Tools, Prevention and Education, Consumer Digital Products

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

The NIDCD supports research on the normal mechanisms of, as well as on diseases and disorders of hearing, balance, smell, taste, voice, speech and language. The Institute also supports research related to disease prevention and health promotion. The NIDCD addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders. The NIDCD also supports efforts to create and refine devices, as well as develop cellular-based applications that may replace or substitute for lost and impaired sensory and communication functions. For more information about areas of interest to the NIDCD, please visit our home page at <http://www.nidcd.nih.gov/> and the NIDCD Strategic Plan website (<https://www.nidcd.nih.gov/about/strategic-plans>). Potential applicants are encouraged to contact the program staff listed in the following descriptions of NIDCD program areas early in the process of preparing the application.

Limited Amount of Award

Total funding support (direct costs, indirect costs, fee) normally may not exceed \$252,131 for Phase I SBIR/STTR awards and \$1,680,879 for Phase II SBIR/STTR awards for 2019-2020. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting the application. The Small Business Administration has allowed NIDCD to make awards that exceed these amounts for the areas noted in Appendix A of this document. All applications must contain sufficient detail to justify the requested budget, and NIDCD may decrease the length of an award and/or the budget as recommended by a review committee or administrative review.

Phase IIB Competing Renewal Awards

The NIDCD will accept Phase IIB SBIR/STTR Competing Renewal grant applications to support use of the final product in:

- Studies required by the FDA to validate safety or efficacy.
- Clinical trials with a larger number of participants to adequately validate efficacy.

Research Topics of Interest to NIDCD

The NIDCD accepts a broad range of small business applications that are significant, innovative, and relevant to its mission. Some examples of research topics within the NIDCD mission areas include topics shown below; further example can be found on the NIDCD Strategic Plan website (<https://www.nidcd.nih.gov/about/strategic-plans>). Priority is given to meritorious applications that are likely to develop innovative technologies, provide clear evidence of effectiveness, and bring novel products to the commercial marketplace.

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

****If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,**

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		NIDCD accepts and supports non-SBIR/STTR clinical trial applications through specific opportunities, which can be found on the NIDCD Funding Opportunities webpage: https://www.nidcd.nih.gov/funding

NIDCD Non-Clinical Trials Topics:

NIDCD will accept applications for development and commercialization of novel products in any of the areas noted below.

Hearing and Balance Program

Development of treatment modalities to prevent or lessen the effects of hearing disorders; development of new hearing aids, cochlear implants, and other assistive devices; development of improved screening technologies to assess hearing loss, especially in neonates and infants; development of new or improved power sources for hearing aids or cochlear implants; development of technologies that provide self-fitting, self-adjusting, or other features that increase performance, accessibility, or affordability of hearing aids; development of new outcome measures for assessing the efficacy of treatments for hearing disorders; development of technologies for the study, diagnosis and treatment of tinnitus; development of technologies for the study, diagnosis and treatment of otitis media including non-invasive diagnostics to identify middle ear pathogens, novel antibacterial strategies, and prophylactic anti-microbial strategies;

development of technologies for the study, diagnosis and treatment of noise-induced and age-related hearing loss.

Development of technologies for the study, diagnosis and treatment of balance disorders, particularly for the elderly; development of clinical tests and instruments to assess balance/vestibular function; development of instruments and tests measuring head stability and vestibular function during natural stimulation of the vestibular system; development of perceptual reporting techniques and psychological indices for clinical assessment of the balance-disordered patient; development of tests and new outcome measures for assessing the efficacy of physical rehabilitative regimens for balance disorders; and development of assistive devices for balance disorders, including neural prostheses for the vestibular system.

Development of new research tools to aid in the study of the auditory and/or balance systems that can provide an improved understanding of fluctuating patterns of neural circuit structure and function over time and across large assemblies of neurons; new animal models of impaired function; improved diagnostic tools for inner ear function, including DNA-based assays and biochemical markers of disease. Development of improved tests and instruments for screening and diagnosis of inner ear function; development of technologies to enable gene transfer to the inner ear, including viral vectors; development of cell type specific markers and probes to examine cell lineage in inner ear regeneration.

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Voice, Speech, and Language Programs

Development of technologies for the study, diagnosis and treatment of voice, speech, and language disorders is strongly encouraged, as are projects that focus on determining the nature, causes, treatment and prevention of communication disorders such as stuttering, Specific Language Impairment, spasmodic dysphonia, dysarthria, and aphasia. Emphasis is on research and development of diagnostic measures and intervention strategies for voice, speech, and language disorders; development of communication and other assistive devices for individuals with voice, speech, and language disorders; development of speech and language assessments and interventions for nonverbal individuals with autism; development of new systems for visual communication by individuals who are deaf or severely hearing impaired; development of new systems of communication for individuals with motor speech impairment, including a brain computer interface (BCI) communication prosthesis; development of innovative treatment delivery systems or intervention protocols; design and development of diagnostic measures or materials for early identification of voice, speech and language impairment in children; development of assessments and treatments for childhood and adult voice, speech and language impairment associated with bilingual or multi-cultural populations; development of assessment measures of sign language abilities; development of improved artificial larynges and tracheoesophageal shunts; development of artificial intelligence computer models that simulate normal and disordered voice, speech and language.

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Taste and Smell Program

Development of easily administered diagnostic tools for testing human chemosensory function throughout the lifespan; development of intervention strategies and targeted drugs for the treatment of taste and smell disorders; preventive measures to limit the deleterious effects of infections, airborne toxins, radiation, chemotherapy and other drugs on chemosensory function; novel therapies to stimulate regeneration of mature sensory neurons in damaged and/or aged tissue; development of olfactory biomarkers for neurodegenerative disease; development of tools to facilitate chemosensory research including mouse models of chemosensory dysfunction and improved neuroimaging, cell labeling, and axonal tracing techniques.

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NIDCD Clinical Trials Topics:

NIDCD will accept applications for support of clinical trials in any of the areas noted above.

For additional information on research topics, contact:

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NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

The NIDCR conducts and fosters research on the etiology, pathogenesis, prevention, diagnosis, and treatment of oral, craniofacial and dental diseases and conditions. For more specific information about areas of interest to the NIDCR, please visit our home page at <http://www.nidcr.nih.gov>.

NIDCR’s small business programs are highly focused on maximizing translational science opportunities – moving rapidly and translating basic dental and orofacial biology into useful products.

Research Topics of Interest to NIDCR

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		NIDCR Clinical Trial Planning and Implementation Cooperative Agreement (UG3/UH3) - Clinical Trial Required NIDCR Behavioral and Social Intervention Clinical Trial Planning and Implementation Cooperative Agreement (UG3/UH3) - Clinical Trial Required

NIDCR Non-Clinical Trials Topics:

Developmental Biology and Mammalian Genetics and Genomics

Emphasis is on understanding the development of craniofacial complex and on the identification of the genetic and environmental contributions to craniofacial disorders. The objective of this scientific program is to elucidate the underlying causes of craniofacial disorders, thereby advancing the fields of diagnosis, treatment, and prevention. Interests in this area include but are not limited to:

- A. Develop novel or improved imaging techniques and analysis methods that enable easy, cost effective, accurate, and deep phenotyping for research and/or diagnosis of dental, oral, and craniofacial disorders.
- B. Develop novel or improved sample collection methods that offer superior features such as high sample quantity and quality for state-of-the-art multi-omics data generation and analyses of dental, oral, and craniofacial conditions; easiness of sampling, shipping, and storage; and overall cost effectiveness.
- C. Develop early pregnancy genetic tests for genetic variants involved in inherited syndromic and non-syndromic craniofacial defects.
- D. Develop devices, including point of care units, to improve the diagnoses and treatment of inherited and acquired craniofacial defects.
- E. Develop advanced methods, assays, and reagents that allow flexible throughput to genetically engineer and functionally characterize organisms in craniofacial development and genetics studies.

Tools for Analysis of Genomic, Phenotypic, and Environmental Data

Emphasis is on development of data analysis tools that maximize the utility of existing data resources in basic and clinical research in the dental, oral, and craniofacial domains. Interests in this area include but are not limited to:

- A. Develop bioinformatic and computational tools for integration and analyses of clinical, environmental, behavioral, phenotypic (including imaging and auditory), molecular, and multi-omics data that enable genetic studies, healthy life styles, disease diagnoses, and disease treatment in dental, oral, and craniofacial domains.

- B. Develop advanced analytics tools to retrieve data from diverse databases such as databases, literature, patient records, etc. and infer hidden relations between data elements to inform basic and clinical research in the dental, oral, and craniofacial domains. Tools that use artificial intelligence algorithms are considered highly relevant.

Infectious Diseases and Immunity

Research relating to the etiology, pathogenesis, prevention, diagnosis and treatment of infectious diseases of the oral cavity is supported by the NIDCR. This includes research on practical ways to effectively use the host immune system to prevent or treat oral infectious diseases and microbial-induced inflammation. Infectious diseases of the oral cavity include caries, periodontitis, candidiasis, peri-implantitis, pulpitis, and various viral, bacterial, and fungal infections of the oral mucosa and research on the diagnosis and prevention of oral manifestations and malignancies of HIV infection and AIDS. Specific examples of technology development needs include but are not limited to:

- A. Develop ways to overcome or eliminate the risk of oral infections in persons who smoke or chew tobacco, drink alcohol, or are immunosuppressed, have diabetes, are malnourished, or are psychologically stressed.
- B. Explore novel methods or agents to eradicate oral biofilms (dental plaque) on teeth, oral soft tissues, and dental implants without adversely affecting the normal oral flora.
- C. Isolate, synthesize or prepare new antibiotics and antimicrobial agents that can overcome bacterial and fungal resistance to current compounds. Formulate combinatorial drug regimens to attack microbes growing in oral biofilms (dental plaque).
- D. Develop controlled release systems for local delivery of synthetic peptides, recombinant proteins, or other chemical or immunotherapeutic agents to prevent, control, and/or treat oral infectious diseases, or the oral manifestations of HIV infection.
- E. Develop biological response modifiers or other immunological approaches to reduce or eliminate microbial-induced chronic inflammation or the tissue destruction associated with chronic inflammation in the oral cavity.
- F. Develop ways to interfere with microbial colonization and growth through the use of antimicrobial agents and chemotherapy.
- G. Identify and exploit the structural features of oral biofilms for increased therapeutics delivery.
- H. Develop computer programs and apply systems biology approaches to model biologically active peptide regions of oral components that have anti-fungal, anti-bacterial and anti-viral activities.
- I. Develop substitutes of naturally occurring chemicals (phytochemicals) known to have a role in controlling opportunistic infections induced by HIV.
- J. Develop synthetic peptides and recombinant proteins of oral components with anti-fungal, anti-bacterial and anti-viral activities including those against HIV and oral opportunistic pathogens.
- K. Develop oral topical formulations with combined microbicide, analgesic, and anti-inflammatory activities to enhance oral mucosal defenses and prevent and/or control oral infections and lesions in HIV-infected and/or immunosuppressed subjects.
- L. Discover, test, standardize, and validate novel biomarkers present in oral biospecimens for screening and clinical diagnosis of HIV, and oral opportunistic pathogens infections and AIDS malignancies. Apply similar strategies as listed below for oral, oropharyngeal and salivary gland cancers to AIDS malignancies.
- M. Develop the next generation of rapid tests and point of care devices to detect, quantify, screen, and diagnose HIV and oral opportunistic pathogens. Develop novel assays to quantify oral mucosal

reservoirs for oral viruses, oral immune responses to viral prophylactic and therapeutic vaccines, and viral changes due to anti-viral treatments.

Oral, Oropharyngeal and Salivary Gland Cancers

Emphasis is on molecular mechanisms of oral epithelial cell deregulation that lead to oral cancers. Research related to early detection, diagnosis, and prevention, and treatment of oral cancers is of particular interest. Examples include but are not limited to the following areas:

- A. Develop imaging techniques for the early detection, diagnosis and prognosis of pre-malignant lesions.
- B. Develop effective pharmacological, immunological and radiological modalities for treatment of pre-malignant and malignant lesions in preclinical models.
- C. Develop novel technologies for the genetic and molecular-targeted therapy (e.g. siRNAs, peptide based therapies) in preclinical models.
- D. Develop genetic animal models of oral cancer premalignancy and oral cancer progression that mimic human oral cancers, including HPV-associated oropharyngeal cancers.
- E. Develop animal models to facilitate the testing of therapeutic and chemopreventive agents for oral cancers.

Temporomandibular Disorders and Orofacial Pain

Emphasis is on research for chronic disabling painful diseases of the oral-craniofacial-dental areas including chronic pain, neuropathies, and diseases of the temporomandibular joint. NIDCR encourages applications that include but are not limited to:

- A. Develop improved methods and technologies for measuring nociceptive, chemosensory, tactile, kinesthetic, or proprioceptive function involving craniofacial structures. Such measures may be useful in screening for deficits, improving diagnosis, or for evaluating responses to orofacial treatments or interventions.
- B. Develop improved biomarkers for neuropathic pain conditions affecting oral-craniofacial tissues or structures.
- C. Develop assays facilitating reliable evaluations of relationships between biological and other risk factors as they relate to onset, and exacerbation of pain and for examining transition from acute pain to chronic pain conditions.
- D. Identify and develop novel pharmacologic or biologic agents, including but not limited to small molecules, peptides, recombinant proteins and nucleic acids to prevent, control, and/or treat orofacial pain.
- F. Develop animal models to facilitate testing of therapeutic agents for orofacial pain.

Saliva, Salivary Diagnostics, and Salivary Gland Diseases

Emphasis is on salivary gland physiology and pathophysiology and in the repair and restoration of the damaged gland. Examples include but are not limited to:

- A. Develop viral, non-viral and gene therapy-based approaches to address compromised salivary gland function. Develop cell and tissue-based strategies and technologies for restoration of damaged or destroyed salivary gland function.
- B. Develop novel compounds or materials that protect and preserve salivary glands from head and neck cancer irradiation therapy.

- C. Develop non-invasive methods for the determination of efficacy and safety of artificial saliva, sialogogues, and their delivery vehicles used in addressing the diminution or lack of saliva (xerostomia) due to Sjögren's Syndrome or head and neck cancer irradiation therapy.
- D. Develop biomarker-based technologies for the identification of Sjögren's Syndrome using blood or saliva as body fluids.
- E. Identify biomarkers derived from oral fluids that are predictive of the onset, progression and recurrence of oral diseases and conditions, such as periodontal diseases, caries, and oral, oropharyngeal and salivary gland cancers.
- F. Develop immunological strategies and immunotherapy-based approaches for addressing xerostomia from Sjögren's Syndrome.
- G. Improve the existing or develop new tools for early detection of salivary gland cancers.

Biotechnology, Biomaterials, and Applications for Regeneration and Restoration of Oral, Dental and Craniofacial Tissues

Emphasis is placed on the development of a broad range of technologies targeted at regeneration and restoration of diseased and injured hard and soft tissues of the oral and craniofacial complex and on translating these applications to the clinic. Tissues of interest include craniofacial and alveolar bone, the periodontal ligament, TMJ bone and cartilage, oral mucosa, facial skeletal muscle, vasculature and nerves. Also of interest are multi-tissue composites and organs, such as vascularized and innervated bone and muscle, salivary gland, tooth, periodontium, bone-periodontal ligament-cementum interface and osteochondral complexes. Specific topics could include but are not limited to:

- A. Develop technologies for design, fabrication, and manufacturing of biomimetic and biocompatible biomaterials and scaffolds, including nanomaterials and self-assembling nano-scaffolds, for tissue engineering and regenerative medicine applications. Projects need to include assessments demonstrating the ability of biomaterials and scaffolds to support generation and regeneration of mineralized tissues that replicate the mechanical, physical and biological properties of dentin, enamel or bone.
- B. Develop cell-based technologies, including stem cell-based technologies. These include, designing strategies for isolation, purification, differentiation, scaled up production, manufacturing, standardization and quality control of stem and progenitor cells and their differentiated progenies, derivation of efficient and predictable methodologies for cellular reprogramming, and advancing technologies for reconstruction of stem cell niches for augmenting tissue regeneration.
- C. Develop bioreactor systems to facilitate design, fabrication, and manufacturing of soft and hard tissues of dental, oral and craniofacial complex. These bioreactors may be able to mimic biophysical forces, such as mechanical and electrical forces that normally guide tissue morphogenesis *in vivo*. Among other desirable features of the bioreactors are maintenance of tissue construct oxygenation and real-time tissue imaging capabilities.
- D. Develop improved dental composite materials, including biomimetic and self-healing materials and adhesive sealants. These include but are not limited to materials to replace Bis-GMA resin-based systems that are suitable for restoring crowns of posterior teeth and exposed roots of the teeth. Any novel dental composite restorative components or systems must include assessments in a physiologically relevant test system that mimics microbial and physicochemical conditions found in the oral cavity.
- E. Develop methods, materials, and devices for orthodontic, prosthetic, periodontic, endodontic and craniofacial applications including those that can be used for craniofacial bone distraction, reconstruction, hard and soft craniofacial tissue healing and regeneration, and scarless craniofacial tissue repair.

- F. Develop miniaturized artificial tissue and organ mimics/tissue chips that can be adapted to high-throughput formats for a broad range of applications, such as analysis of biomaterial and tissue function, drug efficacy and toxicology assays, biocompatibility assays, genetic screening and elucidating mechanisms of dental, oral and craniofacial disease.
- G. Develop mathematical, computational, and bioinformatics approaches for modeling oral and craniofacial tissues and organ function and physiology to address needs of system biology, synthetic biology, and single cell analysis.
- H. Develop new approaches for utilizing novel biomolecules, including growth factors, cytokines, small molecules, siRNAs, and others for counteracting diseases and injuries of oral and craniofacial tissues and promoting their healing and regeneration.
- I. Develop new approaches to study molecular or cellular interactions between hard and soft tissues such as between the nervous system and mineralized tissues. Approaches can include development of new technologies or application of existing technologies that are newly applied to the dental and craniofacial field.
- J. Develop advanced viral and non-viral based biomolecule delivery approaches, including nanotechnology-based technologies that can precisely deliver and release therapeutic proteins, nucleic acids, small molecules, or combinations thereof with predictable temporal kinetics to target specific tissue sites.
- K. Develop imaging diagnostics to accelerate clinical implementation of reliable, reproducible, highly specific and sensitive diagnostic instruments for various applications, including but not limited to dental caries, cracked teeth, pulp vitality, bone quality, and periodontal disease.
- L. Development of biosensors for noninvasive, dynamic real-time monitoring of physiological processes in the human body using the oral cavity as the sensing site. These biosensors will be able to assess health and disease states and receive feedback from body fluids and clinical compounds that are found in or pass through the oral cavity and in certain cases, will be able to communicate these outputs wirelessly and remotely.

Preclinical Research

- A. Preclinical research and development activities for dental and craniofacial technologies (including devices, diagnostic instruments, reconstructive materials, pharmaceuticals, therapeutics, vaccines and biologics) that require review and approval by the FDA as a regulated product before commercial distribution.

NIDCR Clinical Trials Topics:

Special statement regarding clinical trials:

Projects proposing a clinical trial within STTR/SBIR applications must provide detailed justification that funds available through these awards can adequately support the trial especially if the trial is testing a drug under an investigational new drug (IND) or investigational device (IDE) application. The cost and time needed to plan and deploy most Phase II and almost all Phase III clinical trials would exceed the support and project period provided under this program.

In addition to the specific clinical trial topics listed below, we also would consider clinical trials for certain program topics listed above. Products originally developed and preliminarily tested with SBIR/STTR support also can be pursued further with funding mechanisms that support clinical trials, see: <https://grants.nih.gov/grants/guide/pa-files/PAR-18-547.html>. Please contact the NIDCR for more information.

Biomedical Clinical Research

Emphasis is on development of methods, drugs and materials to diagnose or treat oral and craniofacial diseases and conditions. Areas of interest include but are not limited to projects that:

- A. Develop improved methods to detect and predict progression of dental caries, periodontal disease, reversible and irreversible pulpitis.
- B. Develop new or improved methods or materials to enhance oral and craniofacial surgery. This would include both intraoral and extra-oral surgery.
- C. Develop improved methods or materials to mechanically and/or biologically repair or treat tooth structure damaged by dental caries or periodontal disease.
- D. Develop improved appliances to aid suckling by newborn infants with cleft palate and cleft lip.
- E. Develop safe and efficacious methods to diagnose caries, pulp vitality and / or periodontal diseases utilizing non-ionizing radiation.
- F. Develop technologies for local delivery of drugs to treat oral and craniofacial diseases or disorders.
- G. Develop novel non-opioid pharmacological medications for management of acute dental pain.
- H. Develop tools for implementation of precision medicine in the oral cavity.
- I. Develop methods and tools to detect soft tissue pathologies in the oral cavity.
- J. Develop oral devices and materials for monitoring local and systemic conditions.
- K. Develop and test for safety and efficacy methods for diagnosing caries, pulp vitality and / or periodontal diseases that utilize non-ionizing radiation.

Behavioral Clinical Research

Provides support for the development of evidence-based products related to behavioral and social aspects of oral health, oral health prevention or treatment interventions, and other patient-oriented aspects of oral health. This includes support for clinical trials and patient-oriented research to establish safety and initial efficacy of products. NIDCR is especially interested in applications that significantly improve oral health by: 1) being broadly applicable to many populations, 2) contributing to meaningful oral health improvements for a specific population, 3) expediting translation of research findings into oral health improvements, and/or 4) equipping oral health care providers, educators or researchers with tools to improve public oral health. Examples of studies of interest include, but are not limited to, the following:

- A. Develop and test devices or methods to improve time-sampled monitoring of behavioral adherence with preventive or therapeutic regimens specifically relevant to oral diseases/conditions. Such devices or methods could be utilized in a variety of settings, including naturalistic settings, within clinical trials, within oral health care delivery systems, etc.
- B. Develop and test novel compliance and survey measures or tools to identify the underlying causes of insufficient preventive dentistry for specific underserved populations.
- C. Develop, or adapt for use in a new population or setting, novel measures or methods for identifying individual, family, group, or other processes that explain oral health behavior.
- D. Develop and test for safety, efficacy, and/or effectiveness of measures or materials for diagnosing, preventing, or treating oral, dental, and craniofacial conditions and disorders.
- E. Develop, or adapt for use in a new population or setting, oral health interventions utilizing technology to improve efficiency of delivery (e.g., management of chronic pain related to temporomandibular joint disorders, etc.).
- F. Develop, or adapt for use in a new population or setting, interventions addressing health behaviors highly associated with oral health (e.g., tobacco, alcohol, and other drug use; management of diabetes, HIV infection, or other chronic illnesses; etc.).

- G. Develop technologies or modules that utilize existing web-based platforms to improve preventive oral health hygiene for children and adolescents (e.g., social marketing via web-based interaction, virtual reality “worlds”, “massively multiplayer online games”, etc.).
- H. Develop and test innovative methods for facilitating collaborations, referrals, and/or ongoing follow-ups between oral health professionals and other health care professionals.
- I. Develop and test web-based training or other innovative approaches for oral health care professionals to accelerate accurate translation of new knowledge regarding oral diseases and their effective prevention or treatment into clinical or public health practice.
- J. Develop and test the effectiveness of innovative teaching tools to inform oral health professionals or the public regarding oral cancer prevention and early detection.
- K. Develop and test the effectiveness of innovative teaching or educational tools or curricula to inform oral health professionals and dental students regarding the role of genetics and genomics, including the oral microbiome, in oral diseases and conditions and in oral health care.

For additional information on research topics, contact:

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NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life. For additional information about areas of interest to the NIDDK, please visit our home page at <http://www.niddk.nih.gov>. See our SBIR/STTR page at <https://www.niddk.nih.gov/research-funding/research-programs/small-business>.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, the NIDDK may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. For topics listed in APPENDIX A: National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations, the NIDDK generally will not fund Phase I applications greater than \$300,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years (Phase II budgets should not exceed \$1,000,000 total costs in any year). For all other topics, the NIDDK does not generally fund Phase I applications greater than \$252,131 total costs or project periods greater than 2 years; or Phase II applications greater than \$1,680,879 total costs or project periods greater than 3 years (Phase II budgets should not exceed \$1,000,000 total costs in any year). Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards

NIDDK will accept Phase IIB SBIR/STTR Competing Renewal grant applications (only) from NIDDK-supported Phase II awardees that propose to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, and 3) continuing refinements to durable medical equipment (DME) designs such as cost reduction, testing for safety, durability, and reliability, and meeting or establishing standards. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. Such products include, but are not limited to biological products, devices, drugs, medical implants, etc. related to the mission of the NIDDK. The previously funded Phase II SBIR/STTR grant need not have been submitted in response to a particular solicitation, as long as the research is appropriate to the purpose of this solicitation. Budgets up to \$1,000,000 total costs per year and time periods up to 3 years may be requested for this Phase IIB Competing Renewal opportunity. These awards are intended to support completion of research needed to obtain an IND or IDE. Applicants must provide evidence that they have consulted formally with the FDA concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements. Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a timeline related to Federal regulatory approval processes.

Examples of research that would be considered responsive to this announcement are listed below for illustrative purposes and are not exclusive of other appropriate activities.

- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.
- Assessment of devices with regard to performance standards related to the FDA approval process.
- Clinical studies in support of an application for clearance or approval by the FDA (refer to current Notices from the NIDDK, and contact program staff for guidance regarding any research involving human subjects).

Final Progress Reports

As detailed in [NOT-OD-17-085](#), the NIH has implemented the Final Research Performance Progress Reports (Final RPPR) for SBIR/STTR Final Progress Reports.

The NIDDK is interested in tracking the progress of the small business concerns it funds and the products they develop. Funding priority will be given to those small business concerns that show not only their ability to develop products but also their growth as a small business concern towards independence from the SBIR/STTR program.

Additional Programs and Services for NIDDK SBIR/STTR Awardees

The NIDDK encourages awardees to apply for the following free programs:

- Phase I: The [NIH Niche Assessment Program](https://sbir.nih.gov/nap) (<https://sbir.nih.gov/nap>) provides awardees with an in depth market analysis for their technology.
- Phase II: The [NIH Commercialization Accelerator Program](https://sbir.nih.gov/cap) (<https://sbir.nih.gov/cap>) will assist awardees in transferring their products to the marketplace.

The NIDDK may offer additional programs throughout the year, and awardees are encouraged to keep their contact information is current so that they receive announcements regarding these programs.

Research Topics of Interest to NIDDK

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s		X	
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		SBIR Phase II, Phase IIB, Direct Phase II, and Fast-Track applications with NIH-defined clinical trials can be submitted in response to PAR-18-108 (expires September 6, 2019). This funding opportunity announcement does not accept STTR applications or SBIR Phase I applications. NIDDK may issue other clinical trials allowed or optional SBIR funding opportunity announcements for specific topics. For applications with NIH-defined clinical trials to be submitted beyond September 5, 2019, please contact NIDDK SBIR Program Staff.
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		<p>Small businesses are eligible to apply for several non-SBIR/STTR funding opportunities. Comprehensive information on Human Subjects Research at NIDDK can be found here: https://www.nidk.nih.gov/research-funding/human-subjects-research</p> <p>R01 applications with clinical trials may be submitted to PA-18-330, <i>Investigator-Initiated Clinical Trials Targeting Diseases within the Mission of NIDDK (R01 Clinical Trial Required)</i>. Multi-center trials are not appropriate to this FOA.</p> <p>Applications for clinical trials requiring three or more investigator sites should be submitted to NIDDK multi-center clinical study implementation planning cooperative agreement (U34) and NIDDK multi-center clinical study cooperative agreement (U01) FOAs.</p> <p>Clinical trial allowed and optional funding opportunities to which NIDDK is subscribed can be found on NIDDK's Current Funding Opportunities page: https://www.nidk.nih.gov/research-funding/current-opportunities.</p>

NIDDK Non-Clinical Trials Topics:**Diabetes, Endocrinology and Metabolic Diseases**

The Division of Diabetes, Endocrinology and Metabolic Diseases supports basic and clinical research on the etiology, pathogenesis, prevention, diagnosis, and treatment of diabetes mellitus and its complications of diabetic wound healing and diabetic neuropathy; thyroid and adrenal diseases; and rare metabolic disorders; as well as research on basic endocrine and metabolic processes. Research topics of potential interest to small businesses include, but are not limited to:

I. SENSORS, HORMONE REPLACEMENT, AND DELIVERY DEVICES:

- A. Assessment of non-invasive, minimally invasive or implantable sensors for monitoring blood or interstitial fluid glucose for prevention of hypo- and hyperglycemia in diabetic patients. NIDDK will give priority to research that has already progressed to an *in vivo* model or to be clinically tested.
- B. Integration of glucose sensor and hormone delivery systems to create an artificial pancreas.
- C. Development of improved insulin and other pancreatic hormone delivery methods or devices.
- D. Development of novel insulin and glucagon formulations showing improved kinetics and stability.
- E. Development of novel and more accurate non-enzymatic based glucose detection technologies.
- F. Development of telemedicine/remote monitoring approaches that can be incorporated as components/and or adjuvants of an artificial pancreas for better diabetes self-management.
- G. Development of technologies that may promote and facilitate adherence/compliance by users of glucose monitoring and control devices.
- H. Development of biomaterials that can deliver drugs or biologics to a diabetic foot ulcer to improve healing.
- I. Development of sensors, algorithms and patient interfaces that can provide feedback to diabetic individuals with insensate feet to prevent or off-load diabetic foot ulcers.

II. SCREENING TESTS, DIAGNOSTICS AND BIOLOGIC TOOLS:

- A. Development of techniques or products/biomarkers useful for predicting, preventing or delaying progression of diabetes, including tests for identifying patients at risk, and methods of monitoring disease progression.
- B. High throughput - Point of care technologies (reliable, accurate, cost-effective, highly sensitive, standardized having rapid turnaround time) for autoantibody detection, T cell –subsets-auto-reactivity and other immune parameters for autoimmune diabetes diagnosis and follow-up.
- C. Development of methods to measure changes in the immune status that may be used as markers to follow the immune-modulatory activity and beneficial effect (beta cell mass preservation, reduction of inflammation at the target organ, etc.,) of biologic agents tested in clinical trials for the prevention and/or treatment of T1D.
- D. Development of high throughput assays based on biologic pathways likely involved in the pathogenesis of diabetes and its complications.
- E. Development of methods/techniques/assays to measure adipose tissue in different depots in humans, including marrow fat.
- F. Develop validated, highly sensitive, and specific assays for glucagon detection.

- G. Development of reagents for assessment/manipulation of glucagon receptor activity in the pancreatic islet and other tissues.
- H. Reagents to be used to improve our understanding of pancreatic alpha-cell biology particularly in response to glucagon and incretins.
- I. Reagents and assays for the accurate expression and quantitation of functional incretin receptors in the endocrine/exocrine cells of the pancreas and relevant extrapancreatic tissues.
- J. Development of materials and technologies for the support of microphysiological platforms used for pre-clinical testing and/or modeling of physiological and pathophysiological aspects of diabetes and metabolic disorders.
- K. Development and validation of tools for use by health care providers/systems to improve diabetes care and prevention.
- L. Development of techniques and tools to identify islet cell progenitors, methods to predict transplant success with recovered islet preparations, and non-invasive imaging as well as other methods for the *in vivo* measurement/ evaluation of pancreatic beta cell mass, function or inflammation after transplantation of pancreatic islet/beta cells.
- M. Point of care low cost /portable technologies for diabetes and pre-diabetes diagnosis.
- N. Development of innovative technologies to accurately measure and to predict and prevent hypoglycemia.
- O. Development of clinical measures of the molecular and cellular damage from diabetes, such as oxidative stress, advanced glycation end-products and chronic inflammation that can be used as predictive or diagnostic biomarkers for diabetes complications.
- P. Development and validation of biomarkers to monitor disease progression and response to therapy for diabetic neuropathy, including peripheral sensory, autonomic and painful diabetic neuropathy.
- Q. Development of diagnostic and predictive biomarkers for diabetic foot ulcers that can be used to diagnose infections, predict healing, select treatment strategies or determine risk of primary or secondary occurrence of foot ulcers.

III. INTERVENTIONS AND THERAPIES:

Diabetes

- A. Development of immunomodulation/tolerance induction strategies to prevent or slow progression of type 1 diabetes.
- B. Development of methods that protect islet grafts after transplantation with no need of immunosuppression, including alternative transplantation sites, immunoisolation strategies, and immunomodulation/tolerance induction.
- C. Development of reproducible methods that improve yield/viability/function of islets and allow ex-vivo expansion of human islets/insulin producing cells while still retaining appropriate functional islet characteristics and the ability to be successfully transplanted.
- D. Development of methods utilizing replenishable cell sources, especially stem cells that produce functional islet like cells/tissues that can be successfully transplanted or tested in microphysiological systems and/or *in vivo* models of the disease.
- E. Development of educational or psychosocial approaches that increase adherence to recommend diabetes treatment regimens.
- F. Development of novel technologies that may facilitate self -management of diabetes and adherence to treatment.

- G. New implantable and easy to replace technologies that may mimic the beneficial effect of gastric bypass/bariatric surgery for the treatment of diabetes without the need of a major invasive surgical procedure.
- H. Development of educational approaches and new technologies that increase adherence to preventative measures for diabetic foot ulcers in high risk patients or increase adherence to off-loading and other recommended treatment regimens for diabetic foot ulcers.
- I. Development of new therapies or devices to prevent and treat diabetic foot ulcers and neuropathy, including autonomic and painful diabetic neuropathy.
- J. Development of new therapies to correct the underlying metabolic defects that result from diabetes, such as reactive oxygen species production and glycation of proteins.
- K. Development of therapies that can prevent or mitigate episodes of hypoglycemia.

Other Endocrine and Metabolic Disorders

- L. Identification of new ligands for previously unclassified (orphan) nuclear receptors and development of partial agonists or antagonists with therapeutic potential for obesity and endocrine diseases within the mission of NIDDK.
- M. Development of Selective Receptor Modulators (SRMs) with tissue specificity and profiles that provide beneficial effects without the side effects secondary to therapies based on naturally occurring hormones.
- N. Development of novel diagnostic and therapeutic strategies for autoimmune endocrine disorders.

Digestive Diseases and Nutrition

The Division of Digestive Diseases and Nutrition supports research on the function, diseases and disorders of the digestive tract; the esophagus, stomach, intestine, colon, anorectum, pancreas, liver, gallbladder, and biliary tract; research on nutrition and obesity as well as information transfer in the field of digestive diseases and prevention of obesity. Innovative investigator-initiated projects that are not mentioned below are encouraged. Areas that may be of interest to small businesses include, but are not limited to:

I. DIGESTIVE AND LIVER DISEASES (CLINICAL)

- A. Development of assays and new genetic screening methods for detection of biomarkers for genetic predisposition to GI-relevant diseases, pancreatitis and liver diseases.
- B. Development of improved means for detecting Barrett's esophagus, GERD, and other GI disorders.
- C. Development of methods for gastrointestinal endoscopy without the need for sedation.
- D. Development of agents to treat motility disorders (e.g., pseudo-obstructive disorder, chronic constipation, and slow bowel transit).
- E. Development of surrogate markers and non-invasive imaging methods to quantitatively assess GI and liver disease, including pancreatic disorders.
- F. Development of non- or minimally-invasive tools that have improved therapeutic capabilities and visualization capabilities for detecting digestive disorders (e.g., mucosal abnormalities and pathologies).
- G. Development of novel antifibrotic therapies for progressive liver failure.
- H. Development of quantitative tests of hepatic "reserve" which would be of use, for example, in assessing the risk of surgery in patients with liver disease.

- I. Development of humanized monoclonal antibodies against HCV and HBV to be used for prevention of recurrent disease in liver transplant patients.
- J. Development of and validation of therapeutic interventions for treatment and/or progression of pancreatitis and its complications.
- K. Development of more accurate and useful approaches to the diagnosis of chronic pancreatitis by functional, radiologic, endoscopic, or pathologic/cytologic means.

II. DIGESTIVE AND LIVER DISEASES (BASIC)

- A. Development of molecular probes for the diagnosis of mucosal dysplasia in inflammatory bowel disease.
- B. Development of gut immune-modulators, or non-antigenic gliadin in celiac disease.
- C. Development of new techniques, including non-invasive imaging, to measure motility/intestinal transit at various sites within the gastrointestinal tract.
- D. Development of techniques for the preservation and transplantation of the liver, small intestine, and pancreas.
- E. Development of novel proteomic or metabolomic technologies designed to study digestive and liver diseases, and their complications.
- F. Development of a test for determining the hepatotoxic potential of drugs, agents or additives that is more sensitive than testing in mice and reflects the human response to the test compound.
- G. Development of non- and better animal models to study hepatotoxic agents.
- H. Development of non-invasive techniques to detect liver disease.
- I. Creation of artificial organs or development of effective xenographic techniques for liver transplantation.
- J. Development of biomarkers that quantitatively assess the degree of cold and warm ischemia injury in donor liver organs.
- K. Development of non-invasive measures of pancreatic exocrine function.
- L. Development of humanized mouse models of multi-allelic diseases.
- M. Development of measurements to quantitate phenotypic or metabolic markers of disease progression in animal models, thus reducing the numbers of animals needed.

III. NUTRITION, OBESITY, AND EATING DISORDERS

- A. Development of novel methods and tools to accurately evaluate nutritional status, physical activity, and energy expenditure.
- B. Development of novel technologies to accurately measure dietary intake.
- C. Development of better means to detect food borne pathogens with the goals of (1) preventing their inclusion in foodstuffs and (2) better treatment of acute infections.
- D. Development of safe drugs that inhibit appetite or increase energy expenditure.

Kidney, Urologic and Hematologic Diseases

The Division of Kidney, Urologic, and Hematologic Diseases supports research into basic mechanisms of the organ and tissue function, and the diseases of the kidney, urologic and hematologic systems. Projects are expected to help develop an understanding of the physiology, pathophysiology, and related diseases

of the kidney, urinary tract, and blood and blood forming systems so that rational treatments, prevention strategies, and/or arrest of diseases may be devised. Support for advances in the technology of cell and molecular biology that will enhance research in kidney, urologic and hematologic diseases is encouraged. Development of –omics, bioinformatics, and multi-scale technologies for the study of these systems, especially where these systems interact, is also encouraged. Research opportunities of interest to small businesses include, but are not limited to:

I. KIDNEY DISEASES

Areas of research include chronic kidney disease, end-stage renal disease, diabetic nephropathy, polycystic kidney disease, hypertensive nephrosclerosis, acute kidney injury, kidney donation (delayed graft function and chronic rejection), congenital kidney disorders, IgA nephropathy, hemolytic uremic syndrome, fluid and electrolyte disorders, kidney repair and regeneration, and normal and abnormal kidney development and physiology.

Dialysis, Devices and Medical Technologies

- A. Development of innovative forms of renal dialysis which improve efficiency and/or have lower associated morbidity (e.g., tissue engineered artificial kidneys, implantable or wearable dialyzers).
- B. Development of pharmacological agents, devices, techniques, or diagnostics that enhance maturation and longevity of a vascular access.
- C. Development of dialysis membrane technologies with enhanced biocompatibility and anti-fouling properties.
- D. Development of a means to provide continuous anticoagulation.
- E. Development of reliable, non-invasive, online monitoring systems for real-time assessment of treatment parameters such as blood volume, access flow, and urea clearance.
- F. Development of new agents for sterilizing dialysis membranes and development of agents or methods to reduce catheter-related infections in hemodialysis or peritoneal dialysis.
- G. Development of hemodialysis or peritoneal dialysis catheters using improved biomaterials, which decrease the foreign body response, biofouling, and biofilm formation.
- H. Development of devices or techniques to enhance the long-term success of kidney transplantation (e.g., techniques for kidney storage and preservation).
- I. Development of health information technologies or mobile technologies that enhance delivery of care for patients with kidney diseases.
- J. Development of technologies to improve kidney biopsies (i.e., to improve safety or targeting).

Diagnostics and Imaging

- K. Development of non- or minimally-invasive methods for evaluating kidney function, including in individuals with congenital genitourinary conditions.
 - 1. Reliable, non-invasive, non-radioactive methods of measuring glomerular filtration rate (GFR).
 - 2. Translation of biomarkers of acute kidney injury or chronic kidney disease with clinical utility into commercial assays.

3. Translation of biomarkers for early detection of kidney diseases or prediction of kidney disease progression, recovery, or drug response.
- L. Development of improved renal imaging techniques, differential renal function assessment, diagnostic assessment of non-malignant kidney diseases, or measurement of perinatal nephron endowment.
- M. Development of technology to improve collection of real-time data (e.g., biomarkers, diet, physical activity, vital signs, psychological parameters, environmental factors), patient outcomes, and adherence for clinical studies (e.g., studies of gene-environment interactions in the manifestation of kidney diseases).
- N. Development of imaging or molecular analysis technologies to enhance information extraction from renal biopsies and development of antibodies or other probes for unique cell types of the kidney.

Drug Discovery and Development

- O. Lead optimization and preclinical development of pharmacological agents that might be used to intervene in acute or chronic renal disorders and in disorders of renal hemodynamics, blood pressure, electrolyte metabolism, and extracellular volume regulation.
- P. Development of drugs or biologics to stimulate productive kidney repair or regeneration.
- Q. Development of functional nephrons for transplantation.
- R. Development of technologies to enhance the validation of kidney disease targets or to screen compounds for efficacy or toxicity (e.g., kidney organoids or tissue chips, more relevant animal models of acute kidney injury).
- S. Development of data and cell banks (e.g., of diabetic kidney disease families and polycystic kidney disease families) for use by the research community.
- T. Development of preventative measures for acute kidney injury (e.g., during coronary artery bypass grafting, sepsis, or treatment with nephrotoxic agents).

II. UROLOGIC DISEASES

Areas of research include benign prostatic hyperplasia, lower urinary tract symptoms (LUTS) including urinary incontinence, urinary tract infections, urinary stone disease, erectile dysfunction, urologic chronic pelvic pain syndromes (including interstitial cystitis and chronic prostatitis), congenital urologic disorders, repair and regeneration of lower urinary tract organs, and normal and abnormal lower urinary tract development, and genitourinary physiology.

Diagnostics and Imaging

- A. Translation of blood or urine biomarkers in the lower urinary tract or other urologic disorders into commercial assays with clinical utility.
- B. Development of non-invasive or minimally-invasive methods to diagnose bladder inflammation or changes in the urothelium that are not of a cancerous origin.
- C. Development of new technologies or methods with reduced radiation dose for evaluating vesico-ureteral reflux in children and infants.

- D. Development of diagnostic modes to clinically and non-invasively or minimal-invasively measure bladder outlet obstruction before and after surgical or pharmaceutical intervention.
- E. Development of objective diagnostic devices or methods for the assessment of urinary storage and voiding disorders, including stress, urge, and mixed incontinence, in both adults and children.
- F. Development of wireless and non-invasive or minimally-invasive measurement technologies for real-time assessment of lower urinary tract function, which can include neuro-pharmacological/neuro-physiological urodynamics.
- G. Development of radiation-free and accurate imaging technologies for urinary stone disease.

Drug and Device (Therapeutic) Interventions

- H. Lead optimization and preclinical development of pharmacological agents for treatment or prevention of urinary stone disease, urological chronic pelvic pain syndromes, urinary tract infections, or other benign urologic diseases or conditions.
- I. Development of novel neuromodulation devices, which restore function or mitigate pain conditions of the lower urinary tract.
- J. Development of urinary catheters which reduce the incidence of infection in the urinary tract and decrease urethral and bladder inflammation.
- K. Development of technologies for treatment of bladder outlet obstruction.
- L. Development of health information technologies or mobile/wireless technologies that enhance delivery of care for patients with benign urologic diseases or conditions, including transition in lifelong care of congenital genitourinary conditions.
- M. Development of bioengineered materials or structures, including cell-laden structures, for the repair or regeneration of genitourinary organs.

Research Tools

- N. Development of tools for elucidating the role of urinary or gut microbiome in urinary stone disease or other benign urologic diseases or conditions.
- O. Development of novel models of benign prostatic hyperplasia.
- P. Development of technology to improve collection of real-time data (e.g., biomarkers, diet, physical activity, vital signs, psychological parameters, and environmental factors), patient-reported outcomes, and adherence for clinical studies (e.g., studies of gene-environment interactions in the manifestation of urologic diseases).

III. HEMATOLOGIC DISEASES

The NIDDK hematology research program focuses on understanding basic cellular and molecular mechanisms that underlie the production and function of blood cells in health and disease. The program emphasizes translational applications of new insights and knowledge gained from basic research in these areas toward the development of novel or improved approaches for the diagnosis, stratification, and treatment of hematologic diseases. This includes the development of disease biomarkers, gene targeted therapies, hematopoietic stem cell transplantation in heritable blood diseases (e.g., sickle cell disease, thalassemia, hemochromatosis, hemoglobinopathies, iron overload, anemia, and cytopenia), and the measurement and chelation of tissue iron in iron overload disorders. The NIDDK hematology research

program provides resources for basic and preclinical development efforts leading up to IND or IDE submissions but does not fund clinical trials. The program has a particular focus on myeloid lineage and hematopoietic stem cells, including the effects of aging on hematopoiesis.

Drug Discovery and Development

- A. Establishment of robust in vitro or animal models of benign hematologic diseases for drug discovery or development.
- B. Development of therapeutics that target elements of hematopoietic stem cell niches (e.g., stromal cells, osteoblasts, endothelium, macrophages, pericytes, nerve cells).
- C. Development of therapeutics that modulate blood cell production from hematopoietic stem cells and progenitors based upon understanding of physical and chemical regulatory pathways.
- D. Development of therapeutics that modulate metabolism, storage, and transport of iron.

Cell Therapies

- E. Development of equipment, chemically-defined reagents, and methods for high volume ex vivo expansion, isolation, and/or differentiation of highly purified human hematopoietic stem and progenitor cells.
- F. Development of therapeutics that induce fetal hemoglobin synthesis by chemical means, genome editing, or other means.
- G. Development of therapeutics that target blood cell membrane structure.

Diagnostics and Imaging, Medical Technologies, and Research Tools

- H. Development and validation of sensitive, specific, reproducible, quantitative, and clinically applicable assays for measuring levels or expression of iron regulatory molecules (e.g., hepcidin).
- I. Development of technologies to track, purify, monitor or assay single-cells in vivo or in vitro.
- J. Development of non-invasive systems for monitoring circulating blood cells, blood chemistry or blood cell production.
- K. Development of imaging technology for the non-invasive measurement of bone marrow cellularity and function.
- L. Development of imaging technology for the non-invasive measurement of tissue iron loading and distribution.
- M. Development of technologies to understand the roles of mitochondria in benign hematologic diseases.

NIDDK Clinical Trials Topics:

NIDDK will accept clinical trials in most of the areas listed above in the non-clinical trials topics. NIDDK does not support clinical trials in hematologic diseases.

For additional information on research topics, contact:

DIABETES, ENDOCRINOLOGY AND METABOLIC DISEASES

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KIDNEY, UROLOGIC AND HEMATOLOGIC DISEASES

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NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

The mission of the National Institute of Environmental Health Sciences www.niehs.nih.gov is to discover how the environment affects people in order to promote healthier lives, with a vision of providing global leadership for innovative research that improves public health by preventing disease and disability. NIEHS achieves its mission and vision through a multidisciplinary biomedical research program, prevention and intervention efforts, and a communication strategy that encompasses training, education, technology transfer and community outreach.

For additional information about NIEHS's Small Business Programs, please visit <https://www.niehs.nih.gov/funding/grants/mechanisms/sbir/>. In addition to this omnibus program announcement, the NIEHS releases targeted SBIR/STTR Funding Opportunity Announcements (FOAs); sign up for the listserv (<https://list.nih.gov/cgi-bin/wa.exe?SUBED1=sbir-niehs&A=1>) to be notified of FOAs.

Limited Amount of Award

For all NIEHS research interest topic areas other than Hazardous Substances Remediation and Site Characterization SBIR Program included in this PHS 2019-2 Omnibus SBIR/STTR Solicitation, the NIEHS will accept SBIR/STTR applications up to \$225,000 total costs for Phase I and \$1,500,000 for Phase II. Requests for costs above the SBIR/STTR budgetary guidelines of \$168,087 for Phase I and \$1,120,586 for Phase II must be well-justified. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project. The Hazardous Substances Remediation and Site Characterization SBIR Program has different limits on budget requests for both Phase I and Phase II; check under that topic below for the details. NIEHS will generally not fund applications at budget levels exceeding these budget guidelines. For budgetary, administrative, or programmatic reasons, NIEHS may decide not to fund an application or may decrease the length of an award and/or the budget.

Final Progress Reports

As detailed in [NOT-OD-17-085](https://www.nih.gov/news-events/press-releases/details/NOT-OD-17-085), the NIH has implemented the Final Research Performance Progress Reports (Final RPPR) for SBIR/STTR Final Progress Reports.

The NIEHS is interested in tracking the progress of the small business concerns it funds and the products they develop. It is expected that small businesses who have received previous SBIR/STTR grants have had success in commercializing their previously supported technologies. Small businesses that are primarily interested in research and development (and not commercialization) should consider other grant mechanisms at NIH, rather than the SBIR/STTR program. Funding priority will be given to those small business concerns that demonstrate their ability to develop and commercialize products.

Research Topics of Interest to NIEHS

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		ES 18-003 Environmental Health Sciences Core Centers (EHSCC) (P30 Clinical Trial Optional) ES 18-007 Virtual Consortium for Translational/Transdisciplinary Environmental Research (ViCTER) (R01 Clinical Trial Optional)

NIEHS Non-Clinical Trials Topics:

Exposure Assessment Tools

The NIEHS Exposure Biology and the Exposome Program encompasses the totality of the exposures that a person experiences from conception to death along with the associated biological responses to those exposures. Validated tools are needed to measure, analyze, and predict a wide range of internal and external exposures and health outcomes across diverse geographic populations. These tools should be designed fit-for-purpose in collaboration with the stakeholders (e.g., community outreach programs, citizen scientists, disaster response personnel, epidemiologists, or clinical researchers). Examples include:

Sensors and other exposure assessment tools

- Technologies to assess personal exposure in population studies, including networks of fixed site and wearable monitors
- Devices for collecting exposure measurements across multiple stressors and scales (i.e., recording time and location of exposures), with an emphasis on high sensitivity and specificity and low-cost devices, when feasible. High-priority analytes include emerging contaminants (e.g., perfluorinated compounds and herbicides) as well as ultrafine particulates, PAHs, and

- pesticide exposures
- Technologies to collect environmental samples for subsequent targeted and untargeted laboratory analysis
- Sensor technologies that can be integrated into existing smart devices for sensing personal environment
- Personal sensors that are easily worn and durable that can be rapidly deployed after a disaster by researchers to emergency response workers and individuals in the community to help understand dermal and/or airborne exposure levels, locations, and times.

Computational and Informatics-based Tools and Methods

- Informatics tools and platforms to organize, store, retrieve, extract, and integrate information on exposures and health effects data
- Application of machine learning methods and natural language processing for extracting and integrating diverse data types and for generating causal networks from experimental data and public knowledgebases.
- Computational and statistical approaches to integrate exposure data from different sources, including publicly available databases and information on consumer products, and monitoring approaches (e.g., sensors, remote sensing, and biomonitoring), to provide quantitative exposure estimates
- Adapting or developing new methods and tools for automating literature and systematic reviews, including article selection and prioritization, data extraction, study quality evaluation, and summarization of articles. This may include new methods for scanning and compiling information from gray literature and web content for environmental health impacts
- Novel tools and methodologies to extract, analyze, and visualize exposure data from large population studies, especially temporally and spatially-resolved exposure data (such as crowdsourcing and exposure mapping) as well as the relationship between exposures and human health and disease
- Informatic tools that can be used by the research community to rapidly build environmental health disaster research protocols similar to the NIEHS RAPIDD Protocol <https://dr2.nlm.nih.gov/> from existing information, tools, and platforms (e.g., [PhenX](#), [PROMIS](#), and Disaster Research Response [DR2](#) Repository) to support rapid research response efforts in the U.S. and globally.
- Informatic and data management tools for disaster response that enable rapid collation and integration of data from stationary sources and personal exposure monitors and survey information collected from individuals using mobile platforms.
- Mobile devices and Apps for collecting information on environmental exposures from study participants involved in disaster research responses.

Information on the NIEHS Exposure Biology and the Exposome Program can be found at <http://www.niehs.nih.gov/research/supported/exposure/bio/>

Nano Environmental Health and Safety

The NIEHS Nano Environmental Health and Safety (Nano EHS) program is interested in the detection of engineered nanomaterials (ENMs) in the environment, in consumer products, and in biological samples, and is interested in technologies or methods that can predict toxicity potential of ENMs.

High priority engineered nanomaterials of interest are those with a potential for human exposure.

Examples include:

- Sensors that can detect metal, carbonaceous engineered nanomaterials in air, water, and consumer products, and provide a contextual assessment of the toxicological potential
- Biomonitoring technologies for personal monitoring that can detect engineered nanomaterials using non- or minimally-invasive approaches

- Mid- to high- throughput and high-content assays using *in vitro* or tissue chip technologies to screen and rank toxicity of emerging 2D- and anisotropic engineered nanomaterials for cytotoxicity, genotoxicity, and metabolic toxicity.
- Methods and tools to assess leaching of engineered nanomaterials from nanotechnology-based water filtration systems
- Technologies to assess the life cycle of nanomaterials from nano-enabled products in the market

Information on the Nano EHS program can be found at <http://www.niehs.nih.gov/research/supported/exposure/nanohealth/index.cfm>

Toxicity Screening, Testing, and Modeling

NIEHS supports research to identify the hazards, as well as the mechanistic understanding, of the effects of environmental stressors on biological systems that can lead to adverse health outcomes. To increase the ability to characterize or predict the toxicity of environmental stressors, the National Toxicology Program (NTP) <http://ntp.niehs.nih.gov/> at NIEHS is interested in technologies to support the goals and initiatives of the Tox21 Program <http://ntp.niehs.nih.gov/results/tox21/index.html>. Phase III of Tox21 is focused on expanding biological endpoints and relevance to humans. The following efforts support Tox21 and other NTP goals:

These approaches can include the development of physiologically-relevant cell-based systems. *In vitro* approaches should effectively model cellular functions and responses to chemical exposure reflective of responses in humans or animals and may be used to reduce or replace *in vivo* animal use. High priority areas are the development of metabolically competent *in vitro* screening models and assay systems for various tissue types (*e.g.*, liver, GI tract, kidney, neurological, mammary gland, lung, cardiac, and immune function). Examples include:

- Improved human organotypic culture models (OCM) that more accurately predict *in vivo* function for characterizing toxicity and/or disease processes. Priority areas are improved capability for generating more mature cells from embryonic stem (ES) or induced pluripotent (iPS) cells for organotypic models and the ability to conduct *in vitro* pathology studies using OCM or 3D culture models.
- Organotypic models using isolated primary cells from rat or mouse models or other experimental animal models, which can enable comparisons between *in vivo* and *in vitro* toxicity endpoints
- Approaches to characterize and integrate key molecular and cellular changes related to effects of toxicant exposures in carcinogenicity, developmental neurotoxicity, or cardiotoxicity
- Data-rich *in vitro* approaches that incorporate medium-throughput 'omics and/or high-content imaging for toxicity screening
- *In vitro* toxicology screening models to predict 'idiosyncratic' compound-induced effects in humans (*e.g.*, drug-induced liver injury or cytokine storm)
- *In vitro* model systems that incorporate barrier functionality and transport functions into tissue models (*e.g.*, kidney, placenta, or blood-brain barrier)
- Enhanced lower organism models (*e.g.*, zebrafish or *C. elegans*) for toxicity screening
- Stem cell models and assays for evaluating the effects of toxicants on cell differentiation with multiple functional endpoints
- Screening systems that incorporate genetic diversity into toxicology testing (*e.g.*, panels of human iPS cells or rodent stem cells)
- *In vitro* assays to model inflammatory responses to xenobiotics
- Short-term tests, assays, or systems designed specifically to reduce or replace existing regulatory animal studies for acute toxicity (oral or inhalation), reproductive or developmental toxicity, carcinogenicity, or ocular toxicity

Computational approaches for predictive toxicology

- New computational systems and tools for integrating toxicity data, including *in vivo* and *in vitro* data, to analyze and visualize data across different screening systems
- Improved experimental and computational tools for *in vitro* to *in vivo* extrapolation of xenobiotic exposures across a range of assay types
- Computational tools for quantitatively modeling metabolic transformation of xenobiotics
- Computational tools or systems for rapidly assessing results of literature searches, short-term tests, assays, or other relevant testing to help provide screening level risk characterization of complex mixed chemical exposures in response to disasters

Other technologies for enhanced toxicology testing

- Alternative or improved methods for fixing and preserving tissues that maintain cellular structure for histopathology while minimizing degradation of nucleic acids (RNA, miRNA, DNA, methylated DNA), proteins or metabolites, so that archival tissue blocks can be better used for molecular analysis
- Liquid biopsy methods for isolation and novel assays of circulating nucleic acids that reflect environmental chemical exposures or toxicity
- Approaches to improve efficiency of laboratory-based toxicology studies, including more rapid, cost-effective methods for RNA isolation from tissue lysate, and novel methods for removing necrotic cells in complex cell culture models
- Alternative or improved methods for extracting high quality RNA, miRNA, DNA, methylated DNA), proteins, or metabolites from existing archived tissues

Biomarkers of Exposure and Response

To better understand the risks to human health from environmental agents, NIEHS supports the development and validation of biomarkers of exposure, including improved measures of internal dose, DNA adduct identification, and untargeted analysis for metabolite identification, and biomarkers of response, including assays that can distinguish reversible from irreversible changes in target organs or surrogate tissues. Examples include:

Biomonitoring technology

- Personal or point-of-care monitoring technologies for rapid detection of multiple exposures in biospecimens using non- or minimally-invasive approaches
- Improved methods to detect DNA or protein adducts resulting from exogenous exposures

Biological response markers

- Markers of oxidative stress, inflammation, DNA damage response, immune function, mitochondrial dysfunction, or altered epigenetic regulation
- High priority human biomarkers include, but are not limited to: inflammation biomarkers, plasma- or serum-based markers that reflect altered RNA, protein expression, or metabolite profiles, markers developed in exhaled breath, buccal cells, or other easily accessible, non-invasive biological samples, miRNA or other exosome biomarkers, and epigenetic markers in surrogate tissue reflecting modifications in target tissues

Intervention Technologies

NIEHS supports efforts to prevent or reduce exposures to environmental stressors that affect human health. Technologies to reduce exposure may include:

- Technologies for removing contaminants from drinking water for home use
- Approaches for reducing volatile compounds and other inhaled toxicants for use in the home, workplace, and school settings. Examples may include improved air filtration systems as well as technologies to monitor the efficacy of filtration systems

- Technologies and applications that can provide real-time alert about relevant environmental exposures in sensitive populations (such as asthmatic population)

Education/Outreach

As part of its Partnerships for Environmental Public Health (PEPH) Program, NIEHS is interested in developing tools that build capacity, improve environmental health literacy, and support citizen science endeavors. These approaches or resources should be fit for purpose to meet the needs of the following audiences: community members, health care and public health professionals, educators, and students of all ages. Approaches may include:

- Mobile applications that provide environmental health information about exposures of concern in food, air, water, or consumer products. These may include
 - Apps that provide the context for the exposures such as single or multiple, interacting exposures, level of exposure, frequency and proximity to source
 - Apps that can be adapted for various age groups (e.g., children or the elderly), races, ethnicities and/or languages
 - Apps that visualize exposure risks with respect to levels of exposure, sources and health risks
- Devices for collecting and reporting information on exposures in environmental samples for educational purposes in schools or communities
- Systems that can utilize public and voluntary population data from sensors, activity trackers, GIS enabled devices, social communications, and surveillance cameras; for example, to assist disaster response and communication
- Educational resources related to environmental health in school settings or community education programs (e.g., Photovoice projects or GIS mapping)
- Training materials for wider dissemination of risk information (e.g., resources for high school students to train younger students; or community leaders to build capacity of other community residents)
- Continuing medical education classes, on-line courses, or on-line tools to build the environmental health literacy of health care professionals
- Documentaries, short films, or television shows on environmental health science topics with accompanying discussion guides, lessons, or activities to facilitate broader use of the programming
- Tools to disseminate current information on exposure risks or hazards. This may include signage and other materials to communicate hazards, including risks from fish consumption, marine toxins, or air quality alerts in multiple languages for affected communities

Information on the PEPH program can be found at

<https://www.niehs.nih.gov/research/supported/translational/peph/index.cfm>

Hazardous Substances Remediation and Site Characterization SBIR Program

The NIEHS Superfund Research Program (SRP) "Hazardous Substances Detection and Remediation Program" supports Small Business Innovation Research Grants (SBIR, R43, R44) to foster the commercialization of technologies, products, and devices for detection and remediation of hazardous substances in the environment. The SRP is specifically interested in proposals applying new engineering, bioengineering, and biotechnology approaches to develop novel strategies to characterize, monitor, and remediate hazardous substances at contaminated sites.

Topics of interest include, but are not limited to:

Remediation

- Novel technologies for *in situ* remediation of contaminated sediments, soils, and groundwater
- Innovative bioremediation and phytoremediation technologies including development and culturing/propagation of plants, bacterial strains, or fungal species optimized for bioremediation
- Remediation strategies designed to emulate biological processes or functions (e.g. biomimicry) by applying novel replacement materials/technologies to source areas or downgradient plumes
- Technologies to remediate chemical mixtures in environmental media
- Portable adsorption systems for removing chlorinated volatile organic compounds (VOCs) from indoor air to achieve risk-based indoor air standards
- Nano-enabled structures, electrochemical methods, photocatalytic processes, thermal treatments, or filtration-based methods of remediation
- New strategies for delivery of reagents for groundwater remediation: *in situ* chemical oxidation (ISCO), zero valent iron (ZVI), and hydraulic fracturing (note: this excludes gas exploration)
- New strategies for delivery of reagents for recovery/extraction of contaminants in groundwater
- New amendments to stabilize contaminants and/or to stabilize caps for soil and sediment remediation

Site Characterization

- Computational, geographical information system-based, or modeling products for predicting fate and transport of contaminants, rates of remediation, bioavailability, or for identifying contamination sources
- Real-time, on-site monitoring: soil, surface water, groundwater, subsurface, sediments, air (such as volatile releases from sites), etc.
- Nanotechnology-based sensors and probes, biosensors, lab-on-chip, and miniaturized analytical probes; miniaturized data analysis tools
- Products that allow for rapid sample clean-up/preparation for analysis of environmental samples
- Self-contained miniaturized toxicity-screening kits for detecting contaminant-specific hotspots
- Non-targeted or multi-analyte field sampling devices or kits, including sample collection products that can sequester a suite of analytes for later analysis
- Assays or devices to determine the extent to which a contaminant is bioavailable
- Novel geophysical techniques, sensors, and field analytical methods combined with robotics platforms and real-time mapping/data visualization

Examples of remediation and site characterization needs:

- Devices to detect and measure vapor intrusion and solutions for mitigation, including tools to determine when vapor mitigation is complete
- Devices to detect and measure non-aqueous phase liquids (NAPLs) and dense non-aqueous phase liquids (DNAPLs) in the subsurface
- Site characterization techniques and strategies for complex geology (fractured, karst and heterogeneous layered deposits) including understanding the fate of contaminants within rock matrices and properties that affect back diffusion
- Technologies for rapid extraction or processing of soil for incremental sampling methodologies (ISM)
- Technologies for rapid analysis of total and/or bioavailable/bioaccumulating metal fractions in soils and sediments (including easy-to-use kits for soil/sediment screening)
- Technologies for automated elongated mineral fiber counting (e.g. for asbestos samples)
- Active or passive remediation technologies for mining influenced water; technologies to mitigate effects from acidic drainage; portable neutralization treatment systems, etc.
- Remediation technologies for poly- and perfluorinated alkyl substances such as perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA)

- Enhancements to existing remedial technologies (permeable reactive barriers, funnel and gate systems, capping to limit infiltration, etc.) to significantly improve performance
- Novel green or sustainable detection technologies and remediation approaches that: improve energy efficiency and reduce waste generation; and/or are capable of withstanding fire, flooding, land use changes, and other catastrophic events
- Technologies for measuring/treating environmental contamination as part of a disaster response effort

Applicants must demonstrate that the proposed technologies are relevant to Superfund. Per program mandates described in the Superfund Amendment Reauthorization Act (SARA), SRP does not accept applications targeting oil or gas site characterization/remediation. Applicants are strongly encouraged to stay within the statutory budget guidelines whereby total funding support (direct costs, indirect costs, fees) does not exceed \$168,087 for Phase I awards and \$1,120,586 for Phase II awards. Applicants are encouraged to contact NIH program officials prior to submitting any award budget for the "Hazardous Substances Remediation and Site Characterization Small Business Innovation Research Program" in excess of these amounts. **Please note:** the NIEHS Superfund Research Program (SRP) "Hazardous Substances Remediation and Site Characterization Small Business Innovation Research Program" no longer accepts Small Business Technology Transfer Grant (STTR: R41, R42) applications.

<https://www.niehs.nih.gov/research/supported/centers/srp/funding/hwaerp/index.cfm>

Worker Training Program

The NIEHS Worker Training Program (WTP) is interested in the development of Advanced Technology Training (ATT) products for the health and safety training of hazardous materials (HAZMAT) workers; skilled support personnel; emergency responders in biosafety response, infectious disease training and cleanup; and emergency responders in disasters and resiliency training. ATT as defined by the Worker Training Program (WTP) includes, but is not limited to, online training, virtual reality, and serious gaming, which complement all aspects of training from development to evaluation including advance technologies that enhance, supplement, improve, and provide health and safety training for hazardous materials workers. **WTP accepts solicitations via requests for applications (RFA).** Please contact Kathy Ahlmark ahlmark@niehs.nih.gov for information on the next solicitation date, which differs from the standard receipt dates of this NIH omnibus.

Information on the WTP program can be found at https://www.niehs.nih.gov/careers/hazmat/about_wetp/

NIEHS DOES NOT Fund

- Technologies for the detection and remediation of pathogens in the environment - contact EPA or DoD for information on SBIR funding opportunities for this topic.

NIEHS Clinical Trials Topics:

NIEHS will accept SBIR/STTR applications that propose clinical trials related to:

- Development and testing of sensor technology, biomarkers, or biomonitoring technologies, including field testing of new technologies for exposure assessment and biological responses to environmental exposures
- Evaluation of tools or approaches for education and dissemination of information on environmental hazards, including evaluation of changes in behavior

For additional information on research topics, contact:

Dr. Daniel Shaughnessy
National Institute of Environmental Health Sciences
Division of Extramural Research and Training
POB 12233 (K3-12)
Research Triangle Park, NC 27709
(984) 287-3321
Email: shaughn1@niehs.nih.gov

For information on the NIEHS Superfund Research Program - Hazardous Substances Remediation and Site Characterization SBIR Program, contact:

Dr. Heather Henry
National Institute of Environmental Health Sciences
Division of Extramural Research and Training
POB 12233 (K3-12)
Research Triangle Park, NC 27709
(984) 287-3268
Email: henryh@niehs.nih.gov

For administrative and business management questions contact:

Ms. Bryann Benton
National Institute of Environmental Health Sciences
Division of Extramural Research and Training
Grants Management Branch
(919) 323-5577
Email: bryann.benton@nih.gov

NATIONAL EYE INSTITUTE (NEI)

The mission of the NEI is to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NEI may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. For topics listed in APPENDIX A: National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations, NEI does not generally fund Phase I applications greater than \$300,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years.

Phase IIB Competing Renewal Awards

The NEI will only accept SBIR Phase IIB Competing Renewal grant applications from Phase II SBIR awardees to continue the process of developing technologies that ultimately require federal regulatory approval or require extraordinary time and effort in the Research and Development phase. Such technologies include, but are not limited to, pharmacologic agents, biological products, and devices. These technologies should be clearly related to the mission of the NEI. This renewal grant should allow small businesses to reach a stage in the project where interest and investment by third parties is more likely. The NEI expects that the Phase IIB grant will accelerate the transition of SBIR Phase II projects to the commercialization stage. The NEI encourages applicants to establish business relationships with third-party investors and/or strategic partners who can provide substantial financing to help accelerate the commercialization of promising new products and technologies that were initiated with SBIR funding. The Competing Renewal application must be a logical extension of a previously completed Phase II (R44) SBIR grant. NEI grantees seeking SBIR Phase IIB Competing Renewal funding must submit an application within a period no later than the first six receipt dates following expiration of the previous Phase II budget period. Budgets not to exceed \$1,000,000 total costs per year and time periods up to three (3) years may be requested for this SBIR Phase IIB Competing Renewal opportunity.

Although matching funds are not required, the NEI strongly encourages that applicants obtain significant private investment. Competitive preference and funding priority will be given to applicants that demonstrate the ability to secure substantial independent third-party investor funds).

Potential applicants are strongly advised to contact Dr. Jerome Wujek (contact information provided below) before beginning the process of putting an application together.

Research Topics of Interest to NEI

The following topics are meant for illustrative purposes only and are not exclusive of other appropriate activities.

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		R01 PA-18-351 R24 PAR-18-707 UG1 PAR-18-521, PAR-18-522, PAR-18-523

NEI Non-Clinical Trials Topics:

- A. **General Research and Development Topics:** NEI is interested in providing support for the development of new technologies, strategies, research tools, reagents and methods that can be applied to basic and translational research which will benefit vision health. This encompasses research and development of innovative enabling technologies in areas of genomics, proteomics and nanotechnology. More specific topics include drug and high throughput assays; drug delivery systems; gene therapy, cell-based therapy and regenerative medicine; development of in vitro and in vivo disease models; surgical devices and materials; telemedicine, mobile health, and health education; and design/fabrication of new or improved ophthalmic instruments for diagnosis and treatment of eye disorders.

- B. **Retinal Diseases:** New therapeutic approaches for inflammatory and degenerative diseases and for inhibition of abnormal angiogenesis in the retina and choroid; Better methods of diagnosing and treating diabetic retinopathy and other vascular diseases; Non-invasive techniques for early diagnosis of macular degeneration and other retinal degenerative diseases; Instruments and

procedures for improved surgical management of retinal detachments; Retinal prostheses to help restore visual function; Gene therapy/optogenetic methods for light sensitivity restoration in the retina; Better methods for cell or tissue transplantation; New animal models/systems that better mimic human retinal disease.

- C. **Corneal Diseases:** New diagnostic tools, therapeutic agents and drug delivery methods for the treatment of corneal injury, infection, dry eye, ocular pain, and other ocular surface disorders; New biomaterials for corneal prostheses and corneal transplants; Instruments and procedures for correcting the refractive power of the cornea and/or measuring the cornea's optical properties or other physiological properties.
- D. **Lens and Cataract:** New approaches in the post-operative management of cataract surgery; New surgical instruments for cataract extraction and new biomaterials for replacement of the natural lens; Design/fabrication of aspheric, toric, multifocal and accommodating intraocular lenses.
- E. **Glaucoma and Optic Neuropathies:** New therapeutic agents, instruments, and procedures for the diagnosis and treatment of glaucoma; Non-invasive methods to measure changes in the optic nerve head and retinal fiber layer.
- F. **Strabismus, Amblyopia, and Refractive Error:** New approaches to detect and treat strabismus, amblyopia, and myopia; New tools and techniques for vision screening; New or improved methods and materials for correcting the refractive power of the eye and/or measuring the eye's optical properties or other physiological properties; New materials and manufacturing processes for eyeglasses and contact lenses; prosthetic devices (both cortical and subcortical) for vision restoration.
- G. **Visual Impairment and Blindness:** Instruments and methods to better specify, measure, and categorize residual visual function; New or improved devices, systems, or programs that meet the rehabilitative, adaptive, and everyday living needs of visually-impaired/blind people.

NEI Clinical Trials Topics:

- A. **General Research and Development Topics:** NEI is interested in providing support for the development of new technologies, strategies, research tools, reagents and methods that can be applied to basic and translational research which will benefit vision health. This encompasses research and development of innovative enabling technologies in areas of genomics, proteomics and nanotechnology. More specific topics include drug and high throughput assays; drug delivery systems; gene therapy, cell-based therapy and regenerative medicine; development of in vitro and in vivo disease models; surgical devices and materials; telemedicine, mobile health, and health education; and design/fabrication of new or improved ophthalmic instruments for diagnosis and treatment of eye disorders.
- B. **Retinal Diseases:** New therapeutic approaches for inflammatory and degenerative diseases and for inhibition of abnormal angiogenesis in the retina and choroid; Better methods of diagnosing and treating diabetic retinopathy and other vascular diseases; Non-invasive techniques for early diagnosis of macular degeneration and other retinal degenerative diseases; Instruments and procedures for improved surgical management of retinal detachments; Retinal prostheses to help restore visual function; Gene therapy/optogenetic methods for light sensitivity restoration in the retina; Better methods for cell or tissue transplantation.
- C. **Corneal Diseases:** New diagnostic tools, therapeutic agents and drug delivery methods for the treatment of corneal injury, infection, dry eye, ocular pain, and other ocular surface disorders; New biomaterials for corneal prostheses and corneal transplants; Instruments and procedures for correcting the refractive power of the cornea and/or measuring the cornea's optical properties or other physiological properties.

- D. **Lens and Cataract:** New approaches in the post-operative management of cataract surgery; New surgical instruments for cataract extraction and new biomaterials for replacement of the natural lens; Design/fabrication of aspheric, toric, multifocal and accommodating intraocular lenses.
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- F. **Strabismus, Amblyopia, and Refractive Error:** New approaches to detect and treat strabismus, amblyopia, and myopia; New tools and techniques for vision screening; New or improved methods and materials for correcting the refractive power of the eye and/or measuring the eye's optical properties or other physiological properties; New materials and manufacturing processes for eyeglasses and contact lenses; prosthetic devices (both cortical and subcortical) for vision restoration.
- G. **Visual Impairment and Blindness:** Instruments and methods to better specify, measure, and categorize residual visual function; New or improved devices, systems, or programs that meet the rehabilitative, adaptive, and everyday living needs of visually-impaired/blind people.

Additional Information

The NEI's programs are described in more extensive detail in documents which are available from the Institute. For additional information about the research programs of the NEI, please visit our home page at <http://www.nei.nih.gov>.

For more information on research topics, contact:

Jerome Wujek, Ph.D.
Research Resources Officer
Division of Extramural Research
National Eye Institute
6700B Rockledge Drive, Suite 3400
Bethesda, MD 20817
National Eye Institute
301-451-2020, Fax: 301-496-2297
Email: wujekjer@nei.nih.gov

For administrative and business management questions, contact:

Ms. Karen Robinson Smith
Acting Chief Grants Management Officer
Grants Management Branch
Division of Extramural Activities
National Eye Institute, NIH, DHHS
6700B Rockledge Drive, Suite 3400
Bethesda, MD 20892
301-451-2020, Fax: 301-496-9997
Email: kyr@nei.nih.gov

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

The NIGMS supports research and research training in the basic biomedical sciences and in specific clinical areas (i.e., clinical pharmacology, trauma and burn injury, sepsis, wound healing, and anesthesiology). NIGMS supports research of potential interest to small businesses and their collaborators through the:

Division of Biophysics, Biomedical Technology, and Computational Biosciences

Division of Pharmacology, Physiology, and Biological Chemistry

Division of Training, Workforce Development, and Diversity

Division for Research Capacity Building

For additional information about areas of interest to the NIGMS, please visit our home page at <http://www.nigms.nih.gov>. This site includes staff contact information by program area (<http://www.nigms.nih.gov/about/pages/contactbyarea.aspx>).

Limited Amount of Award

According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed a hard cap (\$252,131 for Phase I and \$1,680,879 for Phase II and Phase IIB). NIGMS will not accept applications with budget requests exceeding this hard cap with the exception of projects fitting within the list of SBA-approved topics for awards over the statutory budget limitations; the entire list for NIH (including NIGMS) may be found in Appendix A of this document.

If considering a project with a budget exceeding the hard cap, applicants are strongly encouraged to contact NIGMS program officials prior to submission, and preferably earlier during application preparation. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

Phase IIB Competing Renewal Awards

NIGMS will accept Phase IIB SBIR-only Competing Renewal grant applications to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, or 3) continuing refinements that include but are not limited to cost reduction, testing for performance, safety, reliability and/or durability, and meeting or establishing standards, particularly for basic or clinical research instrumentation or durable medical equipment (DME) designs. This renewal grant should enhance the likelihood that small business will attract interest and investment by third parties. Such products include, but are not limited to research equipment, biological products, devices, drugs, medical implants, etc. within the mission of the NIGMS. Budgets for this Phase IIB Competing Renewal opportunity must follow the guidelines for Phase II applications (described above). For awards that are intended to support completion of research needed to obtain an Investigational New Drug application (IND) or Investigational Device Exemption (IDE), applicants must provide evidence that they have consulted formally with the FDA concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements. Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a timeline related to Federal regulatory approval processes.

Prospective applicants considering a Phase IIB Competing Renewal application are strongly encouraged to contact either the Program person of record for the Phase II award or NIH staff listed at the end of this NIGMS topics announcement.

To assist NIGMS in planning for Phase IIB applications, it is helpful for prospective applicants to submit to the NIGMS SBIR/STTR Coordinator (listed below) a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Phase II grant number
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement Number

The letter is non-binding and does not enter into the review process. It is anticipated that only a small number of NIGMS SBIR Phase II awards would be eligible for a Phase IIB Competing Renewal award.

Research Topics of Interest to NIGMS

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Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		PA-19-118 https://grants.nih.gov/grants/guide/pa-files/PA-19-118.html PA-19-055 https://grants.nih.gov/grants/guide/pa-files/PA-19-055.html PAR-18-630 https://grants.nih.gov/grants/guide/pa-files/PAR-18-630.html

<https://www.nigms.nih.gov/Research/mechanisms/Pages/SBIR.aspx>

<https://www.nigms.nih.gov/Research/mechanisms/Pages/STTR.aspx>

NIGMS Non-Clinical Trials Topics:

Division of Biophysics, Biomedical Technology, and Computational Biosciences

This Division facilitates advances in basic biomedical research by supporting the development of biophysical and computational methods and tools for understanding basic biological questions; physical and theoretical methodologies, bioinformatics tools, and sophisticated quantitative approaches to lay a foundation for advances in disease diagnosis, treatment, and prevention in health and disease; and the creation of innovative tools and new technologies for the study of macromolecular, cellular, and organelle processes and function. Research on membrane synthesis, structure, and function; membrane models; membrane transport; cell division; cell organization; cell motility; and biophysics of proteins, nucleic acids, and biological assemblies, including viral entry, packaging, maturation, and release, as well as the development of instrumentation, components, and methods for the analysis of cellular components and macromolecules. Research on developing a better understanding of fundamental processes and mechanisms of development and inheritance in health and disease, and population genetics.

Example areas that may be of interest to small businesses include, but are not limited to:

1. Development of instrumentation, devices, and methods for detecting, analyzing, and separating biologically important compounds, macromolecules, and their interactions.
2. Development of new methods and materials directed toward the solution of biological macromolecule structures, assemblies and complexes by, but not limited to, x-ray diffraction, electron diffraction, NMR, cryo-EM and mass spectroscopy.

3. Development of new or improved instruments, devices, and related methodologies to facilitate biomedical research. Instrumentation includes, but is not limited to mass spectrometry, nuclear magnetic resonance, optical or laser spectroscopies, X-ray absorption/diffraction/scattering, detectors, electron or confocal microscopies, electrophoresis and other separation techniques, bioreactors, centrifugation, and flow cytometry.
4. Technology for microscopy and imaging: development of new or improved microscopic techniques, instruments, reagents, and supporting software that measures the location and dynamics of molecules in situ, organelles, cells, or tissues on the nano- and micro-scale.
5. Imaging probes and sensors, other reagents and methods, instrumentation, software for microscopy, spectroscopy, and single molecule analysis of molecules, cells, tissues, embryos and small model organisms. Technologies for applications of microscopy, spectroscopy and single molecule analysis in basic biomedical research, including but not limited to light, electron, X-ray and scanning probe microscopy and fluorescence, magnetic and electron paramagnetic spectroscopy. NOT included are small animal and preclinical imaging and high throughput platforms for diagnostic and clinical applications.
6. Development of tools including but not limited to detectors, cameras, light sources, optics, and automated data collection and analysis systems, for studying the structures of biomolecules and biospecimens in the size range of peptides to cells, using diffraction, microscopy and/or spectroscopy techniques.
7. Development of technologies for investigating and manipulating cells: development of tools and methods that manipulate or investigate the properties of cells and their environment. Development of tools for cell engineering, molecular transport and partitioning, and assays for cellular phenotype.
8. Development of novel technologies for proteomics, glycomics, metabolomics, and other aspects of systems biology for discovery and clinical applications, (e.g., sample handling, separations, mass spectrometry, and computational tools for protein identification, data curation and mining, and for integrating genome variation, pathways and networks with biological function).
9. Development and improvement of methods for the expression, solubilization, and purification of regulatory, cellular, and membrane associated proteins, as well as for the preparation of specifically labeled macromolecules and the recovery of proteins from inclusion bodies.
10. Development of novel ligands, inhibitors, and other probes for spectroscopic and microscopic analysis of cellular assemblies and viral structures, macromolecules and components, their localization and function in vivo and at a single molecule level.
11. Improvement of methodology (technology) for genetic analysis (e.g., gene expression, probes), including procedures for the separation and analysis of nucleic acids and proteins as these relate to genetic problems.
12. Improvement in procedures (statistical, computational, laboratory) for the analysis of gene flow and gene dynamics in human populations.
13. Development of improved vectors for gene transfer.
14. Development of valid animal models for genetic diseases and birth defects.
15. Development of tools and technologies to detect and monitor complex human phenotypes or traits.
16. Development of technology to derive and expand pluripotent cell populations from non-embryonic sources, for example, induced pluripotent stem cells (iPS), to scale up the growth of induced pluripotent stem cells in culture and to regulate their differentiation state.
17. Development of markers, reagents and tools to characterize the unique properties of iPS cell lines and to distinguish them from adult stem cells and more differentiated cells.

18. Development of existing human embryonic stem cell lines and new or existing iPS cells as a model system for drug discovery.
19. Development or improvement of methodology for generation of antibodies or other affinity reagents for proteins and other small molecules in non-mammalian genetic model systems.
20. Improvement in procedures (statistical, computational, laboratory) for the high- and medium-throughput analysis of gene expression patterns and regulatory networks.
21. Development or improvement of methods for high throughput detection of epigenomic changes.
22. Development or improvement of methods for characterizing the metabolic interactions of complex communities of microorganisms particularly those involved in host-microbe interactions.
23. Development of improved or novel methodology for structure/function analysis of very large macromolecular complexes involved in transmission or expression of genetic material. Development of new or innovative tools and methods in bioinformatics and computational biology.
24. Development of information and communication technology in support of biomedical research, that apply best practices and proven methods for software design, construction and implementation to promote adoption by a broad biomedical research community.
25. Computational methods for analysis, prediction, and improving methods for determination of macromolecular structures and structure-function relationships.
26. Development of computerized tools that might be used in the presentation of the concepts of cell and structural biology to audiences at a variety of levels.
27. Development of computer software for the analysis of the primary and secondary structures of nucleic acids as these relate to genetic problems.
28. Development of tools and methods for the modeling, simulation or analysis of complex biological systems.
29. Development of collaborative environments and technologies to translate Big Data to knowledge, including but not limited to development of knowledge environments, data integration, data and metadata curation methods, and tools that address data security and privacy issues.
30. Development of tools and methods to collect, interpret, analyze and visualize scientific data through integration and interoperability of different data types.
31. Design and development of software and hardware for improving the effectiveness of computational approaches in biomedical research.
32. Development of computational biology software packages for integrative analysis of biomedical data.
33. Development and enhancement of databases and data formats for biomedical research activities.
34. Development of tools and technologies for a biomedical data science ecosystem for biomedical research. Technologies for findability, interconnectivity, and interoperability of biomedical data sets and resources, integration of existing data management tools and development of new ones, universalization of innovative algorithms and tools.

Division of Pharmacology, Physiology, and Biological Chemistry

Research related to the actions of therapeutics, including anesthetics, and the development of biotechnological methods for their production and investigation. Research on cell signaling molecules and signaling intermediates, particularly those related to G-protein coupled receptors. Research in the field of carbohydrates, especially tool and methods development for this emerging field. Research on pain

management as it relates to anesthesia and the perioperative period. Research on responses to traumatic injury, including burn injury, and methods to mitigate these responses. Research on wound healing and tissue repair. Research on the causes and treatments for common complications of critically ill patients (sepsis, systemic inflammatory response syndrome, multiple organ failure), especially directed towards the role of the inflammatory and innate immune responses. Research on the structure, function, and biosynthesis of cellular components and cellular metabolism, bioenergetics, and mechanisms of enzyme action, regulation, and inhibition. Research leading to the synthesis of new chemical entities or development of new chemical methods to probe biological phenomena or to alter the behavior of biological systems. Examples include, but are not limited to:

A. Biochemistry and Biorelated Chemistry

1. Methods for isolation, characterization, and production of natural and bio-engineered products.
2. Development of synthetic methodology to improve the efficiency (broadly defined) of discovery and production of bio-medically relevant compounds.
3. Development of enzymes, catalytic antibodies, ribozymes, artificial enzymes, and host molecules as drugs or synthetic tools.
4. Development of technologies, including instrumentation, software, reagents, and methods for proteomics, including but not limited to robotics, sample preparation and pre-fractionation, analytical separations, mass spectrometry, intelligent automated data acquisition, and improved informatics technologies.
5. Development of technologies, including instrumentation, software, reagents, and methods for glycomics, including but not limited to development of: specific glycan structural databases, methodologies for synthesis of robust glycan libraries, glycan labeling reagents and glyco-enzyme inhibitors, and analytical tools for determining carbohydrate structure and biological function.
6. Development and application of methods and materials for the elucidation of membrane protein structures at or near atomic resolution.
7. Development of high-throughput methods for sequencing and re-sequencing of mitochondrial genes and relevant nuclear genes and for proteomic and/or functional profiling of mitochondria in diagnosis of mitochondrial diseases.
8. Development of new metal ion chelators and other tools to probe and/or alter the localization and concentration of metal ions in cells and in whole organisms. Research to exploit metal metabolism and metal-regulated cellular control and cell-cell signaling processes to probe and/or alter cell function. Research to develop investigational and therapeutic applications of metal-complexes and to understand the factors governing their pharmacology and toxicology.
9. Development of high-throughput methods and strategies to characterize the function of proteins and enzymes and/or define the functional interrelationships of proteins and enzymes.
10. Development of tools to characterize oxidative stress and oxidative stress related molecules (NO, peroxynitrite, hydrogen peroxide, lipoxidation products modified proteins, DNA modifications, etc.) including the extent and/or localization (by organ/tissue/cell/organelle) of oxidative stress.

B. Pharmacological and Physiological Sciences

1. Isolation, characterization, and development of factors and strategies, methods, or treatments involved in tissue repair, wound healing, sepsis, and traumatic injury, emergency, peri-operative, or critical care conditions, and associated pain management.

2. Improved systems for collection, processing, and analysis of real time physiological data from injured or critically ill patients. Application of systems biology or complexity theory approaches towards understanding the physiology of injured and critically ill organisms. Development of tools, software, algorithms, etc. needed to link clinical, demographic, physiological, genomic, proteomic or other datasets of injured or critically ill organisms.
3. Metabolomics of injury and/or critical illness.
4. Development of strategies, methods, or new technologies to improve the delivery, monitoring, safety and efficacy of anesthesia.
5. Research to improve drug design and delivery.
6. Research to improve drug bioavailability by improved understanding of factors that influence absorption, metabolism, transport, or clearance of therapeutics and underlying mechanisms. Application of pharmacokinetic and pharmaceutical principles to the study of large biomolecules, such as proteins, polypeptides, and oligonucleotides.
7. Research to discover, detect, and understand the genetic basis of individual differences in drug responses (pharmacogenomics).
8. Development of novel in vivo and in vitro methods to predict the safety and toxicities of pharmacologic agents.
9. Development of bioinformatic, mathematical, and/or computational approaches/resources and/or pharmacokinetic modeling programs which utilize ADME parameters of drugs and pharmacogenomic information of individual patients or patient populations to reduce adverse drug reactions in individual patients.
10. Development of ontologies and modules useful for combining and mining databases containing genotype and phenotype information in order to discover correlations for drug effects, either therapeutic or adverse.

Division of Training, Workforce Development, and Diversity

This division supports the development technologies and tools to enhance the research skills of post-high school individuals in the biomedical research workforce pathway, or to increase the efficiencies of NIGMS research training programs. The technologies may be new products or adaptation of existing products designed to be more efficient, cost-effective, culturally appropriate, and/or user-friendly in promoting the development of the biomedical research workforce. Examples for skills development projects include but are not limited to web-based resources, instructional software, interactive media, research-focused curriculum materials, and active learning toolkits. Projects aimed at enhancing NIGMS training programs include but are not limited to technologies to track career outcomes of students and trainees and/or assist in the evaluation of workforce development programs (e.g., survey instruments and/or training activity tracking systems). Projects that will develop skills of individuals from underrepresented groups (see the [NIH interest in Diversity](#)) or increase the efficiencies of diversity enhancing research training programs are encouraged.

Division for Research Capacity Building

Research and development of products, tools, databases, or services in the mission of Division for Research Capacity Building (DRCB), which supports research, research training, faculty development and research infrastructure improvements in states that historically have not received significant levels of research funding from NIH. It also supports faculty research development at institutions that have a historical mission focused on serving students from underrepresented groups, and conducts a science education program designed to improve life science literacy. Topics of interest include, but are not limited to, research capacity building, faculty and professional development, mentoring, and development of educational software and course materials targeting undergraduate and community college students, on topics that range from basic molecular and cellular biology to human diseases, including areas of health

disparities, that disproportionately affect rural, tribal and hard-to-reach populations. To meet the information needs of the target audiences, health education materials must be culturally appropriate.

DRCB is composed of four programs: Institutional Development Award (IDeA), Support of Competitive Research (SCORE) and Native American Research Centers for Health (NARCH), and Science Education Partnership Awards (SEPA).

- A. **Science Education Partnership Awards:** Funding opportunities are available for the development of discovery-oriented educational software, Serious STEM Interactive Digital Media (IDM) and the application of educational technology and tools for health science topics that target pre-kindergarten to grade 12 (P-12) students, teachers and families, and the general public, particularly those from underserved communities. Development of software, IDM technology, or other educational tools may be focused on new products or adaptation of existing products designed to be more efficient, cost-effective, and user-friendly in promoting problem solving, interactive learning, dissemination, and promotion of health science. These resources are intended to create user-friendly, culturally appropriate and effective educational resources.

Examples of responsive applications may include but are not limited to:

1. Web-based, stand-alone computational tools, instructional software, or other interactive media for dissemination of science education;
2. Big Data and bioinformatics tools, software and apps for students, teachers and the business community.
3. Curriculum materials, interactive teaching aids, models for classroom instruction, and teacher education workshops;
4. Serious Science, Technology, Engineering and Mathematics (STEM) IDM resources;
5. Development of health promotion and disease prevention/intervention products that are culturally appropriate for the target populations and communities.

Projects that target the following constituencies are strongly encouraged:

1. P-12 students, teachers, and parents;
2. Students of community colleges, tribal colleges, undergraduate colleges, and minority-serving institutions;
3. Patients and families with health conditions that disproportionately affect minorities and other medically underserved populations, including members of disadvantaged urban and rural communities.

NIGMS Clinical Trials Topics:

NIGMS will accept clinical trials in any area listed above in the non-clinical trials topics.

For additional information on NIGMS research topics and the SBIR/STTR application process, contact:

NIGMS SBIR/STTR COORDINATOR

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For scientific questions about NIGMS-funded SBIR/STTR research, contact:

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Biochemistry and Biorelated Chemistry

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DIVISION OF BIOPHYSICS, BIOMEDICAL TECHNOLOGY, AND COMPUTATIONAL BIOSCIENCES

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DIVISION OF TRAINING, WORKFORCE DEVELOPMENT, AND DIVERSITY

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DIVISION FOR RESEARCH CAPACITY BUILDING

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NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

For the most up-to-date information, please visit the NHLBI SBIR/STTR website (<https://sbir.nih.gov/nhlbi>) and subscribe to our [listserv](http://bit.ly/NHLBI-SBIR-Updates) (<http://bit.ly/NHLBI-SBIR-Updates>). You can also follow us on Twitter [@NHLBI_SBIR](https://twitter.com/NHLBI_SBIR). NHLBI encourages potential applicants to contact us at <http://bit.ly/ContactNHLBIsbir>.

NHLBI plans, conducts, and supports research, clinical trials, and demonstration and education projects related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, and sleep disorders. It also supports research on the clinical use of blood and all aspects of the management and safety of blood resources. The NHLBI SBIR/STTR programs foster basic, applied, and clinical research on all product and service development related to the mission of the NHLBI. The NHLBI has four extramural program divisions, described below.

Phase II Applications

The NHLBI strongly encourages applicants to include a robust regulatory strategy with corresponding milestones in Phase II applications. Applicants are also encouraged to include letters of support or other evidence documenting their regulatory strategy. The NHLBI will consider the strength of the regulatory plan when making funding decisions. For assistance regarding regulatory strategy, explore the “Small Biz Hangout” series on the [NHLBI YouTube channel](#) and submit specific regulatory questions to Chris Sasiela at <http://bit.ly/ContactNHLBIsbir>.

For assistance regarding the commercialization plan, watch the “Small Biz Hangout” for advice on [Writing Your Phase II Commercialization Plan](#) (<http://bit.ly/Ph2CommPlanHangout>) and contact Mike Pieck (nhlbi_sbir@mail.nih.gov) with specific questions.

NHLBI-Supported Funding Opportunity Announcements (FOAs)

In addition to this Omnibus program announcement, the NHLBI releases targeted Funding Opportunity Announcements (FOAs) throughout the year. Sign up for the [listserv](http://bit.ly/NHLBI-SBIR-Updates) (<http://bit.ly/NHLBI-SBIR-Updates>) to be notified of new FOAs.

These FOAs are listed to inform potential applicants about other funding opportunities to which they can apply; applications submitted in response to this Omnibus program announcement are not limited to research and development areas described in the following targeted FOAs. The NHLBI also encourages mission-aligned applications for innovative technologies outside these targeted areas.

(Funding Opportunity Announcements can be released or expire at any time throughout the year; please refer to the [NHLBI SBIR/STTR website](#) for active announcements supported by NHLBI.)

- NHLBI SBIR Phase I Awards for Technologies for Healthy Independent Living for Heart, Lung, Blood and Sleep Disorders: <https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-19-016.html>
- NHLBI SBIR Phase IIB Bridge Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (SBIR): <https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-19-017.html>
- Small Market Awards: SBIR Phase IIB Competing Renewals for Heart, Lung, Blood and Sleep Technologies with Small Commercial Markets (SBIR): <https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-19-018.html>

Phase IIB Competing Renewal Awards

The NHLBI does not accept applications for Phase IIB competing renewal awards through this Omnibus solicitation; however, the NHLBI offers SBIR Phase IIB opportunities through the NHLBI Phase IIB Bridge

Awards and the NHLBI Phase IIB Small Market Awards using separate funding opportunity announcements (Bridge Award: [RFA-HL-19-017](#) ; Small Market Award: [RFA-HL-19-018](#))

The purpose of the NHLBI Phase IIB program is to accelerate the transition of SBIR/STTR Phase II projects to the commercialization stage by promoting partnerships between SBIR/STTR Phase II awardees and third-party investors and/or strategic partners. NHLBI SBIR Phase IIB program encourages business relationships between applicant small business concerns and third-party investors/strategic partners who can provide substantial financing to help accelerate the commercialization of promising new products and technologies that were initiated with SBIR/STTR funding. In particular, applicants are expected to leverage their previous SBIR/STTR support, as well as the opportunity to compete for additional funding through the NHLBI Phase IIB program, to attract and negotiate third-party financing needed to advance a product or technology toward commercialization. Development efforts may include preclinical R&D needed for regulatory filings (e.g., IND or IDE) and/or clinical trials. The Phase IIB Small Market Award focuses on supporting technologies addressing rare diseases or pediatric populations.

The Phase IIB Bridge or Small Market application must represent a continuation of the research and development efforts performed under a previously funded SBIR or STTR Phase II award. The NHLBI welcomes applicants previously funded by any NIH Institute or Center or any other Federal agency, as long as the proposed work applies to the NHLBI mission. Applications may be predicated on a previously funded SBIR or STTR Phase II grant or contract award. Applicants with Phase II contracts or awards from another Federal agency must contact the NHLBI to ensure their application can be received.

Applicants are strongly encouraged to contact Mike Pieck at nhlbi_sbir@mail.nih.gov for additional information.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, the NHLBI may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations of \$252,131 for Phase I and \$1,680,879 for Phase II for specific topics relevant to the NHLBI that can be found below. Generally, the NHLBI does not fund Phase I applications greater than \$300,000 total costs or project periods greater than 2 years. In addition, the NHLBI does not generally fund Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years. **Applicants with budget questions or considering requesting a budget greater than these amounts are strongly encouraged to contact Mike Pieck at <http://bit.ly/ContactNHLBIsbir> before submitting an application.**

NHLBI Topics for Awards over Statutory Budget Limitations

- A. Biomedical technologies (medical devices, instruments, pharmaceuticals, drugs, therapeutics, vaccines, diagnostics and biologics) for heart, lung, blood, and sleep related diseases and disorders requiring Federal regulatory approval (FDA) or clearance to be commercialized.
- B. Small and large animal testing of products of tissue engineering and regenerative medicine, drugs, medical devices, therapeutics, and biologics and studies involving *in vivo* animal experiments for heart, lung, blood, and sleep related diseases and disorders.
- C. Clinical trials and other experiments involving human subjects for heart, lung, blood, and sleep related diseases and disorders.
- D. Therapeutics (drugs, devices, or biologics) development for heart, lung, blood, and sleep related diseases and disorders.
- E. Device development for heart, lung, blood, and sleep related diseases and disorders

- F. Diagnostic development for heart, lung, blood, and sleep related diseases and disorders.
- G. Investigation of biomarkers and biosignatures of heart, lung, blood, and sleep related diseases and disorders.
- H. Technologies to enhance clinical research for heart, lung, blood, and sleep related diseases and disorders.
- I. Advanced instrumentation and high throughput tools for biomedical research in heart, lung, blood, and sleep related diseases and disorders.
- J. Tools and platforms to improve the dissemination and implementation of evidence-based interventions for heart, lung, blood, and sleep related diseases and disorders.

Final Progress Reports

As detailed in [NOT-OD-17-085](#), the NIH has implemented the Final Research Performance Progress Reports (Final RPPR) for SBIR/STTR Final Progress Reports.

The NHLBI is interested in tracking the progress of the small business concerns it funds and the products they develop. Funding priority will be given to those small business concerns that show not only their ability to develop products but also their growth as a small business concern towards independence from the SBIR/STTR program.

Programs and Services for NHLBI Small Business Awardees

The NHLBI offers free assistance to applicants and awardees regarding regulatory approval, commercialization, and business plan development. Visit <http://bit.ly/ContactNHLBIsbir> to connect to:

- Chris Sasiela, Ph.D., RAC - Regulatory Strategist

The NHLBI hosts “Small Biz Hangouts” - a free educational series covering the basics of biomedical technology development. Previous Hangouts are archived on the NHLBI YouTube channel: <http://bit.ly/SmallBizHangouts-YouTube>

Sign up for the NHLBI [listserv](http://bit.ly/NHLBI-SBIR-Updates) (<http://bit.ly/NHLBI-SBIR-Updates>) to learn about upcoming live events. Learn more about available resources at <http://www.nhlbi.nih.gov/about/org/dera/otac/resources>.

The NHLBI encourages awardees to apply for the following free programs:

- Phase I: The NIH [Niche Assessment Program](http://sbir.nih.gov/nap) (<http://sbir.nih.gov/nap>) provides awardees with an in depth market analysis for their technology.
- Phase II: The NIH [Commercialization Assistance Program](http://sbir.nih.gov/cap) (<http://sbir.nih.gov/cap>) will assist awardees in transferring their products to the marketplace.

Research Topics of Interest to NHLBI

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		For information on non-SBIR/STTR clinical trials funding mechanisms for which small businesses are eligible, please visit the NHLBI clinical trials website

NHLBI Non-Clinical Trials Topics:

Cardiovascular Sciences

The Division of Cardiovascular Sciences (DCVS) supports basic, clinical, population, and health services research on the causes, prevention, and treatment of cardiovascular diseases. The research programs of the Division encompass investigator-initiated research, Institute-initiated research in targeted areas of research need and scientific opportunity, specialized centers of research focused on selected research topics, and clinical trials. Research supported by the Division is concerned with the etiology, pathogenesis, prevention, diagnosis, and treatment of coronary artery disease and atherothrombosis; structural heart disease; heart failure and arrhythmias; and hypertension and vascular diseases. A broad array of epidemiological studies is supported by the DCVS to describe disease and risk factor patterns in populations and to identify risk factors for disease. Also supported are clinical trials of interventions to prevent and treat disease; studies of genetic, behavioral, sociocultural, and environmental influences on

disease risk and outcomes; and studies of the application of prevention and treatment strategies to determine how to improve clinical care and public health.

Lung Diseases

The Division of Lung Diseases (DLD) supports research on the causes, diagnosis, prevention, and treatment of lung diseases and sleep disorders. Research is funded through investigator-initiated and Institute-initiated grant and contract programs in areas including asthma, bronchopulmonary dysplasia, chronic obstructive pulmonary disease, cystic fibrosis, respiratory neurobiology, sleep-disordered breathing, critical care and acute lung injury, developmental biology and pediatric pulmonary diseases, immunologic and fibrotic pulmonary disease, rare lung disorders, pulmonary vascular disease, and pulmonary complications of AIDS and tuberculosis.

Blood Diseases and Resources

The Division of Blood Diseases and Resources (DBDR) supports research on the causes, prevention, and treatment of nonmalignant blood diseases, including anemias, sickle cell disease, and thalassemia; premalignant processes such as myelodysplasia and myeloproliferative disorders; hemophilia and other abnormalities of hemostasis and thrombosis; and immune dysfunction. Research supported by the Division encompasses a broad spectrum of topics ranging from basic biology to medical management of blood diseases. The Division has a major responsibility for research to improve the adequacy and safety of the nation's blood supply. It also plays a leading role in transfusion medicine and blood banking, including research to evaluate blood donation screening, manufacturing, and processing technologies. The Division also has a major responsibility supporting research in hematopoiesis and stem cell biology and disease. It also supports hematopoietic stem cell transplantation research, and the application of stem cell biology findings to the development of new cell-based therapies to repair and regenerate human tissues and organs.

Center for Translation Research and Implementation Science

The Center for Translation Research and Implementation Science (CTRIS) plans, fosters, and supports an integrated and coordinated program of research to understand the multi-level processes and factors that are associated with successful integration of evidence-based interventions within specific clinical and public health settings such as worksites, communities, and schools; identifies and makes readily available to implementation and dissemination practitioners emergent knowledge about the late phases of translation research, especially the "T4" phase, for rapid and sustained adoption of effective interventions in real world settings; leads the NHLBI effort in the rigorous, systematic evidentiary reviews and subsequent NHLBI participation in the collaborative model for clinical practice guidelines development; supports training and career development of personnel in "T4" translation research and health inequities relating to heart, lung, and blood diseases; provides a focal point for advice and guidance on matters pertaining to minority health, health inequities and minority participation in research; represents the NHLBI to other governments, other Federal Departments and agencies, international organizations, and the private sector on global health issues; and provides data analytics and portfolio analysis to evaluate and inform future directions of implementation research programs.

The NHLBI encourages applications through this Omnibus solicitation proposing innovative technologies related to any area within the NHLBI mission.

The NHLBI maintains a [list of notices of special interest \(NOSI\)](https://www.nhlbi.nih.gov/grants-and-training/funding-opportunities-and-contacts/all-funding-opportunity-announcements) (<https://www.nhlbi.nih.gov/grants-and-training/funding-opportunities-and-contacts/all-funding-opportunity-announcements>) to the Institute. Instructions for submitting applications in response to these topics are posted on the web page. The list is revised throughout the year, so please check regularly for updates. For more information, contact the NHLBI Small Business team at <http://bit.ly/ContactNHLBIsbir> or the Division contact associated with your technology area listed at the end of the NHLBI section.

NHLBI Clinical Trials Topics:**Cardiovascular Sciences**

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NHLBI to other governments, other Federal Departments and agencies, international organizations, and the private sector on global health issues; and provides data analytics and portfolio analysis to evaluate and inform future directions of implementation research programs.

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For additional information on research areas, please contact:

CARDIOVASCULAR SCIENCES

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BLOOD DISEASES AND RESOURCES

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CENTER FOR TRANSLATION RESEARCH AND IMPLEMENTATION SCIENCE

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NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

The National Human Genome Research Institute (NHGRI) has been guided, since the inception of the Human Genome Project in 1990, by a sequential series of plans, each of which has been developed with considerable input from the scientific community. These plans have always laid out ambitious goals and measurable objectives to gauge progress. NHGRI initiated a planning process in 2008 and concluded with the publication in February 2011 of the strategic plan, “Charting a Course for Genomic Medicine from Base Pairs to Bedside,” (Nature, 10 February 2011; Volume 470). The phenomenal advances that have marked genomics and have allowed genomic applications to transform many important fields have made it an opportune time for the Institute to take a new look at genomics and its future. A new strategic planning process is underway for publication in October 2020.

Research Topics of Interest to NHGRI

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

NHGRI Non-Clinical Trials Topics:

A. Technology and Methods Development

Technology development in DNA sequencing and genotyping are examples of activities that have changed the nature of what scientific research questions are practical to address, have enabled new approaches, and have facilitated the development of new community resource data sets. Many areas of critical importance to the realization of the genomics-based vision for biomedical research require continued technological and methodological developments before pilots and then large-scale approaches can be attempted. Accordingly, the NHGRI will continue to support the development of new, fundamental technologies in all areas of genomics. Important areas in which technology development applications would be responsive to this Program Announcement include (but are not limited to) experimental technologies and computational methods to analyze gene expression and other molecular phenotypes; discovery and characterization of genetic variation; identification of the genetic contributions to health, disease, and drug response; statistical analytic methods for understanding human genomic variation and its relationship to health and disease; and chemical genomics. There is also continued need to support technology development for the comprehensive discovery of functional elements in the human and model organism genomes, and new DNA sequencing technology. Many of these assays would benefit from the ability to work with very small amounts of starting material, to the limit of single cells, along with minimally-invasive human specimens that are easy to collect, handle, and store. As these technologies mature, emphasis should be on high throughput, cost-effective methods that consistently produce very high-quality data.

The Institute also places high priority on contributing selectively to the development of new and needed technology in related areas, such as proteomics and systems biology research, when NHGRI funding can be used to further a truly unique development that will have a significant impact on the field.

Further information on opportunities related to technology and methods development is available at this website: <https://www.genome.gov/10000368/>.

B. Bioinformatics, Computational Genomics and Data Science

The ongoing development of new sequencing technologies has dramatically increased the amount of data produced for genomics in basic science and translation to medicine. NHGRI encourages new computational approaches for the analysis, visualization and integration of genomic information in basic and clinical research and in applications to improve its utility in healthcare. These approaches may include the development of methods for processing, annotating, interpreting, analyzing and sharing of sequencing data with associated phenotypes

and other large-scale genomic data sets such as haplotype maps, genetic variants, transcriptome measurements, functional elements, and in some cases protein interactions. NHGRI also encourages the development of better computational solutions for storage, access, compression, secure sharing, privacy and transfer of large genomic datasets by biomedical researchers.

Some genomic data analysis and display tools have been developed that already are used in the community but would benefit from additional work to support broader dissemination, for example making them efficient, reliable, robust, well-documented, and well-supported, or for deploying them in containers or at scale in a cloud-based platform. NHGRI will support projects to extend the support for these informatics tools to make them more easily adopted by any biomedical research laboratory that wishes to use genomic technologies to address biomedical questions.

Genomic databases are essential resources for the biological and biomedical research communities and relevant regulatory agencies. The creation and maintenance of effective and sustainable databases that take advantage of technology improvements are an important component of NHGRI research funding strategy.

Where possible, existing or emerging community data standards, models, and methods for data representation and exchange should be used in the development of these new methods and tools as well as other approaches to enhance reproducibility. Standards-based approaches are also encouraged to integrate and share genomics and phenotype data for data mining with other sources including for clinical application. Projects that will make genomic digital objects Findable, Accessible, Interoperable, Reusable (FAIR) in the broader community are highly recommended.

Further information on programs related to NHGRI supported research in computational genomics and data science is available at this web site: <http://www.genome.gov/10001735>.

C. Population Genomics and Genomic Medicine

Population genomics applies genomic technologies, such as genome-wide association testing and sequencing, to population studies to identify genes or variants that affect common etiologically complex conditions and predict individual risk. Genomic medicine investigates the value of applying genomic methods in clinical care for the diagnosis, treatment, and prevention of diseases. The research scope of Population Genomics and Genomic Medicine at NHGRI includes: developing resources and statistical methods for observational studies and clinical trials incorporating advanced genomic technologies; conducting proof-of-principle studies that apply genomic technologies to epidemiologic and clinical research; developing research methods and infrastructure needed for future epidemiologic and clinical studies of genetic and environmental contribution to disease; investigations of whether and how clinical genome sequencing impacts disease diagnosis and treatment; studies of approaches to improve the identification and interpretation of genomic variants for dissemination in clinical settings; assessing phenotypic manifestations of genetic variants through electronic medical records (EMRs); integrating genomic results and clinical decision support into EMRs; studies that address current barriers to the implementation of clinical genome sequencing, and assessing the impact of genetic information on clinical utility, health outcomes and delivery of care. For additional information about Genomic Medicine NHGRI, please visit this web site: <http://www.genome.gov/27550079>.

D. Ethical, Legal and Social Implications

NHGRI, through the ELSI Research Program, supports research studies that examine issues and, where appropriate, develop policy options regarding the ethical, legal and social implications of genomics. These studies may focus on issues associated with genomic research, genomic medicine or broader societal effects of genomic information and technologies. More detailed

information on specific ELSI research priorities within each of these broad areas is available on the ELSI Research priorities web site: <http://www.genome.gov/27543732>.

NHGRI Clinical Trials Topics:

The National Human Genome Research Institute (NHGRI) will accept applications designated as clinical trials for all program areas supported by the Institute as outlined above for non-clinical trials SBIRs/STTRs. The broadened definition of clinical trials as defined in [NOT-OD-15-015](#) and <https://grants.nih.gov/policy/clinical-trials/definition.htm> is not intended to expand the scope of applications accepted by NHGRI beyond studies that have a major genomic or Ethical, Legal and Social Implications (ELSI) component and relate clearly to NHGRI's mission. Information on areas of research interest is available on the NHGRI Research Funding Divisions homepage: <https://www.genome.gov/27552836/nhgri-research-funding-divisions/> and the ELSI Research Domains website: <https://www.genome.gov/27543732/elsi-research-domains/>. Additionally, applicants are strongly encouraged to discuss their research plans with NHGRI Program Staff prior to submitting their application.

For more information on research topics, contact:

Michael W. Smith, Ph.D.
Technology Development Program &
Small Business Lead
Coordinator SBIR Grants
301-496-7531
Email: smithmw@mail.nih.gov

Heidi Sofia, Ph.D.
Informatics & Genomic Medicine
Coordinator STTR Grants
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Email: Heidi.Sofia@nih.gov

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

The mission of the National Institute of Mental Health (NIMH) is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. Mental disorders constitute an immense burden on the U.S. population, with major depression now the leading cause of disability in the U.S., and schizophrenia, bipolar disorder, and obsessive-compulsive disorder ranked among the ten leading causes of disability. NIMH also takes a leading role in understanding the impact of behavior on HIV transmission and pathogenesis, and in developing effective behavioral preventive interventions. The NIMH conducts a wide range of research, research training, research capacity development, as well as public information outreach and dissemination to fulfill its mission.

For the Institute to continue fulfilling this vital public health mission, it must foster innovative thinking and ensure that a full array of novel scientific perspectives are used to further discovery in the evolving science of brain, behavior, and experience. In this way, breakthroughs in science can become breakthroughs for all people with mental illnesses.

The NIMH SBIR/STTR programs support small businesses to develop technologies that can advance the mission of the Institute, including in basic neuroscience research relevant to mental disorders, translational and clinical research of mental disorders, clinical diagnosis or treatment of mental disorders, and dissemination of evidence-based mental health care. The NIMH Strategic Plan (<http://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml>) and the National Advisory Mental Health Council's workgroup report "From Discovery to Cure" (http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/fromdiscoverytocure_103739.pdf) present key scientific priorities across these domains, and describe the need for technologies to realize these priorities. Research priorities for the NIMH further include aspects of HIV/AIDS prevention, treatment, and care, in accordance with the Trans-NIH Plan for HIV-Related Research (<http://www.oar.nih.gov/strategicplan/>).

For additional information about areas of interest to the NIMH, please visit our home page at <http://www.nimh.nih.gov>.

Also visit the NIMH SBIR/STTR home page: <http://www.nimh.nih.gov/research-funding/small-business/index.shtml>.

Important notes:

1. It is very helpful for potential SBIR/STTR applicants to contact NIMH prior to submitting an application, to ensure the application is of priority/interest to NIMH. Please see the contacts section.
2. An additional criteria that the federal government considers in supporting a small business with SBIR/STTR funds, is past commercialization performance. It is expected that small businesses who have received previous SBIR/STTR grants, have had success in commercializing their previously supported technologies. Small businesses that are mostly interested in research and development (and not commercialization) should consider other grant mechanisms at NIH, rather than the SBIR/STTR program. Program staff at NIMH can help identify the most appropriate grant mechanism to use.
3. The NIH has received a waiver from the SBA, regarding the funding cap. The technology areas that are included in this waiver can be found in the topic list located in Appendix A of this document. The technologies listed in the Appendix A (under NIMH) are of priority to this institute.

Phase IIB Competing Renewal Awards

The NIMH will accept Phase IIB SBIR/STTR Competing Renewal grant applications in two categories: 1) to continue research and development of technologies that ultimately require federal regulatory approval,

and 2) to continue research and development of complex instrumentation, clinical research tools, or behavioral interventions and treatments.

Technologies in the former category (those that ultimately require federal regulatory approval) include, but are not limited to: pharmacologic agents and drugs, biological products, medical devices, vaccines, etc., related to the mission of the NIMH. Phase IIB SBIR/STTR Competing Renewal grants for such technologies should allow small businesses to get research and development to a stage where interest and investment by third parties is more likely.

Companies that are developing technologies that do not focus on drug development, but that require federal regulatory approval prior to commercialization, may be eligible to submit a Phase IIB Competing Renewal application.

For both technology areas, Phase IIB applications may be submitted through the Omnibus SBIR funding/STTR opportunity announcement. Generally, for this opportunity, budget limits of \$3 million total costs and time periods up to 3 years may be requested. These budget allowances have been approved by the SBA through a waiver.

The following examples would make appropriate topics for proposed NIMH SBIR/STTR Phase IIB Competing Renewal projects. These are meant for illustrative purposes only and are not exclusive of other appropriate activities:

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the Phase I (R43/R41) and initial Phase II (R44/R42) grants. Some *in vivo* or *in vitro* studies would be expected to have been carried out in Phase I or the initial Phase II grant.
- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.
- Studies in normal healthy volunteers to determine a drug's safety profile, metabolism, etc.
- Assessment of devices with regard to performance standards related to the FDA approval process.
- Safety and effectiveness studies of novel medical devices.
- Evaluation of novel imaging approaches for diagnostic purposes.
- Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.

Although technologies in the latter category listed above (complex instrumentation, clinical research tools, or behavioral interventions/treatments) may not require federal regulatory approval, extraordinary time and effort is needed for their research and development. Therefore, NIMH supports Phase IIB Competing Renewal awards of existing Phase II grants for such technologies. The Phase IIB Competing Renewal award for these would provide up to an additional three years of support at total cost funding levels of up to generally \$3 million for the project. These budget allowances have been approved by the SBA through a waiver.

Please contact the Program Director in the appropriate Division or Dr. Margaret Grabb (listed below) before beginning the process of putting an application together. In addition, prospective applicants are encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement (e.g. PA-18-566).

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review

workload and plan the review. It is expected that only a portion of NIMH SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

Research Topics of Interest to NIMH

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
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- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		NIMH will prioritize funding for SBIR/STTR applications with a clinical trial focus that are consistent with the stated research goals and priorities relevant to clinical trials as outlined in the clinical trials FOAs. For more information see: https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/support-for-clinical-trials-at-nimh.shtml
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		NIMH will prioritize funding for SBIR/STTR applications with a clinical trial focus that are consistent with the stated research goals and priorities relevant to clinical trials as outlined in the clinical trials FOAs. For more information see: https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/support-for-clinical-trials-at-nimh.shtml

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		<p>NIMH will prioritize funding for SBIR/STTR applications with a clinical trial focus that are consistent with the stated research goals and priorities relevant to clinical trials as outlined in the clinical trials FOAs.</p> <p>For more information see: https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/support-for-clinical-trials-at-nimh.shtml</p> <p>And:</p> <ul style="list-style-type: none"> • First in Human and Early Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders (U01 Clinical Trial Required) PAR-18-427 • Early Stage Testing of Pharmacologic or Device-based Interventions for the Treatment of Mental Disorders (R61/R33- Clinical Trial Required) RFA-MH-18-702 • Early Stage Testing of Pharmacologic or Device-based Interventions for the Treatment of Mental Disorders (R33- Clinical Trial Required) RFA-MH-18-703 • Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (R61/R33- Clinical Trial Required) RFA-MH-18-704 • Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (R33 Clinical Trial Required) RFA-MH-18-705

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply			<ul style="list-style-type: none"> • Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders (R01 Clinical Trial Required) RFA-MH-18-707 • Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions (R34- Clinical Trial Required) RFA-MH-18-706 • Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (R01 Clinical Trial Required) RFA-MH-18-701 • Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Collaborative R01 - Clinical Trial Required) RFA-MH-18-700

NIMH Non-Clinical Trials Topics:

Division of Neuroscience and Basic Behavioral Science (DNBBS)

The Division of Neuroscience and Basic Behavioral Science provides support for research programs in the areas of basic neuroscience, genetics, basic behavioral science, research training, resource development, technology development, drug discovery, and research dissemination. The Division has the responsibility, in cooperation with other components of the Institute and the research community, for ensuring that relevant basic science knowledge is generated and then harvested to create improved diagnosis, treatment, and prevention of mental and behavioral disorders.

In this Division, the SBIR and STTR programs support research and the development of tools related to basic brain and behavioral science, genetics, and drug discovery and development relevant to the mission of the NIMH. Such tools include: software (such as informatics tools and resources and tools for analyzing data); hardware (such as the development of instrumentation or devices); wetware (such as the use of iRNAs or other bioactive agents as research tools or molecular imaging agents or genetic approaches to label neural circuits or modify circuit functions); and drug discovery related technologies such as high throughput screening (HTS) or computational pharmacology approaches.

AREAS OF EMPHASIS

- Novel imaging probes to study brain structure and function at all levels, from the molecular level to the whole organ, using any imaging modality (PET, fMRI, optical, etc.).
- Drug discovery/drug development of novel compounds which act on molecular pathways (receptors, enzymes, second messengers, etc.) that are not typically targeted with currently available psychiatric drugs, and that have a strong biological justification as a novel mechanism for treatment of psychiatric disorders.
- Novel screening assays for high throughput acquisition and analysis of data about behavior and the brain, from the level of genes to behavior.

- Novel technologies that would enable researchers to study how populations of neural cells work together within and between brain regions, in order to understand how changes in neural activity contributes to mental disorders.
- New or improved technologies to advance microbiome brain research characterizing the relationship between the microbiota-gut-brain (MGB) axis and central nervous system (CNS), and its impact on psychiatric disorders.
- Develop informatics tools to facilitate the analysis and sharing of data between laboratories about behavior and the brain. This could include common data element efforts, but is not limited to that area.
- Technologies consistent with the goals of the BRAIN Initiative: <http://www.braininitiative.nih.gov/>.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

Division of Translational Research (DTR)

The DTR directs, plans, and supports programs of research and research training that translate knowledge from basic science to discover the etiology, pathophysiology, and trajectory of mental disorders and develops effective interventions for children and adults. DTR supports integrative, multidisciplinary research on the following areas: the phenotypic characterization and risk factors for psychiatric disorders; neurobehavioral mechanisms of psychopathology; trajectories of risk and resilience based on the interactive influences of genetics, brain development, environment, and experience; and design and testing of innovative psychosocial, psychopharmacologic, and somatic treatment interventions.

In this Division, the SBIR and STTR Programs support research aimed at facilitating the validation and commercialization of new methods of assessing psychopathology and measuring treatment response to therapeutic agents. In addition, the SBIR and STTR Programs support the clinical development of interventions, including novel pharmacologic agents or brain stimulation devices as well as technology development used to deliver novel psychosocial approaches to the treatment of mental illness in adults, pediatrics and geriatrics. For more information on NIMH supported clinical trials and requirements, see: <https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml>

AREAS OF EMPHASIS

- Develop, test, and validate biological markers (e.g., genetic, proteomic, imaging) for diagnosing or detecting risk/vulnerability, onset, progression, and/or severity of mental disorders, or to evaluate treatment response.
- Develop valid measures of the various constructs in the Research Domain Criteria (RDoC) matrix (see <http://www.nimh.nih.gov/research-funding/rdoc/index.shtml>), e.g., behavioral tasks, psychometrically sophisticated self-report measures, and measures of physiological and neural activity, into a commercial product.
- Web-based tools and biosensors to enhance prevention, early identification and treatment of pediatric mental disorders by various educational and health professionals.
- Development of hardware and software tools to support operations of multi-site clinical trials.
- Development of novel methods to enhance efficiency of early phase clinical trials.
- Novel technologies and data analytic tools to enable quantification of behavioral data that is relevant to research or clinical trials in mental disorders and/or autism.

- Development of imaging technologies that can reveal specific pathologies in major mental disorders.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

Division of AIDS Research (DAR)

The NIMH DAR supports scientific research to understand and alleviate the consequences of HIV infection on the central nervous system, and research to strengthen the provision and outcomes of HIV/AIDS prevention and treatment. Please refer to the NIH HIV/AIDS research priorities and guidelines for determining AIDS funding (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html>). Examples of high-priority research areas for SBIR/STTR applications are described below.

- Develop and test novel, non-invasive diagnostic approaches (instrumentation, imaging, biomarkers, central nervous system [CNS] cell-based *in vitro* models) to detect HIV-1 associated CNS dysfunction and innovative technologies to study the mechanisms involved in HIV-1 associated neuropathogenesis and persistence of HIV-1 in the CNS. or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy.
- Design and test novel therapeutic strategies aimed at amelioration HIV-1 associated CNS dysfunction, and/or eradication of HIV-1 from CNS reservoirs, and/or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy. **Designing novel therapeutic strategies could occur retrospectively (not a clinical trial – using EMR).**
- Design new strategies to reduce adverse effects of anti-retroviral drugs such as neuropsychiatric side effects and drug-drug interactions. **Designing strategies for adverse effects of antiretrovirals could occur retrospectively (not a clinical trial – using EMR).**
- Develop new tools/ techniques to aid in deciphering the complex neuro-immune interactions at a molecular and cellular level in the context of HIV
- Develop or adapt neurological/neuropsychological/neurobehavioral assessments to evaluate HIV-1 associated abnormalities in adults or children in resource poor environments that are adaptable to different cultures and languages. **Designing neurobehavioral assessments could occur retrospectively (not a clinical trial – using EMR).**
- Build and optimize informatics tools to aid in analyzing and characterizing the phenotype of CNS disease modalities associated with HIV by using machine learning, big data and systems biology-based approaches
- Develop technologies, instruments and tools to aid in Improving uptake, adherence, and persistence to biomedical HIV prevention and treatment regimens; Increasing regular HIV testing among those most at risk of acquiring HIV and translating findings from basic behavioral and social science research into processes to improve engagement in HIV care
- Develop innovative approaches to improve the scientific assessment of HIV exposure due to sexual behavior or the scientific assessment of HIV medication adherence through wireless technologies, remote sensing devices, biomarkers, assays, or other novel methods. **Designing approaches for assessment could occur retrospectively (not a clinical trial – using EMR).**
- Develop and test tools, curricula, and strategies that seek to reduce documented racial/ethnic, gender, and age-related disparities in HIV infection, HIV testing, HIV care engagement, or in HIV treatment adherence and treatment outcomes. **Designing strategies for reducing disparities could occur retrospectively (not a clinical trial – using EMR).**

- Develop novel tools and approaches to identify, recruit, enroll, and/or retain those most vulnerable to HIV/AIDS (e.g., African-American MSM, adolescents) in HIV prevention research and/or services. **Developing tools for recruitment and retention of key populations could occur retrospectively (not a clinical trial – using EMR).**
- Develop and test tools, curricula, and strategies to identify the potent, modifiable mechanisms and processes linking mental health and HIV and developing interventions to address the high prevalence of mental health disorders among those living with HIV and those at substantial risk for HIV infection

Prospective applicants are strongly encouraged to contact Dr. Vasudev R Rao (listed below) with questions about the relevance of their interests to the mission of this division.

Division of Services and Intervention Research (DSIR)

The Division of Services and Intervention Research (DSIR) supports two critical areas of research:

- Intervention research to evaluate the effectiveness of pharmacologic, psychosocial, somatic, rehabilitative and combination interventions on mental and behavior disorders-including acute and longer-term therapeutic effects on functioning across domains for children, adolescents, and adults.
- Mental health services research to improve the access, continuity, cost, quality and outcomes of mental health care, as well as to improve the dissemination and implementation of effective interventions in clinical and community settings, to strengthen the public health impact of NIMH research.

The intervention research program addresses the effectiveness of treatment and preventive interventions in usual practice and community settings with the purpose of informing clinicians, patients, families, and health policy makers on evidence based practices. In funding decisions, special emphasis is placed on the potential clinical impact of the research activities and on the implications of the research findings for improving community practice and health outcomes. Types of interventions include the full range of behavioral, psychotherapeutic, pharmacologic, and non-pharmacologic somatic or alternative interventions, as well as rehabilitation or other adjunctive services, e.g., integrated approaches to chronic mental illness. Examples of areas of interest are:

- Analyses of naturalistic databases to evaluate the effectiveness of preventive and treatment interventions.
- Identifying moderators and mediators of intervention effects as a step to design and test personalized interventions. **Moderator/mediator identification could occur retrospectively (not a clinical trial – using EMR).**
- Evaluating the combined or sequential use of interventions. **Evaluation of combined/sequential interventions could occur retrospectively (not a clinical trial – using EMR).**
- Determining the optimal duration, frequency and intensity of an intervention to optimize improvements in symptoms and functioning, establishing the utility of continuation or maintenance treatment (that is, for prevention of relapse or recurrence). **Evaluation of the optimal length of an intervention could occur retrospectively (not a clinical trial – using EMR).**
- Evaluating the long-term impact of therapeutic interventions on symptoms, functioning, and quality of life. **Evaluation of the optimal length of an intervention could occur retrospectively (not a clinical trial) – using EMR or survey data).**

Services research covers all mental health services across the lifespan for all mental health disorders and aligns with NIMH strategic research priority 4 (<https://www.nimh.nih.gov/about/strategic-planning-reports/strategic-research-priorities/srp-objective-4/index.shtml>), which includes but is not limited to:

- Service settings at the patient, provider, health system, and cross system levels to include primary care, specialty mental health, integrated care, general health, and other delivery settings (such as employment, educational, veteran, military, and criminal justice settings).
- Enhanced capacity for conducting services research by developing and utilizing innovative and established methodologies, including health economics, to inform decisions about service delivery and financing of care.
- The clinical epidemiology of mental disorders to include development and use of data sets from health surveillance activities, decision support tools, administrative claims, mobile apps and similar technologies, electronic health record, disease registries, and other databases where epidemiological data (to include big data) reside.

In this Division, the SBIR and STTR Programs support research and development of novel tools related to clinical trials (including preventive, treatment, and rehabilitative interventions alone and/or in combination), methodology, clinical epidemiology, services research, effectiveness research, health disparities (including rural populations) and the dissemination and implementation of evidence-based treatments/research into clinical and community settings in areas directly related to the mission of the NIMH. Such tools may include applied behavioral science and technology, software, hardware and associated technologies. Included are technology-assisted approaches to assessment (e.g., technology-assisted screening and diagnosis) and intervention (e.g., m-health and other technology platforms to support the delivery of preventive, therapeutic, and services interventions). In this realm, NIMH encourages efforts to employ technology-assisted approaches to expand the reach, efficiency, continuity, quality, and/or boost the therapeutic benefit of research-informed strategies, rather than mere translation of research-supported strategies onto new or emerging technology platforms. Collaboration with NIMH supported researchers for the development of software for new analytic techniques and/or decision-making algorithms is encouraged. Also supported is research and the development or adaptation of tools and technologies to be used to enhance the training and development of new generations of researchers and practitioners and to keep established researchers and practitioners up-to-date on the findings, implementation, and methods of interventions and services research.

Prospective applicants are strongly encouraged to contact Dr. Adam Haim (listed below) with questions about the relevance of their interests to the mission of this division.

NIMH Clinical Trials Topics:

Division of Neuroscience and Basic Behavioral Science (DNBBS)

The Division of Neuroscience and Basic Behavioral Science provides support for research programs in the areas of basic neuroscience, genetics, basic behavioral science, research training, resource development, technology development, drug discovery, and research dissemination. The Division has the responsibility, in cooperation with other components of the Institute and the research community, for ensuring that relevant basic science knowledge is generated and then harvested to create improved diagnosis, treatment, and prevention of mental and behavioral disorders.

In this Division, the SBIR and STTR programs support research and the development of tools related to basic brain and behavioral science, genetics, and drug discovery and development relevant to the mission of the NIMH. Such tools include: software (such as informatics tools and resources and tools for analyzing data); hardware (such as the development of instrumentation or devices); wetware (such as the use of iRNAs or other bioactive agents as research tools or molecular imaging agents or genetic

approaches to label neural circuits or modify circuit functions); and drug discovery related technologies such as high throughput screening (HTS) or computational pharmacology approaches.

AREAS OF EMPHASIS

- Novel imaging probes to study brain structure and function at all levels, from the molecular level to the whole organ, using any imaging modality (PET, fMRI, optical, etc.).
- Drug discovery/drug development of novel compounds which act on molecular pathways (receptors, enzymes, second messengers, etc.) that are not typically targeted with currently available psychiatric drugs, and that have a strong biological justification as a novel mechanism for treatment of psychiatric disorders.
- Novel screening assays for high throughput acquisition and analysis of data about behavior and the brain, from the level of genes to behavior.
- Novel technologies that would enable researchers to study how populations of neural cells work together within and between brain regions, in order to understand how changes in neural activity contributes to mental disorders.
- New or improved technologies to advance microbiome brain research characterizing the relationship between the microbiota-gut-brain (MGB) axis and central nervous system (CNS), and its impact on psychiatric disorders.
- Technologies consistent with the goals of the BRAIN Initiative: <http://www.braininitiative.nih.gov/>.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

Division of Translational Research (DTR)

The DTR directs, plans, and supports programs of research and research training that translate knowledge from basic science to discover the etiology, pathophysiology, and trajectory of mental disorders and develops effective interventions for children and adults. DTR supports integrative, multidisciplinary research on the following areas: the phenotypic characterization and risk factors for psychiatric disorders; neurobehavioral mechanisms of psychopathology; trajectories of risk and resilience based on the interactive influences of genetics, brain development, environment, and experience; and design and testing of innovative psychosocial, psychopharmacologic, and somatic treatment interventions.

In this Division, the SBIR and STTR Programs support research aimed at facilitating the validation and commercialization of new methods of assessing psychopathology and measuring treatment response to therapeutic agents. In addition, the SBIR and STTR Programs support the clinical development of interventions, including novel pharmacologic agents and brain stimulation devices, as well as technology development used to deliver novel psychosocial approaches to the treatment of mental illness in adults, pediatrics and geriatrics. For more information on NIMH supported clinical trials and requirements, see: <https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml>

AREAS OF EMPHASIS

- Develop valid measures of the various constructs in the Research Domain Criteria (RDoC) matrix (see <http://www.nimh.nih.gov/research-funding/rdoc/index.shtml>), e.g., behavioral tasks, psychometrically sophisticated self-report measures, and measures of physiological and neural activity, into a commercial product.

- Conduct early stage, proof of concept clinical trials to advance the development of novel therapeutics. The clinical trials are expected to include biological/behavioral data to assess target engagement and to help determine potential success or failure of the compound before moving on to larger clinical trials (see NOT-MH-11-015 <http://grants.nih.gov/grants/guide/notice-files/NOT-MH-11-015.html>).
- Develop, test and validate reliable and stable biomarkers that can identify at-risk individuals prior to disease onset, improve diagnosis and classification, predict treatment response, or to measure disease progression. Biomarkers are also needed in clinical trials to identify dose ranges, to identify a specific subpopulation of subjects to enroll in a treatment trial, or to measure efficacy or toxicity/side effects.
- Development of novel diagnostic tools and innovative measures of treatment response and disease progression, preclinical or clinical efficacy testing, or toxicity measures for drug development.
- Development of hardware and software tools to enable refined physiological and behavioral assessment of normal and atypical neurodevelopment focused on pediatrics, adult and geriatric age ranges.
- Web-based tools and biosensors to enhance prevention, early identification and treatment of pediatric mental disorders by various educational and health professionals.
- Development of hardware and software tools to support operations of multi-site clinical trials.
- Development of novel methods to enhance efficiency of early phase clinical trials.
- Novel technologies and data analytic tools to enable quantification of behavioral data that is relevant to research or clinical trials in mental disorders and/or autism.
- Development of imaging technologies that can reveal specific pathologies in major mental disorders.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

Division of AIDS Research (DAR)

The NIMH DAR supports scientific research to understand and alleviate the consequences of HIV infection on the central nervous system, and research to strengthen the provision and outcomes of HIV/AIDS prevention and treatment. Please refer to the NIH HIV/AIDS research priorities and guidelines for determining AIDS funding (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html>). Examples of high-priority research areas for SBIR/STTR applications are described below.

- Develop and test novel, non-invasive diagnostic approaches (instrumentation, imaging, biomarkers, central nervous system [CNS] cell-based *in vitro* models) to detect HIV-1 associated CNS dysfunction and innovative technologies to study the mechanisms involved in HIV-1 associated neuropathogenesis and persistence of HIV-1 in the CNS. or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy.
- Design and test novel therapeutic strategies aimed at amelioration HIV-1 associated CNS dysfunction, and/or eradication of HIV-1 from CNS reservoirs, and/or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy. **Designing novel therapeutic strategies could occur retrospectively (not a clinical trial – using EMR).**

- Design new strategies to reduce adverse effects of anti-retroviral drugs such as neuropsychiatric side effects and drug-drug interactions. **Designing strategies for adverse effects of antiretrovirals could occur retrospectively (not a clinical trial – using EMR).**
- Develop new tools/ techniques to aid in deciphering the complex neuro-immune interactions at a molecular and cellular level in the context of HIV
- Develop or adapt neurological/neuropsychological/neurobehavioral assessments to evaluate HIV-1 associated abnormalities in adults or children in resource poor environments that are adaptable to different cultures and languages. **Designing neurobehavioral assessments could occur retrospectively (not a clinical trial – using EMR).**
- Build and optimize informatics tools to aid in analyzing and characterizing the phenotype of CNS disease modalities associated with HIV by using machine learning, big data and systems biology-based approaches
- Develop technologies, instruments and tools to aid in Improving uptake, adherence, and persistence to biomedical HIV prevention and treatment regimens; Increasing regular HIV testing among those most at risk of acquiring HIV and translating findings from basic behavioral and social science research into processes to improve engagement in HIV care
- Develop innovative approaches to improve the scientific assessment of HIV exposure due to sexual behavior or the scientific assessment of HIV medication adherence through wireless technologies, remote sensing devices, biomarkers, assays, or other novel methods. **Designing approaches for assessment could occur retrospectively (not a clinical trial – using EMR).**
- Develop and test tools, curricula, and strategies that seek to reduce documented racial/ethnic, gender, and age-related disparities in HIV infection, HIV testing, HIV care engagement, or in HIV treatment adherence and treatment outcomes. **Designing strategies for reducing disparities could occur retrospectively (not a clinical trial – using EMR).**
- Develop novel tools and approaches to identify, recruit, enroll, and/or retain those most vulnerable to HIV/AIDS (e.g., African-American MSM, adolescents) in HIV prevention research and/or services. **Developing tools for recruitment and retention of key populations could occur retrospectively (not a clinical trial – using EMR).**
- Develop and test tools, curricula, and strategies to identify the potent, modifiable mechanisms and processes linking mental health and HIV and developing interventions to address the high prevalence of mental health disorders among those living with HIV and those at substantial risk for HIV infection

Prospective applicants are strongly encouraged to contact Dr. Vasudev R. Rao (listed below) with questions about the relevance of their interests to the mission of this division.

Division of Services and Intervention Research (DSIR)

The Division of Services and Intervention Research (DSIR) supports two critical areas of research:

- Intervention research to evaluate the effectiveness of pharmacologic, psychosocial, somatic, rehabilitative and combination interventions on mental and behavior disorders-including acute and longer-term therapeutic effects on functioning across domains for children, adolescents, and adults.
- Mental health services research to improve the access, continuity, cost, quality and outcomes of mental health care, as well as to improve the dissemination and implementation of effective

interventions in clinical and community settings, to strengthen the public health impact of NIMH research.

The intervention research program addresses the effectiveness of treatment and preventive interventions in usual practice and community settings with the purpose of informing clinicians, patients, families, and health policy makers on evidence based practices. In funding decisions, special emphasis is placed on the potential clinical impact of the research activities and on the implications of the research findings for improving community practice and health outcomes. Types of interventions include the full range of behavioral, psychotherapeutic, pharmacologic, and non-pharmacologic somatic or alternative interventions, as well as rehabilitation or other adjunctive services, e.g., integrated approaches to chronic mental illness. Examples of areas of interest are:

- Randomized clinical trials evaluating the effectiveness of preventive and treatment interventions.
- Identifying moderators and mediators of intervention effects as a step to design and test personalized interventions. **Moderator/mediator identification could occur prospectively (within the context of a clinical trial).**
- Evaluating the combined or sequential use of interventions. **Evaluation of combined/sequential interventions could occur prospectively (within the context of a clinical trial).**
- Determining the optimal duration, frequency and intensity of an intervention to optimize improvements in symptoms and functioning, establishing the utility of continuation or maintenance treatment (that is, for prevention of relapse or recurrence). **Evaluation of the optimal length of an intervention could occur prospectively (within the context of a clinical trial).**
- Evaluating the long-term impact of therapeutic interventions on symptoms, functioning, and quality of life. **Evaluation of the optimal length of an intervention could occur prospectively (within the context of a clinical trial).**

Services research covers all mental health services across the lifespan for all mental health disorders and aligns with NIMH strategic research priority 4 (<https://www.nimh.nih.gov/about/strategic-planning-reports/strategic-research-priorities/srp-objective-4/index.shtml>), which includes but is not limited to:

- Interventions and other research to improve access, continuity, engagement, quality, uptake, equity, efficiency, and cost of care.
- The dissemination and implementation of evidence-based interventions, programs, support tools, or other practices or technologies into service settings.

In this Division, the SBIR and STTR Programs support research and development of novel tools related to clinical trials (including preventive, treatment, and rehabilitative interventions alone and/or in combination), methodology, clinical epidemiology, services research, effectiveness research, health disparities (including rural populations) and the dissemination and implementation of evidence-based treatments/research into clinical and community settings in areas directly related to the mission of the NIMH. Such tools may include applied behavioral science and technology, software, hardware and associated technologies. Included are technology-assisted approaches to assessment (e.g., technology-assisted screening and diagnosis) and intervention (e.g., m-health and other technology platforms to support the delivery of preventive, therapeutic, and services interventions). In this realm, NIMH encourages efforts to employ technology-assisted approaches to expand the reach, efficiency, continuity, quality, and/or boost the therapeutic benefit of research-informed strategies, rather than mere translation of research-supported strategies onto new or emerging technology platforms. Collaboration with NIMH supported researchers for the development of software for new analytic techniques and/or decision-making algorithms is encouraged. Also supported is research and the development or adaptation of tools

and technologies to be used to enhance the training and development of new generations of researchers and practitioners and to keep established researchers and practitioners up-to-date on the findings, implementation, and methods of interventions and services research.

Prospective applicants are strongly encouraged to contact Dr. Adam Haim (listed below) with questions about the relevance of their interests to the mission of this division.

Program Contacts

Margaret Grabb, Ph.D. (general questions about the NIMH SBIR program, Phase IIB program, DNBBS, DTR divisional interests)

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Dr. Vasudev R Rao M.B.B.S, M.S. (DAR divisional interests)
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NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

The mission of the National Institute on Minority Health and Health Disparities (NIMHD) is to promote minority health and to lead, coordinate, support, and assess the National Institutes of Health (NIH) effort to reduce and ultimately eliminate health disparities. In this effort, the NIMHD conducts and supports basic, clinical, social and behavioral research; facilitates the development of research infrastructure and training; fosters emerging programs; and reaches out to racial/ethnic minority and other health disparity communities.

The Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program enable the Nation's small businesses to apply their unique research and development capabilities toward accomplishing NIMHD's mission.

Through small business Phase I, Phase II, and Fast-track awards, NIMHD supports multi- and trans-disciplinary research and development leading to novel and or improved products capable of contributing to NIMHD's mission. Research and development may proceed or be initiated at the molecular, cellular, individual, community or population level. Funding support for focus groups, phase I/II clinical trials, and other studies as needed to develop and test the proposed product may be requested. Additionally, NIMHD seeks innovative strategies for improving minority health, elimination of health disparities, and enhancing health and well-being where small businesses engage, collaborate or partner with health disparity communities from conception, application submission, and through completion of NIMHD funding periods and beyond. Applications partnering with community health centers or other patient providers as appropriate are also encouraged and of interest. Support for the development of innovative technologies or services for enhancing minority health and well-being through partnerships with community-based small businesses, such as beauty salons, barbershops, pharmacies, etc., that engage with racial and ethnic minority or health disparity populations on a regular basis, can also be requested. Technology that leverages indigenous community advisors and supporters in health promotion or prevention efforts may contribute to overall community health improvement and well-being through the processes of community empowerment and increased community cohesion.

An overarching objective of NIMHD's investments in SBIR/STTR programs is to ensure that racial and ethnic minorities and health disparity populations benefit equally from innovations in health promotion and prevention, biotechnology, imaging technologies, technologies for computational biology and informatics, including, for example, systems, and structural biology; and technologies designed to advance personalized medicine, electronic health records, and systems, etc. New or improved instruments, devices, and related methodologies to facilitate biomedical or behavioral research and efforts that seek to simplify via redesign or design new instruments, devices, and methods likely to increase access, reduce costs, and improve quality are of special interest.

Research Topics of Interest to NIMHD

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		https://sbir.nih.gov/funding/individual-announcements
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

NIMHD Non-Clinical Trials Topics:

Research that results in a product, process or service that will improve minority health and reduce and eliminate health disparities by one or more of the following:

- A. Biological and Non-Biological Determinants of Health
- B. Community-Based Participatory Research
- C. Comparative Effectiveness Research in Community Settings
- D. Community/Minority Participation in Clinical Trials, Genomic Medicine and the Future of Health Disparities Research
- E. Faith-Based Research
- F. Global Health and Health Disparities
- G. Research Infrastructure in Minority Institutions
- H. Telehealth and Health Disparities
- I. Translating and Disseminating Scientific Knowledge into Practice and Policy

NIMHD Clinical Trials Topics:

Research that results in a product, process or service that will improve minority health and reduce and eliminate health disparities by one or more of the following:

- A. Biological and Non-Biological Determinants of Health
- B. Community-Based Participatory Research
- C. Clinical Research and Comparative Effectiveness Research in Community Settings
- D. Community/Minority Participation in Clinical Trials, Genomic Medicine and the Future of Health Disparities Research
- E. Faith-Based Research
- F. Global Health and Health Disparities
- G. Research infrastructure in Minority Institutions
- H. Telehealth and Health Disparities
- I. Translating and Disseminating Scientific Knowledge into Practice and Policy

For additional information about the areas of interest to the NIMHD, please visit our home page at <http://www.nimhd.nih.gov/>.

For additional information on research topics, contact:

Mr. Vincent A. Thomas, Jr., MSW, MPA
Program Manager
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6707 Democracy Blvd.
Suite 800, MSC 5465
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301-402-2516, Fax: 301-480-4049
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For administrative and business management questions, contact:

Ms. Priscilla Grant, J.D., C.R.A.
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6707 Democracy Blvd.
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NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

The mission of NINDS is to reduce the burden of neurological disease—a burden borne by every age group, by every segment of society, by people all over the world (<https://www.ninds.nih.gov/About-NINDS/Who-We-Are/Mission>). To this end, the Institute supports and conducts research on the healthy and diseased brain, spinal cord, and peripheral nerves. The NINDS SBIR/STTR (<https://www.ninds.nih.gov/Funding/Small-Business-Grants>) program funds small business concerns to conduct innovative neuroscience research and/or development (R/R&D) that has both the potential for commercialization and public benefit.

Limited Amount of Award and Budget Waivers

NINDS will allow awards to exceed the statutory guideline amounts by up to 50% (up to \$252,131 for Phase I and \$1,680,879 for Phase II, total funding support) with appropriate justification from the applicant. In addition, NINDS will allow Phase I project periods of up to 2 years and Phase II project periods of up to 3 years with appropriate justification. For budgetary, administrative, or programmatic reasons, NINDS may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application.

NIH has received a waiver from SBA to exceed the hard cap for specific topics that can be found in **APPENDIX A: National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations** and only these specific topics can apply and receive awards over the hard cap. Generally, NINDS does not fund Phase I applications greater than \$700,000 total funding support, with no more than \$500,000 total cost in any year or project periods greater than 2 years. In addition, the NINDS does not generally fund Phase II applications greater than \$3,000,000 total funding support, with no more than \$1,500,000 total cost in any year, or project periods greater than 3 years. Information about the NINDS budget guidelines can be found on the NINDS SBIR webpage: <https://www.ninds.nih.gov/Funding/Small-Business-Grants/Budget-Information>. Applicants considering a requested budget greater than \$252,131 for Phase I or \$1,680,879 for Phase II are strongly encouraged to contact program staff before submitting an application.

For all other funding opportunities, applications should follow the guidelines in the Award Budget section of those announcements carefully. Additional information can be found on the NINDS SBIR/STTR webpage at: <https://www.ninds.nih.gov/Funding/Small-Business-Grants/Budget-Information>.

Phase IIB Competing Renewal Awards

NINDS only accepts Phase IIB SBIR/STTR Competing Renewal applications through specific opportunities that focus on the commercialization of SBIR and STTR developed technologies. These opportunities can be found on the NINDS Funding Opportunities webpage: <https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities>. Contact Stephanie Fertig at fertigs@ninds.nih.gov for additional information.

Research Topics of Interest to NINDS

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s		X	
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		NINDS accepts and supports SBIR and STTR clinical trial applications through specific opportunities, which can be found on the NINDS Funding Opportunities webpage: https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities .
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		NINDS accepts and supports non-SBIR/STTR clinical trial applications through specific opportunities, which can be found on the NINDS Funding Opportunities webpage: https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities .

NINDS Non-Clinical Trials Topics:

General Areas of Interest

The NINDS accepts a broad range of small business applications that are significant, innovative, and relevant to its mission. Examples of research topics within the mission of NINDS are shown below. This list is not all inclusive and some research areas fall into multiple categories.

1. Therapeutics and Diagnostics Development for Neurological Disorders, including biomarker and diagnostic assays, therapeutics (drugs, biologics, and/or devices) for treatment of neurological disorders, and technologies/methodologies to deliver therapeutics to the nervous system.
2. Clinical and Rehabilitation Tools, including intraoperative technologies for neurosurgeons, rehabilitation devices and programs for neurological disorders, and brain monitoring systems
3. Technology and Tools, including technologies to image the nervous system, neural interfaces technologies, and tools for neuroscience research and drug development.

In addition to the research topics listed, NINDS also encourages applications in specific program areas. For additional information about NINDS funding opportunities, please visit the NINDS Funding Opportunities webpage at: <https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities>.

NINDS Priorities

NINDS priorities are given to meritorious research proposals with the greatest potential to advance the NINDS mission (see <https://www.ninds.nih.gov/About-NINDS/Who-We-Are/Mission>). NINDS is especially interested in:

1. Novel and innovative technologies that are new to the SBIR or STTR programs.
2. Technologies coming to the SBIR or STTR programs for their first indication or market opportunity.
3. Companies and applicants that are new to the SBIR and STTR programs.
4. NINDS Cooperative Agreement (U44) Translational Programs. NINDS has specific translational programs that utilize the SBIR cooperative agreement mechanism (U44) as noted below. If eligible, companies are encouraged to apply through these programs.

NINDS SBIR and STTR funding decisions are based on a combination of factors:

1. potential for high impact on advancing the NINDS mission and the other programmatic priorities described in NOT-NS-18-002 (<https://grants.nih.gov/grants/guide/notice-files/NOT-NS-18-002.html>);
2. potential for commercialization;
3. portfolio balance (to determine whether similar projects have already been funded, search NIH Reporter <http://projectreporter.nih.gov/reporter.cfm>);
4. the quality of the previous performance of the applicant and/or company in the SBIR and/or STTR program, including evidence of Phase III activities;
5. for Phase II applicants, the results of the Phase I;
6. the peer review scores and critiques; and
7. availability of funds.

Translational Research

The NINDS offers a variety of specific funding opportunities and programs to accelerate the preclinical discovery and development of new therapeutic interventions for neurological disorders. These programs have specific funding opportunities and allow for budgets over the hard cap. All three programs utilize the cooperative agreement (U44) mechanism, which is milestone-driven and involves NIH program staff participation in developing the project plan, monitoring research progress, and appropriate go/no-go decision-making. SBIR applicants considering projects involving translational research are strongly encouraged to contact program staff well in advance of submission.

- **Cooperative Research to Enable and Advance Translational Enterprises for Biotechnology Products and Biologics (CREATE Bio)** is dedicated to biotechnology product- and biologics-based therapies, which broadly include modalities such as peptides, proteins, oligonucleotides, gene therapies, and cell therapies. The program supports lead optimization, IND-enabling studies for the candidate, and early-phase clinical trials. Contact: Chris Boshoff (chris.boshoff@nih.gov)
- **Translational Neural Devices Program** provides support for projects that focus on pre-clinical and pilot clinical studies for therapeutic devices. Activities supported in this program include implementation of clinical prototype devices, preclinical safety and efficacy testing, design verification and validation activities, pursuit of regulatory approval for the clinical study, and a clinical study. Contact: Nick Langhals (nick.langhals@nih.gov)

- **Blueprint Neurotherapeutics Network (BPN)** provides both funding and non-dilutive support for small molecule drug discovery and development, from hit-to-lead chemistry through phase I clinical testing. The program offers funding, access to NIH-funded contract research organizations (CROs), and access to consultants with expertise in various aspects of drug discovery and development. Contact: Charles Cywin (cywincl@mail.nih.gov)

Information about these and other programs can be found at <https://www.ninds.nih.gov/Current-Research/Research-Funded-NINDS/Translational-Research>.

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is a Presidential project aimed at revolutionizing our understanding of the human brain. NIH is one of several federal agencies involved in the BRAIN Initiative. Planning for the NIH component of the BRAIN Initiative is guided by the long-term scientific plan, "BRAIN 2025: A Scientific Vision," which details seven high-priority research areas. This report can be found at <https://braininitiative.nih.gov/>.

NIH has a number of specific funding opportunity announcements through the BRAIN Initiative that are targeted to small business concerns. These funding opportunities can be found at <https://www.braininitiative.nih.gov/funding/>. Applicants are encouraged to consider if these funding opportunities may be appropriate to their research. Contact Stephanie Fertig at fertigs@ninds.nih.gov for additional information.

NINDS Clinical Trials Topics:

NINDS accepts clinical trials in any the "General Areas of Interest" topics listed above in the "NINDS Non-Clinical Trials Topics" section.

NINDS is committed to identifying effective treatments for neurological disorders by supporting well-executed clinical trials. NINDS accepts and supports SBIR and STTR clinical trial applications within the NINDS mission through specific opportunities, which can be found on the NINDS SBIR webpage: <https://www.ninds.nih.gov/Funding/Small-Business-Grants/Areas-Interest#CT>. Other human subjects research can be submitted through the SBIR and STTR Parent (Clinical Trials Not Allowed) solicitation. However, NINDS may decline funding of any application that includes human subjects for programmatic or administrative reasons. SBIR applicants considering projects involving human subjects research are strongly encouraged to contact program staff in advance of submission.

For additional information on the NINDS SBIR/STTR program, contact:

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Emily Caporello, Ph.D.
Project Manager
301-496-1779
Email: emily.caporello@nih.gov

For financial and grants management questions, contact:

Tijuanna Decoster, Ph.D.
Chief, Grants Management Branch
301-496-9231, Fax: 301-402-4370
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NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

The National Institute of Nursing Research (NINR) supports research focused on biological and behavioral aspects of critical health problems that confront the Nation. Rapid advances in technology and genomic science, as well as significant changes in demographics and health care policies and practice, have inspired the field of nursing science to identify innovative approaches and interventions that improve health outcomes. Emphasis is on seeking ways to reduce the burden of illness and disability by understanding and easing the effects of acute and chronic illness and associated symptoms, improving health-related quality of life by preventing or delaying the onset of disease or slowing its progression, establishing better approaches to promote health and prevent disease, and improving clinical environments by testing interventions that influence patient health outcomes and reduce costs and demand for care.

For additional information about areas of interest to the NINR, please visit our home page at <http://www.ninr.nih.gov/>, and also at <http://www.ninr.nih.gov/researchandfunding>.

NINR does not accept Phase IIB applications.

Research Topics of Interest to NINR

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

NINR Non-Clinical Trials Topics:

- A. Technologies to be used in the hospital, long-term care, hospice, assisted living facility, or home setting that improve symptom identification/assessment, diagnosis, evaluation and management in persons with acute and chronic conditions, particularly in individuals that cannot self-report. Examples of symptoms include (but are not limited to) pain, fatigue, cognitive impairment, nausea, behavioral symptoms.
- B. Assistive and monitoring devices that can monitor symptoms and/or improve quality of life for individuals with chronic diseases/conditions.
- C. Technology-based, behavioral interventions that lead to improved, personalized strategies to prevent and ameliorate adverse symptoms across the lifespan and in diverse populations and settings.
- D. Technologies to assist patients to adhere to behavioral and medical regimens, including medical devices to enable providers and/or research scientists to monitor successful adherence to complex behavioral and medication regimens.
- E. Devices that improve delivery of care to allow patients to better self-manage.
- F. Technologies that monitor and/or promote short and long term self-management behavior changes.
- G. Biological and behavioral monitoring devices for patients in at-risk populations (such as rural, minority or other underserved populations).
- H. Develop, test, and compare effective strategies that incorporate mHealth tools that promote patient, caregiver self-management.
- I. Technological devices to increase awareness and screening, identify risk and protective factors (socio-demographic, behavioral, lifestyle, environmental), prevent disease, and maintain health across the lifespan.
- J. Tailored interventions to help people make healthy lifestyle choices that impact them, their families, and communities, given multiple roles and responsibilities (e.g., work, child birth, caregiving)
- K. Technologies to disseminate research information to nurses practicing in clinical settings and in the community.

- L. Development and application of new and existing knowledge to the implementation of health information technology, and access to and use of electronic health records and other forms of big data.
- M. Telehealth and mHealth technologies to improve patient outcomes through, for instance, increasing quality, type, and speed of health information sharing.
- N. Web-based information and communication technologies for data collection on hospice and palliative care symptoms and need of care to improve the effectiveness and efficiency of patient report data and integration into appropriate hospice/palliative care
- O. Use of Health Information technology for data collection, management and care integration across the spectrum of hospice and palliative care
- P. Technologies (e.g., telecommunications) to provide support mechanisms of caregivers of hospice/palliative patients
- Q. IT implementation across the spectrum of palliative and hospice settings that highlight the potential of informatics to improve palliative and hospice care
- R. Home-based telehealth applications for individuals and family caregivers in palliative and hospice care
- S. Technologies to enable healthcare providers at clinical sites to communicate with hospice and palliative care patients at their home---“virtual visit” technologies.
- T. Devices to assist in providing palliative care for patients with serious life-limiting illnesses through the disease trajectory whether in active treatment or at the end of life.

NINR Clinical Trials Topics:

- A. Technologies to be used in the hospital, long-term care, hospice, assisted living facility, or home setting that improve symptom identification/assessment, diagnosis, evaluation and management in persons with acute and chronic conditions, particularly in individuals that cannot self-report. Examples of symptoms include (but are not limited to) pain, fatigue, cognitive impairment, nausea, behavioral symptoms.
- B. Assistive and monitoring devices that can monitor symptoms and/or improve quality of life for individuals with chronic diseases/conditions.
- C. Technology-based, behavioral interventions that lead to improved, personalized strategies to prevent and ameliorate adverse symptoms across the lifespan and in diverse populations and settings.
- D. Technologies to assist patients to adhere to behavioral and medical regimens, including medical devices to enable providers and/or research scientists to monitor successful adherence to complex behavioral and medication regimens.
- E. Devices that improve delivery of care to allow patients to better self-manage.
- F. Technologies that monitor and/or promote short and long term self-management behavior changes.
- G. Biological and behavioral monitoring devices for patients in at-risk populations (such as rural, minority or other underserved populations).
- H. Develop, test, and compare effective strategies that incorporate mHealth tools that promote patient, caregiver self-management.
- I. Technological devices to increase awareness and screening, identify risk and protective factors (socio-demographic, behavioral, lifestyle, environmental), prevent disease, and maintain health across the lifespan.

- J. Tailored interventions to help people make healthy lifestyle choices that impact them, their families, and communities, given multiple roles and responsibilities (e.g., work, child birth, caregiving)
- K. Technologies to disseminate research information to nurses practicing in clinical settings and in the community.
- L. Development and application of new and existing knowledge to the implementation of health information technology, and access to and use of electronic health records and other forms of big data.
- M. Telehealth and mHealth technologies to improve patient outcomes through, for instance, increasing quality, type, and speed of health information sharing.
- N. Web-based information and communication technologies for data collection on hospice and palliative care symptoms and need of care to improve the effectiveness and efficiency of patient report data and integration into appropriate hospice/palliative care
- O. Use of Health Information technology for data collection, management and care integration across the spectrum of hospice and palliative care
- P. Technologies (e.g., telecommunications) to provide support mechanisms of caregivers of hospice/palliative patients
- Q. IT implementation across the spectrum of palliative and hospice settings that highlight the potential of informatics to improve palliative and hospice care
- R. Home-based telehealth applications for individuals and family caregivers in palliative and hospice care
- S. Technologies to enable healthcare providers at clinical sites to communicate with hospice and palliative care patients at their home---“virtual visit” technologies.
- T. Devices to assist in providing palliative care for patients with serious life-limiting illnesses through the disease trajectory whether in active treatment or at the end of life.

For additional information on research topics, contact:

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NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

NCATS is transforming translational science to improve human health; it relies on the power of data, new technologies and teamwork to develop, demonstrate and disseminate innovations that reduce, remove or bypass costly and time-consuming bottlenecks in translational research.

NCATS small business funding is designed specifically to transform the translational science process so that new treatments and cures for diseases can be delivered to patients more quickly. The Center supports the development of technologies, assays, drugs, devices, instruments, and methodologies that may have broad application to any stage of the translational process from preclinical development to clinical research and to implementation science in patient care and public health. For additional information, please visit <http://www.ncats.nih.gov>.

NCATS is committed to supporting small business Phase I, Phase II, Fast-track and Phase IIB Competing Renewal awards through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Programs (STTR). For additional information, please visit <http://ncats.nih.gov/smallbusiness>.

Limited Amount of Award

For budgetary, administrative or programmatic reasons, NCATS may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Generally, NCATS will not fund:

- Phase I applications greater than \$225,000 total costs or project periods greater than 2 years
- Phase II applications greater than \$1,500,000 total costs or project periods greater than 3 years

For certain topical areas (Appendix A), the Small Business Administration has approved an NIH SBIR/STTR Topic Waiver list for which the NCATS generally will not fund:

- Phase I applications greater than \$325,000 total costs or project periods greater than 2 years
- Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years

Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards

Occasionally, NCATS may accept Phase IIB SBIR Competing Renewal grant applications of NCATS supported Phase II awards to continue research and development of products that have a potential to address bottlenecks in the translational process, and where additional time and effort is needed to reach a stage where interest and investment by third parties would be likely. Such products are expected to have broad applicability and be consistent with the mission of NCATS. Budgets for Phase IIB grant applications should be approved by NCATS Program staff prior to submission.

Research Topics of Interest to NCATS

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?	X	

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s		X	
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		U01 – however the SBC can <u>only</u> participate if repurposing an existing drug or biologic (therapeutics) that have already completed at least a Phase I trial for a different indication by the time an award is made. These pharma drugs and biologics are listed in PAR-18-332. https://grants.nih.gov/grants/guide/pa-files/PAR-18-332.html

NCATS Non-Clinical Trials Topics:

Preclinical Drug Discovery and Development

- Innovative platforms for identification and prioritization of targets for therapeutic intervention with clear clinical impact; such as those that are: implicated for disease, have genetic variations that have been identified in functional regions of receptor targets, and/or have high potential for biased

signaling that would promote the beneficial effects of receptor signaling and reduce the unwanted effects

- Tools and technologies to enable high throughput screening of compound activity on currently “non-druggable” targets
- Assays for high-throughput screening of rare-diseases-related targets
- Co-crystallization high-throughput screening techniques
- Fluorescence probes to replace antibodies for determination of cellular protein translocation
- Phenotypic assay development, including stem cell technology platforms for human “disease-in-a-dish” applications and the evaluation of toxicity
- Interventions that target molecular pathways or mechanisms common to multiple diseases
- Platforms for non-antibody biologics, cell-based therapies and gene therapy discovery
- Small molecule and biologics analytical characterization
- Accelerated bioengineering approaches to the development and clinical application of biomedical materials, devices, therapeutics and/or diagnostics
- Development of novel technologies for enzyme replacement therapies (e.g., new cell culture/expression system) to solve a major bottlenecks in rare diseases research
- Innovative methods to determine alternative uses for existing therapeutic interventions for high priority areas, such as rare diseases and pain.
- Tools and technologies that increase the predictivity or efficiency of medicinal chemistry, biologic or other intervention optimization
- Technologies to deliver nucleic acid therapeutics to tissues other than the liver
- Methodologies and technologies to increase efficiencies of manufacturing therapeutics
- Development of novel high-throughput technologies that focus on making translational research more efficient
- GMP production of exosome/extracellular vesicles
- Generation of producer lines for large scale production of exosomes/extracellular vesicles
- Extracellular RNA-based biomarkers and therapeutics of human diseases
- Approaches to targeting the human microbiome for therapeutic or diagnostic purposes
- Scale up, manufacturing and characterization of IPS cells
- 3D printing technologies
- Technologies to substantially improve the efficiency and reduce the cost of clinical grade gene therapy vector manufacturing
- Development of in vitro human tissue models (organs, 3D printing)
- Technologies to allow therapeutic proteins other than lysosomal enzymes to be secreted and taken up by other cells via cross-correction
- Novel strategies to prevent deleterious immune responses to gene therapy, genome editing and/or enzyme replacement therapy
- Establishing more robust phenotypic screens that may help prioritize candidate compounds for further testing
- Innovative technology for non-small molecule delivery
- High-throughput epigenetics screening/characterization tools and technologies
- Microphysiological systems (MPS)/Tissue Chips, including MPS/Tissue Chips that incorporate known functional variants, e.g. ACMG 59 or CPIC A alleles, for study comparison using the same derived genetic background across a set of tissue chips with the functional variant

Biomedical, Clinical, & Health Research Informatics

- Searchable access to information about research resources, facilities, methods, cells, genetic tests, molecules, biologic reagents, animals, assays, and/or technologies with evidence about their use in research studies

- Cloud-based tools and methods for meaningful sharing, re-use and integration of research data
- Novel platforms, technologies and tools for: (1) enabling clinical and translational research, particularly those with mechanisms for inclusion of patient-reported data and (2) integration of patient data collected from multiple devices and multiple/diverse clinical studies
- Development of personalized phenotypic profiling (as well as personalized intervention) based on patient-centered integration of data from multiple data sources, including social media
- Development of predictive models for translational science
- Digital applications and tools (including telemedicine platforms) that facilitate/enhance translational research and medicine in rural populations
- Generic Disease Registry template platforms that can be reused for multiple diseases.
- Mobile device validation tools to ensure data from different brands or versions have compatible results.
- Tools to assess with algorithms developed with artificial intelligence, machine learning.
- Tools that allow for persistent identifier and attribution for data contributors that give credit to the data producers while ensuring that shared data has not been altered
- Patient Mobile Tool Platforms that facilitate tool developers to build “apps” that integrate into their medical records.
- Tools and environments that enable an easy interrogation of publicly available data

Clinical, Dissemination and Implementation Research

- Tools and technologies that increase the efficiency of human subjects research, that facilitate the rapid diagnosis and/or clinical trial recruitment and subject tracking, institutional review board evaluation, and/or regulatory processes
- Increased efficiency of clinical research conduct, including but not limited to regulatory decision support, patient eligibility analysis and recruitment and retention tracking
- Tools, technologies, and other strategies to evaluate and improve the process of informed consent
- Educational tools for clinical and translational science
- Computational or Web-based health research methods, including:
 - Platforms for generally applicable and scalable multi-disease registries and natural history studies
 - Clinical trial designs and analyses (e.g., for pragmatic clinical trials)
- Approaches, tools, platforms and environments to integrate data in novel ways for development of new biomarkers that can be tested in translational research paradigms for which there are barriers or bottlenecks
- Strategies to enhance the quality and accelerate the conduct of dissemination and implementation research
- Sustainable solutions for effective tools and environments in translational research
- Development and validation of patient reported outcomes, clinician reported outcomes, and biomarkers for rare diseases that are not already supported by a disease-specific NIH ICs
- Tools, technologies and other strategies that address medication adherence in clinical settings
- Tools, technologies and other strategies that address and improve community engagement
- Tools and technologies that address the rapid diagnosis, clinical management of rare diseases
- Patient empowerment tools/apps that allow users to compare their treatment, outcomes to normative populations existing treatment guidelines
- Telemedicine or digital health applications that focus on research in rural populations
- Tools and technologies that help characterize human disease states and assist in assessing the impact of interventions

NCATS Clinical Trials Topics:

NCATS will not accept SBIR applications that propose clinical trials, and all of the topics listed must be for projects that do not propose clinical trials.

For additional information on research topics, please contact:

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NCATS SBIR/STTR Program Director
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For Administrative, business management and grants policy questions, please contact:

Ms. Artisha Eatmon
Grants Management Specialist, SBIR/STTR Project Liaison
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Email: Artisha.eatmon@nih.gov

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH (NCCIH)

The mission of NCCIH is to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care.

The following narrative indicates the scope of projects suitable for the SBIR/STTR program that fit within the mission of NCCIH. For additional information about areas of interest to NCCIH and a listing of NCCIH's currently funded applications, please visit <http://www.nccih.nih.gov/research>. Business concerns interested in exploring SBIR/STTR grant opportunities with NCCIH are encouraged to contact NCCIH Program Officers prior to submitting an application.

Limited Amount of Award

As listed in [NOT-AT-19-014](#), "NCCIH Policy Change to Budget Limit and Grant Durations for SBIR/STTR Phase I and Phase II Applications", for budgetary, administrative or programmatic reasons, NCCIH may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

Through this Notice, NCCIH has revised its budget and duration policies for SBIR/STTR Phase I and Phase II applications. Generally, NCCIH will not fund:

- Phase I applications greater than \$225,000 total costs for the duration of the project or project periods greater than 2 years
- Phase II applications greater than \$1,500,000 total costs for the duration of the project or project periods greater than 3 years
- For "National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations", the Small Business Administration (SBA) has approved an NIH SBIR/STTR Topic Waiver list for which the NCCIH generally will not fund:
- Phase I applications greater than \$325,000 total costs for the duration of the project or project periods greater than 2 years.
- Phase II applications greater than \$2,000,000 total costs for the duration of the project or project periods greater than 3 years.

Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Research Topics of Interest to NCCIH

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

****If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,**

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		<p>For applications involving clinical studies that fall within the NIH definition of a clinical trial, NCCIH will not support clinical trials aiming to test efficacy/effectiveness (meaning the study is powered on a primary outcome that is a clinical assessment used in clinical diagnosis of disease or monitoring of disease severity) of an intervention as a part of SBIR/STTR Phase I application. Applicants seeking to conduct efficacy or effectiveness clinical trials should pursue funding via other Funding Opportunity Announcements (FOAs) such as the Omnibus SBIR/STTR Phase II and Fast-Track.</p> <p>NCCIH recognizes a difference between "clinical trials" that are designed to answer specific questions about the clinical effect of interventions and mechanistic studies that have the primary goal of understanding how an intervention works.</p> <p>A clinical outcome study has the objective of determining the clinical safety, tolerability, feasibility, efficacy and/or effectiveness of pharmacologic, non-pharmacologic, behavioral, biologic, surgical, or device (invasive or non-invasive) interventions.</p> <p>A mechanistic study has the objective to understand the mechanism(s) of action of an intervention, a biological or behavioral process, or the pathophysiology of a disease/condition.</p> <p>NCCIH continues to accept clinical trials of all types on Omnibus SBIR/STTR Phase II and Fast-Track applications.</p>

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		Development and/or Validation of Devices or Electronic Systems to Monitor or Enhance Mind and Body Interventions (R43/R44) Development and/or Validation of Devices or Electronic Systems to Monitor or Enhance Mind and Body Interventions (R41/R42) See NOT-AT-19-012 for "NCCIH Policy for SBIR and STTR Phase I Applications Proposing Clinical Trials to the Omnibus"

<p>Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply</p>	<p>X</p>	<p>Phased Innovation Award for Mechanistic Studies to Optimize Mind and Body Interventions in NCCIH High Priority Research Topics (R61/R33 Clinical Trial Required)</p> <p>Mechanisms Underlying the Contribution of Sleep Disturbances to Pain (R01 Clinical Trial Optional)</p> <p>Mechanisms Underlying the Contribution of Sleep Disturbances to Pain (R21 Clinical Trial Optional)</p> <p>Feasibility Clinical Trials of Mind and Body Interventions for NCCIH High Priority Research Topics (R34 Clinical Trial Required)</p> <p>Innovation Award for Mechanistic Studies to Optimize Mind and Body Interventions in NCCIH High Priority Research Topics (R33 Clinical Trial Required)</p> <p>NCCIH Natural Product Early Phase Clinical Trial Award (R33 Clinical Trial Required)NCCIH Natural Product Early Phase Clinical Trial Phased Innovation Award (R61/R33 Clinical Trial Required)</p> <p>NCCIH Natural Product Phase II Clinical Trial Cooperative Agreement (U01 Clinical Trial Required)</p> <p>NCCIH Mind and Body Clinical Trial Cooperative Agreement (U01 Clinical Trial Required)</p> <p>Center of Excellence for Research on Complementary and Integrative Health (P01 Clinical Trial Optional)</p> <p>Mind and Body Intervention Multi-Site Clinical Trial Data Coordinating Center (Collaborative U24 Clinical Trial Required)</p> <p>Clinical Coordinating Center for NCCIH Multi-Site Investigator-Initiated Clinical Trials of Mind and Body Interventions (Collaborative UG3/UH3 Clinical Trial Required)</p> <p>Natural Product Multi-Site Clinical Trial Data Coordinating Center (Collaborative U24 Clinical Trial Required)</p> <p>Fundamental Science Research on Mind and Body Approaches (R21 Clinical Trial Optional)</p>
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Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
			Fundamental Science Research on Mind and Body Approaches (R01 Clinical Trial Optional) Clinical Coordinating Center for NCCIH Multi-Site Investigator-Initiated Clinical Trials of Natural Products (Collaborative UG3/UH3 Clinical Trial Required)

NCCIH Non-Clinical Trials Topics:

Natural Products (including botanicals, herbs, probiotics, prebiotics, dietary supplements, or special medicinal diets):

- Development and validation of technologies for standardization and characterization of biologically active ingredients in natural products
- Development and validation of technologies for taxonomic identification of botanical raw materials or detection of adulterants
- Clinical testing of natural products for the management of hard to treat symptoms such as pain, sleep disorders, or mild to moderate depression to allow development of an evidence base that would lead to FDA approval of a drug indication for the natural product
- Development and validation of technologies for the identification and characterization of bioactive metabolites derived from oral consumption of natural products
- Development and validation of methods for the sustainable production of low yield natural products of commercial interest
- Development of novel analytical tools and technologies to study the microbiome, including its composition, genetics, and bioactivity that can help clarify associations between the human microbiome and the brain
- Development of gut microbiome monitoring assays for validating safety and functional analysis of genomic and microbiota interactions

Mind and Body Approaches (including meditation, mindfulness, hypnosis, yoga, Tai Chi, acupuncture, manual therapies, etc.):

- Development, testing, and validation of appropriate objective and/or quantitative measures and instruments to assess or monitor mind and body approaches in different contexts (e.g., classrooms, families, child welfare, juvenile justice etc.)
- Development, testing, and validation of measures and tools to assess training or fidelity of implementation of mind and body approaches in different settings (e.g., healthcare, community, families, schools, child welfare, juvenile justice)
- Development and testing of technologies for the implementation of mind and body approaches in group or individual settings. Examples include the use of mobile health technologies such as smart phone apps, sensors, on-line delivery, phone-based delivery, etc.
- Development and validation of methods for standardization and characterization of the active components of mind and body approaches
- Development and validation of technical imaging tools or instruments for studying manual therapies including but not limited to massage, acupuncture, or spinal manipulation

General Tool/Technology Development:

- Development and validation of biomarkers which correlate with efficacy of complementary and integrative health approaches
- Development and validation of standardized, reliable and economical tools that correlate with brain imaging in response to mind and body interventions
- Development and validation of tools, technology and instruments, including gaming technology, for the accurate assessment of adherence and/or fidelity to the use of mind and body practices, interventions, and natural products
- Development and validation of tools to improve patient-reported outcome measures of importance in clinical studies of complementary and integrative health approaches
- Development, pilot test, and validate wireless technologies for real-time data collection and monitoring of brain activity or other physiological signals for mind and body approaches
- Development or adaption of biochemical or epigenetic monitoring devices for complementary health approaches
- Development and validation of tools to improve biological and physiological outcome measures for use in clinical studies of complementary or integrative health approaches
- Development or adaptation of technologies for objective assessment of pain with relevance to complementary and integrative health approaches
- Development of sleep monitoring technologies or biomarker panels to assess sleep deprivation, sleep deficiency, circadian rhythm dysregulation, and connection of sleep disturbances with health risks

NCCIH Clinical Trials Topics:

Natural Products (including botanicals, herbs, probiotics, prebiotics, dietary supplements, or special medicinal diets):

- Development and validation of technologies for standardization and characterization of biologically active ingredients in natural products
- Clinical testing of natural products for the management of hard to treat symptoms such as pain, sleep disorders, or mild to moderate depression to allow development of an evidence base that would lead to FDA approval of a drug indication for the natural product
- Development and validation of technologies for the identification and characterization of bioactive metabolites derived from oral consumption of natural products
- Development of novel analytical tools and technologies to study the microbiome, including its composition, genetics, and bioactivity that can help clarify associations between the human microbiome and the brain
- Development of gut microbiome monitoring assays for validating safety and functional analysis of genomic and microbiota interactions

Mind and Body Approaches (including meditation, mindfulness, hypnosis, yoga, Tai Chi, acupuncture, manual therapies, etc.):

- Development, testing, and validation of appropriate objective and/or quantitative measures and instruments to assess or monitor mind and body approaches
- Development, testing, and validation of measures and tools to assess training or fidelity of implementation of mind and body approaches in different settings (e.g., healthcare, community, families, schools, child welfare, juvenile justice)
- Development and testing of technologies for the implementation of mind and body approaches in group or individual settings. Examples include the use of mobile health technologies such as smart phone apps, sensors, on-line delivery, phone-based delivery, etc.
- Development and validation of methods for standardization and characterization of the active components of mind and body approaches

- Development and validation of technical imaging tools or instruments for studying manual therapies including but not limited to massage, acupuncture, or spinal manipulation

General Tool/Technology Development:

- Development and validation of biomarkers which correlate with efficacy of complementary and integrative health approaches
- Development and validation of standardized, reliable and economical tools that correlate with brain imaging in response to mind and body interventions
- Development and validation of tools, technology and instruments, including gaming technology, for the accurate assessment of adherence and/or fidelity to the use of mind and body practices, interventions, and natural products
- Development and validation of tools to improve patient-reported outcome measures of importance in clinical studies of complementary and integrative health approaches
- Development, pilot test, and validate wireless technologies for real-time data collection and monitoring of brain activity or other physiological signals for mind and body approaches
- Development or adaption of biochemical or epigenetic monitoring devices for complementary health approaches
- Development and validation of tools to improve biological and physiological outcome measures for use in clinical studies of complementary or integrative health approaches
- Development or adaptation of technologies for objective assessment of pain with relevance to complementary and integrative health approaches
- Development of sleep monitoring technologies or biomarker panels to assess sleep deprivation, sleep deficiency, circadian rhythm dysregulation, and connection of sleep disturbances with health risks

For additional information on research topics, please contact:

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NATIONAL LIBRARY OF MEDICINE (NLM)

The National Library of Medicine (NLM) offers support for research and development projects in biomedical informatics and data science. Biomedical informatics and data science research applies computer and information sciences to improve the access, storage, retrieval, management, dissemination and use of biomedical information. Grants are made to U.S. small businesses that seek to undertake informatics research and development leading to commercialization. Critical research areas include: representation of medical knowledge in computers; organization and retrieval issues for image databases; enhancement of human intellectual capacities through virtual reality, dynamic modeling, artificial intelligence, and machine learning; medical decision-making; linguistic analyses of medical languages and nomenclatures; investigations of topics relevant to health information or library science; biotechnology informatics issues; and informatics for disaster management. For additional information about areas of interest to NLM and a listing of NLM funded applications, please visit <http://www.nlm.nih.gov/ep>. Business concerns interested in exploring SBIR/STTR grant opportunities with NLM are encouraged to contact the NLM representatives prior to submitting an application.

Research Topics of Interest to NLM

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?	X	

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s		X	

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

NLM's SBIR/STTR grant programs are focused on areas of particular interest from small business. The following narrative indicates the scope of projects suitable for the SBIR/STTR program that fit within the mission of NLM. They are not listed in priority order.

NLM Non-Clinical Trials Topics:

- Visualization approaches to complex biomedical data at multiple levels
- Approaches to help consumers and patients visualize their health data in the context of social and behavioral determinants
- Tools for modeling the impact of behavior and social determinants of health on physiological systems
- Tools and approaches for data integration of large disparate data resources
- Technological approaches to protecting confidentiality while storing, sharing and using biomedical data
- AI techniques for annotating, curating and managing biomedical data resources
- Self-managing, self-documenting datasets
- Tools to enhance security of biomedical data, including personal health data, for multi-party use (meaning, two or more users using the data at once)
- New Technologies that facilitate real-time decisions in clinical practice and public health, using personal health data in electronic records or clinical trials
- Use of formal and informal data sources to track disease outbreaks, pandemics
- Tools for understanding and predicting climate and environmental effects on human health
- AI techniques for characterizing and minimizing the impact of errors or incompleteness in a health data set

NLM Clinical Trials Topics:

NLM will not accept SBIR applications that propose clinical trials, and all of the topics listed must be for projects that do not propose clinical trials.

For additional information on research topics, contact:

Dr. Jane Ye
Program Officer
Division of Extramural Programs
National Library of Medicine
301-594-4882, Fax: 301-402-2952
Email: yej@mail.nih.gov

For administrative and business management questions, contact:

Ms. Samantha Tempchin
Grants Management Officer
Extramural Programs Division
National Library of Medicine
301-496-4222, Fax: 301-402-0421
Email: samantha.tempchin@nih.gov

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI), OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS (ORIP)

ORIP supports high-quality, disease-free animal models and specialized animal research facilities to help meet the needs of biomedical researchers to understand, detect, treat, and prevent a wide range of human diseases. This support enables discoveries at molecular, cellular, and organ levels that lead to animal-based studies which then are translated to patient-oriented clinical research, aiming to find treatments to cure or ameliorate common and rare diseases. Through the small business Phase I, Phase II, Fast-track, and Phase IIB Competing Renewal awards, ORIP is especially interested in funding research to develop biomedical methods and technologies that improve animal models of human diseases, and the care, use, and management of laboratory animals. ORIP also encourage the development and implementation of technologies to directly benefit the welfare of research animals and to directly improve animal facilities that support biomedical and behavioral research.

A list of some potential ORIP program topics follows the description of our Phase IIB Competing Renewal Awards. For additional information about ORIP, please visit our home page at <https://orip.nih.gov/>.

Phase IIB Competing Renewal Awards

ORIP will only accept Phase IIB SBIR Competing Renewal grant applications of ORIP-supported Phase II awards to continue research and development of methods, technologies, tools and devices for basic or translational research where extraordinary time and effort is needed for completion of these projects. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to reach a stage where interest and investment by third parties would be more likely. Such products are expected to have broad applicability, consistent with the mission of ORIP. Budgets that do not exceed \$1 M per year in total costs (for up to 2 years), may be requested for this Phase IIB Competing Renewal opportunity; however it is expected that, in most cases, the requested budget would not exceed the final year budget of the applicant's previous Phase II award. This opportunity is available for the SBIR program only.

Please contact your Program Officer before beginning the process of preparing a Phase IIB Competing Renewal application. In addition, prospective applicants are strongly encouraged to submit to the Program Contact (listed after each section), a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other Key Personnel
- Participating organizations
- Funding Opportunity Announcement Number (e.g., PA-18-XXX)

A letter of intent is not required, is not binding, and does not enter into the review of a subsequent application. It is expected that only a few of ORIP SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

Research Topics of Interest to ORIP

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?	X	

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Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s		X	
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

ORIP Non-Clinical Trials Topics:

Division of Comparative Medicine

- A. Development of improved reagents and cost-effective methods and technologies to accurately screen and diagnose selected diseases of laboratory animal, and to perform overall assessments of animal quality and health status. An urgent need currently exists for the development of improved methods for detection of active tuberculosis in nonhuman primates.
- B. Development of improved reagents and techniques to isolate and propagate embryonic and somatic stem cells from laboratory animals. Improvement of the *in vitro* and *in vivo* methods to efficiently generate induced pluripotent stem cells from laboratory animal species and to reprogram the differentiated cells to other lineages.
- C. Development of technology to identify molecular phenotype(s) of a single stem cell or induced pluripotent stem cell from laboratory animals.

- D. Development of improved reagents, techniques, and equipment for genomic and transcriptomic analysis and data-mining from tissue or cells of laboratory animals and animal models of human diseases.
- E. Development of new technologies for rapid characterization and deep phenotyping of large numbers of animals.
- F. Development of technologies to identify biomarkers for clinical diagnostics in well validated disease models.
- G. Development of vaccines and new therapeutic agents to prevent and/or control selected laboratory animal diseases. One high priority need is to develop methods to control and prevent Herpes B virus in nonhuman primates.
- H. Identification, development, and characterization of spontaneous and engineered vertebrate animal models for studies of various human diseases, excluding most random mutagenesis projects performed on rodents.
- I. Development of technologies and robust tools for the effective preservation of biomedical models.
- J. Development and refinement of high throughput technologies and devices for the cryopreservation, and long-term maintenance and revival of cells, tissues, and laboratory animal embryos, and gametes, especially for *Drosophila*, zebrafish and other aquatic stocks.
- K. Development of technologies and devices for the effective monitoring of frozen and cryopreserved cells, biological materials/tissues and laboratory animal embryos, and gametes.
- L. Development of technologies for improved embryo transfer within a single animal species or of intraspecific embryo transfer to allow preservation of rare, or unique, animal species that may have unique value in biomedical research as animal models for human disease.
- M. Development of improved reagents, machine learning technologies, devices, and high throughput technology to perform, analyze, capture and process data gathered in “omics” studies (genomics, transcriptomics, phenomics, proteomics, glycomics, epigenomics, metabolomics, among others) in normal, disease and intervention conditions in animal/biological models to support/validate pre-clinical analyses.
- N. Development of biological tools and reagents for reconstruction, remodeling, repair and regeneration of tissues damaged by injury or disease. Development of the technologies and procedures to test efficacy and safety of these experiments in animal models. Approaches to detect and track the implanted cells and tissues *in vivo*.
- O. Development of *in vitro* animal cell culture techniques and computational methods to reduce the number of animals used in studies and replace certain tests conducted in animal models with new complementary methods.
- P. Development of acellular biomaterials, biosensors and reagents to promote, detect and track reconstruction, remodeling, repair and regeneration of tissues damaged by injury or disease.
- Q. Development of reagents (including antibodies), assays, and technologies that will facilitate research using aquatic biomedical models such as zebrafish or *Xenopus* for understanding basic aspects of development, physiology, or genetics.
- R. Development of reagents (including antibodies), assays, and technologies that will facilitate research using nonhuman primates (NHPs) for understanding basic aspects of development, physiology, or genetics. A high priority need are reagents for other NHP species besides rhesus macaque.
- S. Development of rapid and sensitive technology for the accurate detection and diagnosis of polymicrobial infections in biomedical laboratory animal models, including those agents involved in vertical transmission of diseases into embryos and larvae.

- T. Technologies for improved sex determination of embryos, neonatal, and juvenile stages of animals, with one high priority need being nonmammalian species.

Miguel Contreras, Ph.D.
Division of Comparative Medicine,
Office of Research Infrastructure Programs,
Division of Program Coordination, Planning and Strategic Initiatives,
Office of the Director
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Email: contre1@mail.nih.gov

Division of Construction and Instruments

The Division of Construction and Instruments supports the development and implementation of technologies to directly benefit the welfare of research animals and to directly improve animal facilities that support biomedical and behavioral research. In particular, the areas being supported include research on tools and equipment, their use to improve and ease care, and to facilitate monitoring of healthy animals. Another area of interest encompasses research to improve laboratory equipment to maintain the environmental conditions and to upkeep the infrastructure of animal facilities. Of special importance is the employment of green technologies. Examples of topics of special interest include (but are not limited to) research leading to the development of better, more reliable, and more efficient:

- A. Equipment such as vacuum cleaners, air filters, hoods, snorkels, autoclaves for animal research facilities, for barrier facilities, and other facilities with special needs and requirements;
- B. Equipment to distribute water and food, and monitor their intake by research animals;
- C. Equipment to increase the quality of life and prevent injuries of research animals and research staff and investigators;
- D. Equipment to monitor and protect the well-being of animals;
- E. Equipment and its use for maintenance of disease-free colonies and healthy animals;
- F. Equipment to disinfect devices, furnishings, and other apparatus in animal facilities such as aquaria, cages, tunnels, and racks;
- G. Cost-effective husbandry and colony management techniques, equipment, and/or new approaches to improve laboratory animal welfare and assure efficient and appropriate research use;
- H. Specialized equipment and caging for laboratory animals to permit optimal environmental control and operational efficiency, including improvements in caging, identification/tagging of animals and remote monitoring in animal facilities.

ORIP Clinical Trials Topics:

ORIP will not accept SBIR applications that propose clinical trials, and all of the topics listed must be for projects that do not propose clinical trials.

Research for the development of equipment and protocols for specific research needs is not within the scope of the ORIP mission.

For additional information on research topics, contact:

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

CDC will accept SBIR grant applications on September 5, 2019; January 6, 2020; and April 6, 2020 submission dates.

CDC's Mission: CDC works [24/7](#) to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

CDC Role:

- Detecting and responding to new and emerging health threats
- Tackling the biggest health problems causing death and disability for Americans
- Putting science and advanced technology into action to prevent disease
- Promoting healthy and safe behaviors, communities and environment
- Developing leaders and training the public health workforce, including disease detectives
- Taking the health pulse of our nation

Those functions are the backbone of CDC's mission. Each of CDC's component organizations undertakes these activities in conducting its specific programs. The steps needed to accomplish this mission are also based on scientific excellence, requiring well-trained public health practitioners and leaders dedicated to high standards of quality and ethical practice.

CDC encourages investigator-initiated applications that focus on support for prevention, detection and response to emerging health threats. Please see CDC's SBIR site for more information.

Research Topics of Interest to CDC

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

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Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

CDC will accept SBIR applications that both propose clinical trials and do not propose clinical trials, and all of the topics listed below cover both.

Limited Amount of Award

CDC will not fund:

- Phase I applications greater than \$150,000 total costs.
- Phase II applications greater than \$1,000,000 total costs

For additional information about CDC, please visit our home page at <http://www.cdc.gov>.

Questions of a general nature about the CDC SBIR program should be directed to:

Sean David Griffiths, MPH
 Small Business Innovation Research Program (SBIR) Manager
 Office of Science, Office of Technology and Innovation
 Centers for Disease Control and Prevention (CDC)
 1600 Clifton Road NE, Mailstop D-72
 Atlanta, GA 30329
 Phone: 404-639-4641; Fax: 404-639-4903
 Email: SBIR@cdc.gov

Or

Miriam Kelly, PhD
Innovation Team Lead
Office of Science, Office of Technology and Innovation
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop D-72
Atlanta, GA 30329
Phone: 404-639-4784; Fax: 404-639-4903
Email: SBIR@cdc.gov

CENTER FOR GLOBAL HEALTH (CGH)

The Center for Global Health (CGH) leads the execution of the CDC's global strategy; works in partnership to assist Ministries of Health to plan, manage effectively, and evaluate health programs; achieves U.S. Government program and international organization goals to improve health, including disease eradication and elimination targets; expands CDC's global health programs that focus on the leading causes of mortality, morbidity and disability, especially chronic disease and injuries; generates and applies new knowledge to achieve health goals; and strengthens health systems and their impact.

Please visit their web site at: <http://www.cdc.gov/globalhealth/index.html>

(1) Identification of New Antigen Targets for Multiplex Malaria Rapid Test

Background: Malaria case management practices changed in 2010 when the World Health Organization (WHO) recommended parasitological confirmation of all suspected malaria cases before treatment with an antimalarial drug. Previously, all febrile patients in sub-Saharan Africa were presumed to have malaria and treated accordingly with an antimalarial drug. This practice led to inappropriate treatment of millions of febrile non-malaria cases resulting in wastage and, more importantly, risking death due to inappropriate treatment of non-malaria diseases. Malaria microscopy, which was the primary means of malaria diagnosis, required infrastructure and competency levels difficult to achieve in many settings. Driven by the availability of quality malaria rapid diagnostic tests (RDTs) that could sensitively detect clinical malaria cases with minimal training of users, the WHO changed malaria case management guidelines recommending testing of all suspected malaria cases and treatment of only those with positive tests. In sub-Saharan Africa, *P. falciparum*, the most deadly of the human malaria parasites accounts for over 90% of all cases and close to 100% of all deaths. As a result, the WHO has recommended prioritization of *P. falciparum* parasite detection using histidine rich protein 2 (HRP2)-based RDTs as the primary means of diagnosis. HRP2 is a stable antigen abundantly produced by *P. falciparum* and not by the other three human malaria parasites and has been the basis for most used RDT over the last decade.

Since that recommendation, the global malaria prevention community has aggressively promoted malaria RDTs and their use outside laboratory settings. RDTs now account for over 70% of malaria testing worldwide and are used by trained community health workers in areas that are hard to reach and which have little or no access to health facilities. The increase in testing rates for malaria worldwide from about 35% in 2009 to over 80% in 2017 has primarily been a result of increased RDT use. RDTs have therefore become critical tools in malaria prevention and case management activities globally. By ensuring appropriate treatment of infected individuals and reducing inappropriate provision of anti-malarials (preventing wastage), RDTs play a major role in malaria prevention.

However, recent reports from several sub-Saharan African countries have described emergence of *P. falciparum* parasites that do not produce the HRP2 antigen because the gene coding for HRP2 is deleted. Malaria infections with HRP2 gene-deleted parasites produce false negative results on HRP2 RDTs and are therefore not appropriately treated. This is a significant drawback to a tool that has contributed to malaria control in the last decade and highlights urgent need for new solutions. HRP2 is a target for about 90% of all RDTs procured globally and having alternate targets is critical for the continued utility of RDTs.

Specific Research Areas of Interest: A possible solution to overcoming the threat of HRP2 deleted parasites is to develop malaria RDTs with alternate targets with similar or better characteristics as HRP2.

This requires identification of new diagnostic markers (parasite biomolecules) not just for *P. falciparum* but also the other three human malaria parasites (*Plasmodium vivax*, *Plasmodium malariae* and *Plasmodium ovale*). There is information in the published literature on malaria parasite protein expression that can be explored to identify targets appropriate for use in RDT development. Using this information, antigens/biomarkers abundantly produced by the parasite and secreted into the blood of infected persons or on the infected red blood cell surface and which have adequate expression and stability profiles can be explored for development of new malaria RDTs. Identified potential targets will need to be screened to determine their binding properties with associated antibodies. The goal of the project is to be able to demonstrate that selected targets can be detected in supernatants from laboratory-cultured *P. falciparum* parasites, clinical samples of *P. falciparum* and non-*P. falciparum* malaria infections from globally representative samples including a subset of samples showed falsely negative results with HRP-2 RTD. Other experiments will need to include temperature stability and binding affinity testing of the selected markers. It is anticipated that a desirable product will incorporate multiple antibodies in a single product (multiplex) that will detect malaria infections regardless of whether the gene coding for HRP2 is deleted and will improve RDT sensitivity compared to currently available tests for the four human malaria parasites. However, more sensitive RDTs targeting the four parasites individually will also be acceptable.

Impact and Commercialization Potential: CDC works in preventing malaria worldwide as a means of protecting US travelers to endemic countries as well as military and diplomatic personnel stationed abroad. Malaria prevention and elimination is also part of CDC's Division for Parasitic Diseases and Malaria mission of protecting the global community from parasitic diseases. Through its co-implementation of the US President's Malaria Initiative, the Malaria Branch has a goal of reducing malaria morbidity and mortality in 24 African countries using evidence-based public health and research activities. Prompt and accurate diagnosis of malaria is critical in accomplishing this mission and this requires a reliable and easy to use rapid diagnostic test as proposed in this application. Almost 300 million RDTs are sold worldwide annually. Even after including cases diagnosed by microscopy approximately 20% of suspected malaria cases do not receive a test. Therefore, there is growth potential in the market, especially for products that can overcome the limitations of current tests.

(2) Development of Immersive Virtual or Augmented Reality Laboratory (AR/VR) Training Modules

Background: Laboratory science plays a vital role in the early detection, monitoring and response to a variety of diseases and health events as well as in surveillance to monitor the impact of vaccination programs. Efficient laboratory systems enables countries to better detect, respond, control and prevent the spread of disease. CDC global health programs support the improvement of global laboratory systems through training programs focused on various aspects of laboratory operations and management. Specific training includes workforce development, core laboratory competencies and management, facility and equipment maintenance, quality management system implementation, biosafety and biosecurity, as well as specific disease diagnostics (e.g. Zika, Ebola). Although the traditional hands-on practical approach is the mainstay of laboratory trainings, new and emerging technology-based approaches, such as electronic and mobile learning (E-Learning and M-learning); virtual learning (virtual classrooms), and immersive virtual reality (tactical and strategic immersions) techniques have been increasingly applied. CDC is actively promoting the development and utilization of cost-effective public health laboratory competency training tools using these innovative technologies.

Specific Research Areas of Interest: The goals for the proposed research are to address the limited availability of innovative virtual and augmented reality (VR/AR) training tools to improve public health laboratory capacity globally.

Examples of specific research areas of interest include, but are not limited to:

1. Development and field testing of immersive virtual and/or augmented reality laboratory training tools covering modules on guided instruction of standard operating procedures (SOPs) followed by immersive simulation to perform the SOPs.

2. Development and field testing of immersive virtual reality laboratory training tools covering visualization and interactive operation guides for complex, priority laboratory equipment (e.g. equipment used for molecular techniques, serology, immunology and culture)
3. Development and field testing of immersive virtual reality laboratory training tools covering step-by-step processes to mitigate laboratory biohazards, such as proper use and maintenance of engineering controls (e.g. biosafety cabinet) and personal protective equipment (PPE) (e.g. respirator, gowning & gloving) to optimize performance and maximize safety of laboratory operations.

Impact and Commercialization Potential: This research will result in increased availability of innovative and cost-effective immersive VR/AR laboratory training tools for global public health laboratory competency training programs that will complement the resource-intensive, hands-on, “wet” laboratory trainings that utilize live clinical specimens. The commercialization potential of these training products is high, as VR/AR training tools for other highly technical subjects have been successfully commercialized by different companies (e.g. Virtual Surgical Training, Flight Simulators, and Undergraduate Science Training etc.).

Visit the CGH homepage for more information on CGH’s research program areas
<http://www.cdc.gov/globalhealth/index.html>

For CGH programmatic information, contact:

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For grants specific, administrative information, contact:

Angie Willard
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NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES (NCBDDD)

The mission of CDC’s National Center on Birth Defects and Developmental Disabilities (NCBDDD) is to promote the health of babies, children and adults and to enhance the potential for full, productive living. To achieve its mission, the Center works to identify the causes of birth defects and developmental disabilities, helps children to develop and reach their full potential, and promotes health and well-being

among people of all ages with disabilities, including blood disorders. NCBDDD seeks to accomplish these goals through research, partnerships, and prevention and education programs.

Please visit their web site at: <http://www.cdc.gov/ncbddd/index.html>

(3) Improving Newborn Screening of Coarctation of the Aorta

Background: There are approximately 6000 infants born each year in the United States with nonsyndromic critical congenital heart disease, a condition that typically requires surgical intervention during infancy in order to survive. Before the advent of newborn screening for critical congenital heart disease, approximately 30% of these children were discharged home after birth without a diagnosis having been made. In 2011, critical congenital heart disease was added to the United States Recommended Uniform Screening Panel, with all states now including this condition as part of their newborn screening panel as of 2018. Newborn screening for critical congenital heart disease has been shown to lead to earlier diagnosis, earlier treatment, and, as a result, improved survival of children with this condition. However, the sensitivity of current screening practices remains poor at only 50%.

The current non-invasive method of newborn screening for critical congenital heart disease includes using pulse oximetry on the right hand and either foot of an infant to determine the oxygen saturation of blood. Low levels of oxygen saturation or notable differences in saturation between the right hand and either foot suggest that a child might have critical congenital heart disease. Subsequent testing is then performed to either confirm or rule out critical congenital heart disease. This method works well for most of the 12 main types of critical congenital heart disease. However, for the most common type, coarctation of the aorta, screening with pulse oximetry has a sensitivity of only 32%.

Coarctation of the aorta is a narrowing of the aorta such that the lower half of a child's body does not receive adequate blood flow. Left untreated, this condition may lead to cardiogenic shock and death. Sometimes a patent ductus arteriosus, a blood vessel bypassing the narrowing in the aorta, provides blood flow with a lower oxygen saturation to the bottom half of the body. Current screening practices may detect coarctation if a patent ductus arteriosus is present, but this is often not the case. Attempts have been made to improve detection by studying the perfusion index, a measure of the pulsatility of blood flow in the distal circulation. However, these efforts have not been very successful. Thus, there is an unmet need for a reliable method to screen for coarctation of the aorta in the newborn.

Specific Research Areas of Interest: The goal of this project is to design, develop, and test the feasibility of a new method of reliably screening for coarctation of the aorta in a newborn infant at approximately 24 hours of age. This new method may include new equipment and/or new software that can be added to existing equipment (e.g. pulse oximeters), or a new application of existing technology. This new method must balance the screening ideals of high sensitivity, high specificity, affordability, and ease of use.

Impact and Commercialization Potential: Reliable screening of coarctation of the aorta would lead to earlier diagnosis and treatment for up to 560 additional newborns each year in the United States; this, in turn, would lead to improved survival for infants with coarctation of the aorta. Furthermore, the overall sensitivity of newborn screening for critical congenital heart disease would increase from 50% to 82%.

Successful technology can be implemented for screening of all newborns (approximately 4 million newborns in the United States each year) in birthing hospitals, including newborn nurseries and neonatal intensive care units (NICUs). This can be either new stand-alone technology that is added to current newborn screening practices, or adjunct technology that is incorporated into current pulse oximetry practices.

(4) Innovation in Measurement of Head Circumference at Birth

Background: Accurate measurement of head circumference is a critical step in establishing a diagnosis of microcephaly (small head circumference) associated with Zika virus and other intrauterine infections. In spite of staff training and guidelines for measurement and interpretation of results, current measurement methods remain problematic. Head circumference is an indication of brain growth and development and is usually correlated with later developmental functioning. A small brain is often an indication of poor neurological functioning and is a risk for intellectual disability, cerebral palsy, epilepsy, sensory disorders and perhaps even milder disabilities such as behavioral disorders and learning disabilities later in childhood. The recent reports of congenital Zika virus infection have focused on microcephaly (defined as for live births, head circumference at birth less than the 3rd percentile for gestational age and sex) as the most obvious physical sign of underlying brain abnormality. In fact, it was the presence of microcephaly that initially brought to the attention of clinicians and public health officials, the association of congenital Zika virus infection with a range of other brain abnormalities. However, researchers quickly discovered that measurement of head circumference at birth is not standardized and measurements are often inconsistent. It is sometimes difficult to measure a small irregularly shaped head without the usual cranial landmarks, and the measurement tools themselves (e.g., tape measures) are sometimes of poor quality. Identification of infants who are candidates for further work-up for congenital Zika virus infection is hampered by the need to standardize the measurement of head circumference. We recognize the need to improve the ability to assess the presence of microcephaly in a population of infants at risk for Zika virus infection, as well as to identify other intrauterine infections that may have a phenotype similar to congenital Zika virus infection.

Specific Research Areas of Interest: The goal of the project is to design a prototype of a screening tool for microcephaly among infants in the newborn period and identify mechanisms for soliciting expert opinion on the screening tool. The tool should be inexpensive and easy to use, with minimal technical training on the part of the user, and it needs to be either disposable or sterilizable. An example is a disposable “cap,” shaped like a typical infant’s head and made out of a non-stretchable plastic material. The opening of the “cap” would be for an infant (sex-specific) with a normal head circumference (e.g., 10th percentile head circumference for a 40-week gestation infant). Smaller openings of the cap or different caps would reflect percentiles for the specific sex and gestational age of the infant’s head being measured. The user would select the infant’s gestational age and sex, select the corresponding cap and if the cap is too large, it would indicate that the infant’s head is below the designated percentile (e.g., head circumference <10th percentile).

Impact and Commercialization Potential: This project would contribute to the ability to reliably identify infants with microcephaly potentially associated with a congenital intrauterine infection, with congenital Zika virus infection being the most recent concern in affected geographic areas. There are other prenatally acquired infections and teratogenic conditions for which the identification of microcephaly is important (e.g., congenital cytomegalovirus infection, fetal alcohol syndrome). There would still be a need for training and guidance related to interpretation of results, but accuracy of measurement would be increased and confidence of results enhanced. Early identification of affected infants can lead to timelier referral for more definitive diagnostic evaluation and initiation of developmental services. Early referral and intervention provides the best opportunity for providing family support and lessening the impact of later developmental disorders.

This product has the potential to become the standard for screening for microcephaly in all infants at birth if found to be less expensive and more reliable than current methods for measurement of head circumference.

Visit the NCBDDD homepage for more information on NCBDDD’s research program areas
<http://www.cdc.gov/ncbddd/index.html>

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NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION (NCCDPHP)

The CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) carries out a variety of activities that improve the nation's health by preventing a range of chronic diseases such as arthritis, cancer, diabetes, heart disease, obesity and stroke, while promoting health and wellness in the areas of reproductive health, oral health, nutrition and physical activity. The Center's activities include supporting states' implementation of public health programs; public health surveillance; translation research; and developing tools and resources for stakeholders at the national, state, and community levels.

Please visit their web site at: <http://www.cdc.gov/chronicdisease/index.htm>

(5) Mobile Application for Perinatal Mental Health and Substance Use Screening

Background: Approximately 7%-14% of pregnant and non-pregnant reproductive-aged women suffer from depression and 12%-15% suffer from anxiety. Although depression and anxiety are distinct disorders, they often co-occur with approximately half of women with either disorder experiencing both conditions. The co-occurrence of substance use disorders with mental health conditions increases the complexity of diagnosis and treatment; over 80% of women with major depression also have substance use disorders. From 2015-2017, 8.5% of pregnant women reported using illicit drugs, 11.5% reported drinking alcohol and 14.7% reported smoking cigarettes. Both mental health and substance use disorders are associated with adverse pregnancy outcomes, including fetal alcohol syndrome, neonatal abstinence syndrome, birth defects and infant death. Thus, identification, assessment, and referral to treatment of mental health conditions and substance use disorder surrounding the time of pregnancy is critical. Furthermore, as intimate partner violence (IPV) is common and may affect the health and well-being of the maternal-infant dyad, screening for IPV is important.

The American College of Obstetricians and Gynecologists (ACOG) recommends screening for depression, anxiety and substance use disorders during the perinatal period. ACOG lists 18 evidence-based drug screening and assessment tools and depression screening tools. The number of tools that

exist may make it difficult for health care providers to assess which tools are appropriate. Moreover, not all health care providers who care for pregnant and postpartum women feel comfortable or have extensive experience making treatment and/or referral decisions for women with co-occurring conditions or IPV. This represents an opportunity for a mobile application (app) – which can be used on multiple platforms, including smartphones, tablets or other internet-connected devices – to positively impact patient care and outcomes.

Innovative tools and interventions have the potential to aid in patient care, and there is enthusiasm for them among health care providers. A survey of physicians by the American Medical Association found that most physicians believe mobile health apps can improve practice efficiencies, patient safety and diagnostic ability. Health care providers now commonly have familiarity with apps that allow them to access information in patients' electronic health records and to communicate with staff members. These apps have proliferated in recent years, with an estimated 325,000 available in 2017. However, the quality of these apps varies widely and it is important to provide rigorously evaluated and evidence-based options to assist health care providers in caring for patients.

Specific Research Areas of Interest: The purpose of this project is to develop and evaluate a mobile app providing decision support related to mental health, substance use, and IPV screening, assessment, treatment and/or referral for providers (for example and not limited to, obstetrician-gynecologists, family medicine physicians, nurse practitioners, etc.) who care for pregnant and postpartum women. This mobile app should:

- Contain evidence-based tools related to identification, assessment, and management or referral to treatment for mental health (including, depression, anxiety, severe mental illness such as bipolar disorder), substance use disorder (including alcohol, tobacco, marijuana, opioid), and IPV surrounding the time of pregnancy. Included screening tools are expected to be listed as recommended tools in ACOG committee opinions and have a moderate to high ability to capture true cases of mental health, substance use disorder, or IPV. A balance in the ability to capture true non-cases is expected.
- Be interactive, easily utilized by providers, and include decision support tools to assist health care providers (for example and not limited to, obstetrician-gynecologists, family medicine physicians, nurse practitioners, etc.) in choosing which screening tools to use during a patient encounter
- Guide health care providers through screening
- Upon a positive screen, assist in assessment of the condition and in appropriate management and treatment and/or referral of the condition(s)
- Be designed to be acceptable to professional health care providers and health organizations and systems that care for pregnant and postpartum women.

The proposed activity will require an applicant with capacity to:

- Design and develop complex mobile applications for multiple platforms
- Collaborate with subject matter experts or professional organizations to select appropriate existing evidence-based tools and content to be developed into decision support tools related to identification, assessment, and management or referral to treatment for mental health (including, depression, anxiety, severe mental illness such as bipolar disorder), substance use disorder (including alcohol, tobacco, marijuana, opioid), and IPV surrounding the time of pregnancy
- Develop functioning algorithms representing the decision support tools developed in collaboration with subject matter experts

- Optimize the presentation of these tools to the end user
- Conduct concept and feasibility testing to identify any issues with guidelines, app operation and acceptability to providers

Impact and Commercialization Potential: Mobile technology is an important tool to support health care providers and health care systems in caring for their patients, with real potential to improve efficiency and accuracy in identifying and assessing mental health, substance use disorders, and IPV in pregnant and postpartum women, and aiding in the delivery of appropriate management and referral to treatment. Mobile devices, as compared to conventional computers, give providers greater freedom to interact face-to-face with patients while using apps and also have touchscreens interfaces that may increase convenience and intuitiveness. The benefits this tool provides may ultimately improve outcomes for pregnant and postpartum women and their infants. The product is prime for rapid scalability, as it will be available through multiple channels to large numbers of health care providers and systems, and can be integrated easily into their normal workflows. Once launched, the product will be evaluated initially by tracking app downloads usage statistics, and related technological means. Commercialization opportunities include development of new technology for 1) packaging existing health-related content into an app format more easily, and 2) Monetizing through advertisements or through sales to individual health care providers, health care systems, or professional clinical organizations. If successful, the product may be adapted for other audiences and for expanded health issues.

(6) Identifying Severe Maternal Morbidity and Mortality using Machine Learning

Background: Severe maternal morbidity (SMM) includes unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health, including death. SMM may be viewed, in the appropriate contexts, as sentinel events for maternal death or other long-term outcomes. A *sentinel event* is "a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following: death, permanent harm, or temporary harm." Identifying, understanding, and tracking patterns of SMM is essential to developing interventions to improve the quality of maternal care, and thus reducing the incidence of SMM, length of hospital stay, medical costs, and long-term adverse outcomes.

Multidisciplinary expert groups have called for all obstetric hospitals to review their SMM cases to look for opportunities for improvement in care that could lead to improved maternal outcomes. These calls were supported by the American College of Obstetricians and Gynecologists (ACOG), the Society of Maternal Fetal Medicine (SMFM), the Association of Women's Health, Obstetric and Neonatal Nurses, the American College of Nurse-Midwives, and other groups. However, to date, there is no consensus on which conditions represent SMM.

To identify delivery hospitalizations with SMM, CDC used administrative hospital discharge data and International Classification of Diseases (ICD) diagnosis and procedure codes. A [list of 18 indicators](#), (including blood transfusions, hysterectomy, and assisted ventilation) and corresponding ICD codes (both ICD-9 and ICD-10) were used to identify delivery hospitalizations with SMM. Using this coding, CDC found the overall rate of SMM was 144 per 10,000 delivery hospitalizations in 2014, affecting more than 50,000 pregnancies. This is likely to be an underestimate of the true burden of severe morbidity during pregnancy and delivery.

ACOG has noted, however, that definitions of SMM that rely on diagnostic codes, such as CDC's definition have limitations, including missed cases, low positive predictive value, and difficulty to operationalize in delivery hospitals.

ACOG and SMFM recommended using two criteria to screen for SMM: 1) transfusion of 4 or more units of blood and 2) admission of a pregnant or postpartum woman to an ICU. These criteria have high sensitivity, specificity, and positive predictive value for identifying SMM. These screening criteria are the minimum recommended criteria and institutions may choose to incorporate additional screening criteria.

Moreover, screen-positive cases or individual outcomes and diagnoses are not automatically considered sentinel events. Currently the context determined from detailed manual review is needed to determine if an individual case was correctly classified as a sentinel event, leading to a long-term adverse outcome.

Quality clinical care improvement efforts are based on identifying cases with potential SMM that merit further record review. However, unlike death certificate reviews, SMM is not always reported and may not be well coded in, or extracted from, record systems. This is an area where machine learning (ML) may help identify cases.

In addition to the identification of SMM cases, there is a need to identify predictors (risk factors) of SMM. These likely include, but are not limited to, maternal age, pre-pregnancy obesity, preexisting chronic medical conditions, and cesarean delivery. However, there have been few studies in the US that examined risk factors associated with SMMs and these often used a statistical model using clinical and socio-demographic patient data from a single care center.

Thus, there is a need to improve identification and predictors of SMM cases in delivery hospitals, especially those that lead to maternal death, and to reduce reliance on manual record review. ML may help in this process.

Many large nationally representative administrative data have been available to identify SMMs, such as Healthcare Cost and Utilization Project (HCUP), including the largest collection of longitudinal hospital care data in the United States, Medicaid Extract Analytical File (MAX data), large claims data for commercially insured patients, electronic medical record (EMR), and prescription drug data. These data can also be linked to other administrative data, survey data, and community and neighborhood data to provide more information to identify risk factors of SMMs than traditionally considered, such as socio-determinants of health. The availability of these big data make it possible to explore a comprehensive list of risk factors contributing to SMMs in a predictive model.

In addition, CDC has access to electronic medical record (EMR) data, with chief complaint, through the CDC [National Syndromic Surveillance Program](#) (NSSP) BioSense program. BioSense data include patient encounter data from emergency departments, urgent care, ambulatory care, inpatient healthcare settings, pharmacy, and laboratory. Real-time data for an event, a disease, or an outbreak of public health significance are monitored daily with lag time for some facilities for up to 1 week. This data may be useful for ML to identify SMM cases and predictors of risk.

The use of ML in development of predictive models/algorithms for clinical decision support has gained more attention recently. ML may process “big data” automatically, cheaper and faster. Differently from the commonly used statistical models, ML does not make assumptions of the models. Rather, the goal of ML is to understand the data structure and, based on the ability of the computers to probe the data for structure, to find the most accurate prediction. It is ideal for the data related SMMs: large administrative datasets and the potentially rich information from linkage data, and the importance of having an accurate prediction.

Specific Research Areas of Interest: The goal of the project is to develop algorithms using machine learning to 1) identify SMM cases and 2) to estimate the risk of a pregnant woman developing SMMs with sensitivity and specificity that are equal to or better than the current standard in clinical practice. At a minimum, these algorithms should be able to:

- Contain the classifiers that are clinically meaningful that the clinicians can readily to use.
- Explore different machine learning methods to develop the most appropriate algorithm with sensitivity and specificity that is comparable or better than the current clinical standards.
- Compare the algorithms with the traditional statistical models to show the superiority of the machine learning algorithms.

- Develop models using heterogeneous data that contains diverse population, such as different socio-economic status.
- Validate using new datasets.

The proposed activity will require an applicant with capacity to:

- Strong knowledge and experience in machine learning
- Collaborate with subject matter experts and clinicians to select appropriate classifiers/risk factors for the algorithm
- Strong experience working with large claims data and administrative data are preferred
- Familiarity with predictive models and medical decision making

Impact and Commercialization Potential: An improved algorithm that can predict and identify SMM in real-time would be an important tool to support health care providers and health care systems. This would aid in the delivery of appropriate clinical care and reduce risk of subsequent adverse outcomes such as maternal death. These benefits may ultimately improve outcomes for pregnant women and their infants. Successful project may result in developing software packages for the health care systems, insurance companies, hospitals, and health care providers to purchase to facilitate clinical decision-making and improving value based care

(7) Electronic Transmission of Assisted Reproductive Technology Pregnancy Outcome Data

Background: The Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992 mandates that clinics performing assisted reproductive technology (ART) in the United States (U.S.) annually provide pregnancy success rates data to the Centers for Disease Control and Prevention (CDC). ART is any procedure involving the handling of eggs or embryos for the purpose of establishing pregnancy. Fertility clinics report ART cycle-level data to the CDC, including details of each ART procedure performed, outcomes of the ART procedure (e.g. pregnant versus not pregnant), and outcomes of any resultant pregnancy (e.g. live birth versus no live birth). Fertility clinics provide care to patients undergoing ART treatment; therefore, detailed information about the ART treatment procedure is collected directly by the fertility clinic. However, if a patient achieves pregnancy, the patient receives subsequent prenatal and obstetric care from other healthcare providers such as obstetrician/gynecologists. ART clinics may face obstacles in collecting pregnancy outcome information in an effective and efficient manner from ART patients that have achieved pregnancy. They mostly rely on traditional mechanisms, including telephone, mail, and email, to obtain these data from either the patient or the patient's obstetric provider, and they often have to make multiple attempts to get the required information. This process can be even more challenging if patients come from outside of the state or outside of the U.S. to receive ART treatment and then return home to care for the pregnancy.

The CDC uses the ART surveillance data, including the pregnancy outcome data, for several purposes, including the publishing of clinic-specific success rates on an annual basis, the publishing of other annual reports which describe the characteristics of ART treatment procedures and outcomes at a national and state level, as well for linkage with vital records data in order to generate more robust surveillance and research datasets. Data linkage allows additional research on short- and long-term maternal and infant outcomes such as complications of labor and delivery, neonatal complications, as well as conditions identified after birth.

Pregnancy outcome information is a vital component of ART surveillance. The accuracy of pregnancy outcome information in the ART surveillance system is critical for reporting ART success rates, understanding maternal and treatment characteristics associated with treatment success, and ensuring the accuracy of data linkages between ART surveillance data and vital records. Some fertility clinics may

lack a user-friendly, convenient, secure, and verified information delivery mechanism for patients to either: (1) personally report pregnancy outcomes to the fertility clinic in a safe and secure manner and/or (2) provide information on their obstetric provider and consent to the release of pregnancy outcome information to the fertility clinic. Nationwide, approximately 500 fertility clinics in the US perform ART, are required to report ART surveillance data per the FCSRCA and may face the challenge of obtaining pregnancy outcome information from their patients.

Specific Research Areas of Interest: The desired primary goal of this project is an effective technology solution that facilitates electronic transmission of pregnancy outcome data from the patient and/or obstetric provider to the fertility clinic. The technology solution should be user-friendly and convenient for both the ART patient and the fertility clinic, such as a phone application. It should also be secure, as it would involve the transmission of sensitive data.

A possible secondary goal of the project would be to use the technology solution as a platform for fertility patients and fertility treatment providers to communicate during the treatment process via a seamless and secure channel. For example, patients could track the timing of medication administration, report side effects and ask questions, while providers could track adherence to the treatment plan, adjust dosage, and schedule appointments. In addition, the technology solution can serve as a crowdsourcing research project that can improve knowledge about long-term health of patients undergoing infertility treatments and their children by collecting information directly from patients.

Impact and Commercialization Potential: The desired primary goal of this project is an effective technology solution that facilitates electronic transmission of pregnancy outcome data from the patient and/or obstetric provider to the fertility clinic. The collection of pregnancy outcome data by fertility clinics may be limited due to patients moving from fertility treatment providers to obstetric providers after the establishment of pregnancy and due to a reliance on traditional mechanisms, including telephone, mail, and email, for collection of the information. The problem described above affects (1) infertility patients undergoing ART, (2) fertility clinics who collect and/or report this information, and (3) organizations performing ART surveillance, such as the CDC. Infertility patients will benefit from having a seamless and secure communication channel with their fertility treatment provider, which can save them time and allow reporting of pregnancy outcome data at their convenience. It may also provide a more sensitive approach for collecting the information in the event that a pregnancy does not result in a live birth. Having a convenient and secure information delivery mechanism will help fertility clinics save resources typically spent on sending patient reminders or contacting patients. Finally, organizations performing ART surveillance will benefit in receiving more complete and accurate pregnancy outcome data. The estimated national discrepancy rate for pregnancy outcome data in CDC's ART data has been relatively low, ranging from 0.7% to 3.5% over the last five years; however, clinic-specific discrepancy rates can be substantially higher. Since the CDC publishes both national and clinic-specific success rates as a part of annual reporting requirements, implementation of an effective technology solution will support compliance with the FCSRCA and potentially improve the accuracy of both national and clinic-specific success rates. In addition, improved completion and accuracy of pregnancy outcome data will ultimately improve ART surveillance and the quality of research aimed at improving perinatal outcomes of fertility treatments. For example, recent efforts to link fetal death records in four states resulted in linkage rates ranging from 64% to 80%, rates substantially lower than linkage rates for birth certificate data, which typically are around 90%. One factor possibly contributing to lower linkage rates is the quality of fetal death reporting in the National ART Surveillance System (NASS). Therefore, improving the accuracy of pregnancy outcome data in the CDC's ART surveillance database may help to improve these linkage rates, and thus improve the quality of surveillance and research conducted using linked data. In addition, it can be used by providers to see where there are gaps in patient centered outcomes such as regimen adherence and satisfaction with services. Overall, this project has the potential to strengthen collaboration between small technology-promoting businesses, healthcare, and public health in the area of fertility treatments and outcomes.

This project requires an effective technology solution that facilitates secure electronic transmission of pregnancy outcome data from the patient to the fertility clinic. The solution should include a tangible product such as a phone application, which either could be sold to fertility clinics, or could contain paid advertisements and be made freely available to clinics. The approach will need to ensure protection of privacy for patients and for clinic data. As previously mentioned, nearly 500 fertility clinics in the US perform ART and are required to report ART surveillance data per the FCSRCA. Clinics could reduce resources spent if a cost-saving, secure technology solution to facilitate collection of pregnancy outcome data was available. In addition, fertility clinics that do not perform ART may be interested in utilizing the solution. Many clinics track their own success rates to understand the effectiveness of the treatment they are offering and for marketing purposes. Therefore, fertility clinics performing services such as ovulation induction or intrauterine insemination in the absence of ART (i.e., clinics not required to report per the FCSRCA) may still be interested in purchasing the software. In addition, adding another component to the technology solution, such as providing a platform for fertility patients and fertility treatment providers to communicate during the treatment process or after receiving treatment via a seamless and secure channel, may improve marketability. Adding ability to conduct crowdsourcing research can further improve utility of the product for researchers and public health professionals.

(8) Food Service Guidelines Algorithmic Database Processing and ID Tool

Background: Nutrition and Obesity are key objectives for Healthy People 2020. As part of the effort to encourage availability of healthier and sustainably produced food and beverage options, numerous business industry standards and practice guidelines have been developed. For example, the US federal government has developed food service guidelines based on nutrition (Dietary Guidelines for Americans), environmental sustainability, industry best practices for facility efficiency, food safety, and local economic development. Food service guidelines, such as the updated 2017 Food Service Guidelines for Federal Facilities, are used widely by institutional purchasers including government facilities, worksites, hospitals, universities and schools. Notably, these guidelines provide desired food standards but do not list specific food products meeting the guidelines. The difficulty in identifying qualifying products is a major obstacle in using food service guidelines, particularly when guideline specifications may differ slightly from one jurisdiction to another. For example, New York City's (NYC) and Los Angeles (LA) County's food service operations, which serve 25 million people combined, have reported difficulty meeting their own food service guidelines because their primary suppliers do not have the resources (i.e., time, staff) to determine which of their products meet guidelines.

Access to foods that meet food service guidelines is crucial for vendors or food service operators whose institutional clients have specific food service guidelines for food sold in their venues. Easy identification of foods that meet specific standards is also helpful for retailers who want to market specific products to personal or demographic interests. A food service guidelines algorithmic database processing and ID tool (FIDT) will increase the ease of operationalizing food service guidelines by providing lists of specific food products that comply with a desired set of guidelines or other user defined attributes. FIDT will enable distributors to provide their customers (e.g., food service operators) with a wider range of products that meet specific guidelines and attributes included in food service contracts. The tool will also enable food service operators to quickly identify and select products that align with required nutrition standards or that appeal to specific health conscious market segments. In areas that have difficulty in accessing healthier foods (i.e., rural areas and inner cities), this tool can incentivize broader distribution and easier access of those foods, thereby enabling healthier foods and beverages to flow through the food supply chain.

Lastly, FIDT will allow the user to choose from a number of different nutrition standards or guidelines that a food service operation may be trying to implement, thereby reducing the labor and time burden placed on staff to do individual product analysis against multiple sets of standards. More specifically, a food or beverage product could be analyzed against several different sets of guidelines or standards simultaneously, demonstrating the additional efficiencies that could be created with FIDT in the food management sector. For example, a NYC dining facility that runs a USDA-sponsored afterschool program

can choose those products that meet NYC's procurement standards as well as USDA's school nutrition standards.

Specific Research Areas of Interest: The goal of this project is to:

1. Create a computer software application food ID tool (FIDT) that enables food suppliers (i.e., distributors, brokers, manufacturers) to identify food and beverage products that align with food and nutrition guidelines required by their customers (i.e., cafeterias, vending operations, food stores, etc.). The FIDT should be designed to analyze products against several different sets of guidelines or standards.
2. Develop computer, tablet, and/or mobile application for both suppliers and operators that identifies single foods that meet guidelines as needed. For example, if a cafeteria patron requests that the operator stock a certain product, the dining manager can check to see if the product meets requirements in real time.

The FIDT will be a computer application designed to help suppliers identify food products that align with food and nutrition guideline specifications as requested by their customers, which include food service companies providing meals, snacks, or vending. FIDT enables suppliers (i.e., distributors, manufacturers) to process their food databases (e.g., nutrient data for ingredients, packaged products, and recipes) to determine if they meet food service guideline (FSG) requirements. FIDT should:

- Be easily utilized by manufacturers and distributors to determine which of their foods align with various guidelines;
- Have a second interface available to operators to: 1) determine if customer-requested or desired foods meet specific guidelines (e.g., does a newly marketed Grab N' Go snack pack meet guidelines); and 2) to create a list or catalog of products that meet standards to aid product selection and purchase from their food suppliers;
- Process various types of databases containing nutrition and other information to determine the ingredients or foods that meet particular sets of guidelines. For example, FIDT will be able to determine which foods meet the federal food service guidelines, the NYC food service guidelines or LA County's food service guidelines;
- Allow databases to be easily searched/navigated and have the ability to generate and sort lists of products meeting specific guidelines as requested by customers. For example, FIDT will enable groups such as the National Association of Blind Merchants to house a list of products, potentially from a particular distributor, meeting particular guidelines for their members;
- Include product cost information from the supplier so the user can also choose the most affordable product that also meets given guidelines;
- Be secure so that data are private *until* users enable sharing downstream to clients, including food service and vending operators;
 - Incorporate user-testing and heuristics that can be used over time to improve interface and outcomes.

Impact and Commercialization Potential: Currently, public health departments and other organizations responsible for procurement of food service contracts must use scarce resources to develop lists of products that meet guidelines. This creates an attributable time and cost burden and does not provide a consistent tool for the user. By placing the ability to determine foods that meet guidelines within the hands of suppliers, it eliminates not only the burden, but enables suppliers to use a new type of tool to enhance their business model and advances competition in the marketplace. Commercialization of this tool not only impacts suppliers, but can also impact business opportunities and advance competition for food service operators, food manufacturers, and producers.

(9) Innovative Approaches for Maternal and Infant Safety in Maternity Hospitals

Background: The Surgeon General's [Call to Action to Support Breastfeeding \(2011\)](#) identifies breastfeeding as one of the most effective preventive measures to protect the health of mothers and their infants. Among the key actions identified is for the health care system to ensure that maternity practices are fully supportive of breastfeeding and cites the [Ten Steps to Successful Breastfeeding](#) (Ten Steps) as the evidence-based standard for maternity care.

In the United States (US), nearly all infants are born in hospitals, and although their stay is typically short, experiences during this time have lasting effects. Skin-to-skin contact (SSC) between mothers and healthy infants immediately after birth and rooming-in are evidence-based practices that promote breastfeeding and align with steps four and nine of the Ten Steps. However, some concerns related to infant safety during immediate SSC and rooming-in throughout the hospital stay have been raised. These safety concerns include newborn falls/drops and newborn sleep practices.

Although rare, adverse events, such as infant falls/drops and/or Sudden Unexpected Postnatal Collapse (SUPC) pose potential risks to the safety of infants and may occur during unobserved SSC and in at-risk situations during rooming-in throughout the hospital stay. To date, there is limited research in this area. A 2016 clinical report by the American Academy of Pediatrics titled, [Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns](#), suggests that the use of standardized methods and procedures may help prevent these adverse events.

The authors provide suggestions to support safe implementation of SSC and rooming-in throughout the hospital stay, and these suggestions include environmental enhancements and improvements in assessment, monitoring, care practices, documentation, and staff training. In addition, in 2018 the Joint Commission published a Quick Safety issue which provides a description of newborn falls/drops, associated risk factors, and safety actions for hospitals to consider to develop a process to help prevent newborn falls/drops ([Quick Safety Issue 40 2018 Newborn falls drops.pdf](#)). Also, in 2018 the American College of Obstetricians and Gynecologists (ACOG) updated a committee opinion, [Optimizing Support for Breastfeeding as Part of Obstetric Practice](#) which provides guidance for obstetrician-gynecologists and other obstetric care providers on how to enable women to achieve their breastfeeding goals. The committee opinion includes guidance for care during the intrapartum period, including the components of safe positioning for the newborn while in SSC.

Specific Research Areas of Interest: The project goals are to develop creative, innovative approaches, including but not limited to technological applications to standardize methods and procedures to support safe implementation of SSC for healthy infants and safe rooming-in throughout the hospital stay. Technologic approaches to facilitate safe implementation and documentation of SSC and rooming-in throughout the hospital stay should be compatible with consumer/user (i.e., mothers, families, hospital maternity staff, and medical providers) preferences and integrate seamlessly with electronic medical records.

The proposed activities will require an applicant with capacity to: identify, define, and develop design specifications for one or more innovative approaches, systems, methods, procedures, and/or tools for use by hospital staff to promote safe implementation of SSC for healthy infants and safe rooming-in throughout the hospital stay.

At the conclusion of the period of performance, the awardee will provide the design specifications for the proposed innovative approach and a report/assessment of the feasibility of and commercial potential for further developing this approach. The approach should take into account consumer and user (i.e., mothers, families, hospital maternity staff, and medical providers) preferences, should be user friendly, promote infant and maternal safety, maximize hospital maternity staff efficiency, and conform to all applicable industry standards. The assessment should address, at a minimum, how the approach addresses consumer/user preferences, as well as cost, challenges and barriers related to development

and implementation, issues related to patent and/or licensing agreements; the assessment should also address the viability of the proposed innovation and establish proof of concept.

Impact and Commercialization Potential: CDC has been working for over a decade to improve maternity care practices that support breastfeeding through the administration of the [Maternity Practices in Infant Nutrition and Care \(mPINC\) survey](#) and [through projects to support hospitals in the safe implementation](#) of the Ten Steps and earning the [Baby-Friendly Hospital designation](#). These efforts have made a positive impact on the number of infants receiving evidence-based breastfeeding supportive maternity care in US hospitals, with the number of births occurring at hospitals designated as “Baby-Friendly” increasing from less than 1.7% in 2007 to greater than 26.1% in 2018. Because of the many health benefits of breastfeeding for mothers and infants, maternity hospitals have an interest in providing their consumers with safe, quality, evidence-based maternity care that supports breastfeeding. Innovative approaches, including but not limited to technological approaches, that promote maternal and infant safety and efficiency in staff time related to assessing, monitoring and documenting maternal and infant safety are needed to continue to ensure public health goals related to evidence-based maternity care supportive of breastfeeding to all healthy infants. As nearly all infants in the US are born in hospitals, this work has the potential to impact the nearly 4 million infants born each year.

Although adverse events are uncommon occurrences, these events can result in injury or death of the infant, emotional distress for mothers and families, costs related to treatment of injuries incurred as a result of adverse events, and legal implications for hospitals.

There are approximately 3,300 maternity facilities in the United States, and nearly 4 million infants born each year in these facilities. Of these facilities, 416 are Baby-Friendly designated and represent approximately 20% of US annual births. These facilities may represent a potential commercial market willing to be early adopters of innovative approaches, systems, methods, procedures, and/or tools that improve maternal and infant safety during SSC and rooming-in during the hospital stay, reduce costs related to treatment for injuries sustained as a result of adverse events, and improve staff efficiency in documenting maternity care practices.

Visit the NCCDPHP homepage for more information on NCCDPHP’s research program areas <http://www.cdc.gov/chronicdisease/index.htm>

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NATIONAL CENTER FOR EMERGING AND ZOOONOTIC INFECTIOUS DISEASES (NCEZID)

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) aims to prevent disease, disability, and death caused by a wide range of infectious diseases. NCEZID focuses on diseases that have been around for many years, emerging diseases (those that are new or just recently identified), and zoonotic diseases (those spread from animals to people). Work is guided in part by a holistic "One Health" strategy, which recognizes the vital interconnectedness of microbes and the environment. Through a comprehensive approach involving many scientific disciplines, better health for humans and animals and an improved environment can be attained.

Please visit their web site at: <http://www.cdc.gov/ncezid>

(10) Antibiotic Resistant Healthcare-Associate Infections

Background: Healthcare-associated infections (HAI) are a threat to patient safety. CDC provides national leadership in surveillance, outbreak investigations, laboratory research, and prevention of healthcare-associated infections. CDC uses knowledge gained through these activities to detect infections and develop new strategies to prevent healthcare-associated infections. Healthcare-associated infections (HAIs) can be found to effect 1 in 25 hospitalized patients on any given day in the United States, leading to an annual burden of 722,000 infections and 75,000 deaths. Meanwhile, among 18 antibiotic resistant (AR) organisms identified by CDC in 2013 as urgent, serious, and concerning threats, nearly half are primarily healthcare-associated. Whereas 1 in 7 HAIs in hospitals overall are caused by AR-threat bacteria, in some types of hospitals, AR-threat bacteria cause 1 in 4 infections. In all cases, HAIs caused by AR-threats are more difficult to treat and some are now untreatable. There are three broad, current strategies that clinicians and nurses need to employ to prevent these AR HAIs: following recommendations for preventing invasive device and surgical procedure-related infections, preventing cross-transmission of AR HAI pathogens, and practicing optimal antibiotic stewardship. In addition, there is a great need for innovation and commercial development in the following three priority areas.

Specific Research Areas of Interest:

The goals for the proposed research are to address antibiotic resistant healthcare-associated infections. Examples of specific research areas of interest include, but are not limited to:

- 1) Development of novel diagnostics that either: A) offer a more rapid and definitive diagnosis of whether a patient does or does not require an antibiotic (alternatively whether it is safe to stop an antibiotic), or B) better detect (i.e., earlier, more rapidly, and more accurately) whether a patient is infected or colonized (and thereby may transmit) with an AR HAI pathogen.
- 2) Novel therapeutics and preventatives based upon preservation or restoration of the human microbiome

Impact and Commercialization Potential: This research will lead to the development of practical and innovative solutions to address the matrix of complex problems caused by antibiotic resistant healthcare-associated infections. Successful and novel innovation that will reduce disease, disability, and death will have huge commercial potential across many markets.

(11) Detection, Transmission, Ecology, and Prevention of Antimicrobial Resistance in Enteric Bacteria

Background: Overuse of antimicrobial drugs in agriculture, medicine, and industry has resulted in continual pressure for pathogenic organisms to evolve mechanisms by which to evade these drugs. The National Antimicrobial Resistance Monitoring System (NARMS) is a collaborative effort of state public

health departments, FDA, CDC, and USDA to monitor trends in antimicrobial resistance over time using a 'farm to fork' approach. Although the advent of advanced molecular detection techniques has increased our ability to detect bacterial resistance patterns, there are knowledge gaps that remain to be addressed. Detection of resistance to clinically-relevant drugs requires a laboratory setting and takes days, if not longer, and more research is needed to link data generated by molecular detection to clinical outcome. Finally, the laboratory community has realized that the exciting potential of culture-independent tests may also have an undesired outcome; the loss of important organic material for future study.

Specific Research Areas of Interest: The goals for the proposed research are to detect, transmit, and prevent antimicrobial resistance in enteric bacteria.

Examples of specific research areas of interest include, but are not limited to:

1. Rapid, portable, point of care diagnostic and field assays that simultaneously identify bacterial agents and clinically relevant resistance markers
 - Lateral flow technology to detect biomarkers
 - High throughput molecular tests
2. Development of an in vitro system to simulate myriad physiological conditions (human or ruminant gut, for example) in which enteric bacteria develop drug resistance 3D polymer scaffold or 3D-printed substrate 'organ' for growth of bacteria in the presence of secretory immune factors to which antimicrobials may be applied or dosed
3. A matrix for archiving bacterial cultures that does not require a cold-chain or frozen storage
 - Preserves the integrity of the organisms
 - Storage matrix requires a tiny footprint, similar to filter paper.

Impact and Commercialization Potential: Using an effective in vitro "microbiome" system to study development, rate of transmission and ecology of antimicrobial resistance would require less time and human capital than the large clinical studies that are required to evaluate current and new antimicrobial pharmaceuticals. A system such as this could help to narrow one of the major knowledge gaps in understanding antimicrobial resistance; the correlation between laboratory-determined antimicrobial breakpoints and clinical outcomes. A simple rapid method of preserving important bacteria and organic material related to bacterial resistance would be embraced by the reference and research community. Existing rapid tests could be modified to add detection of clinically-relevant resistance markers, thereby dramatically decreasing time to treatment decision. Reduction of footprint and ambient storage would reduce operating and shipping costs that are currently associated with these materials.

(12) Rapid Diagnostic Test for *Candida* species Identification and Multidrug Resistance Profiling

Background: Invasive candidiasis is a serious fungal infection caused by *Candida* species that can affect the heart, brain, bones, eyes, and other parts of the body, including the bloodstream (candidemia). Affecting more than 250,000 people worldwide every year, invasive candidiasis is the most common fungal disease among hospitalized patients in the developing world. For the United States and Europe, candidemia is a leading cause of nosocomial bloodstream infections. Despite antifungal therapy, mortality can be as high as 40%, and with the rise of emerging multidrug-resistant *Candida* species, mortality is projected to increase.

The emerging species *Candida auris* was first reported in 2009, and since then has been identified on five continents. Known to colonize skin, contaminate hospital surfaces and be capable of resistance to all three major classes of antifungals, *C. auris* poses a major public health threat. Importantly, the emergence of multidrug-resistance and newly emerging multidrug-resistant *Candida* species like *C. auris* is inevitable; in addition, the type and level of drug resistance is unknown until a patient's *Candida* species is tested. Thus, it is crucial to develop point-of-care tests that can not only identify *Candida* species in a patient specimen but also determine antifungal drug susceptibility. A hybrid rapid diagnostic test (RDT) to both identify *Candida* species and detect antifungal drug susceptibility would help provide timely, appropriate treatment and reduce the spread of these resistant organisms.

RDTs, like the lateral flow assay, have revolutionized public health responses; one such success story is the Cryptococcal Antigen Lateral Flow Assay for the diagnosis of meningitis caused by the fungus *Cryptococcus neoformans*. As for *Candida* diagnosis, current methods are time-consuming or expensive. They rely on culture, DNA sequencing and/or matrix-assisted laser desorption/ionization-time of flight (MALDI-TOF) assays. Culture is considered the gold-standard, but estimated sensitivity is as low as 50% and average time of assay is one week. DNA sequencing and MALDI-TOF are much more accurate but are often not feasible for low-resource settings. Regarding drug susceptibility testing, the E-test is a promising culture-dependent tool that allows minimum inhibitory concentration (MIC) drug determination of various antifungals within two days. The ability to combine *Candida* species identification with antifungal drug susceptibility testing into a point-of-care, culture-independent diagnostic test would revolutionize the diagnosis and treatment of invasive candidiasis and provide an innovative proof-of-concept for many other infectious diseases.

Specific Research Areas of Interest: The specific research aim is the development of a hybrid RDT that performs both identification of *Candida* species and profiling of antifungal drug susceptibility in a simple, point-of-care manner. Ideally, the RDT would also be able to be used on colonized as well as infected individuals using body fluids and/or skin swabs. Specific examples of research goals include:

1. Develop a lateral flow assay for *Candida* species identification.
2. Determine the type and volume of specimen needed.
3. Determine which, if any, *Candida* species can be identified or differentiated at the species level. For example, an RDT that identifies both the major species, *Candida albicans*, and also other species. There would be an identification band for *C. albicans* and a separate identification band(s) for species other than *C. albicans*, such as *C. auris* and/or other *Candida* species.c.
4. Demonstrate test sensitivity and specificity using clinical specimens as well as artificially spiked body fluids/swabs.

Impact and Commercialization Potential: If the research demonstrates that a hybrid RDT that both identifies *Candida* species and profiles antifungal susceptibility is feasible, the small business concern selected for this research could file an assay-specific patent for appropriate innovative technologies. Given that invasive candidiasis caused by multidrug-resistant *Candida* species is a major problem in hospital settings throughout the world, this diagnostic would be in great demand. Moreover, this would be the first diagnostic of its kind that could both identify a pathogen and assess drug susceptibility without employing DNA sequencing and culture-based methods. As such, innovations stemming from the development of this hybrid RDT could be applied to RDT development for many other diseases where emerging pathogens and antimicrobial resistance are an overwhelming challenge.

(13) Vector Borne Diseases: Detection, Prevention, Diagnosis and Response

Background: Bacterial and viral vector borne diseases are transmitted to humans primarily through vectors such as an infected mosquito, tick or flea. Some of these diseases have long been present in the United States while others have recently emerged.

Vector-borne diseases are a major public health concern. Lyme disease causes over 300,000 estimated human illnesses annually in the U.S. Tick-borne rickettsial diseases, such as Rocky Mountain spotted fever, ehrlichiosis, and anaplasmosis, are responsible for over 4,000 U.S. cases each year, including some that result in death. Dengue fever causes millions of cases worldwide, including thousands of cases in Puerto Rico each year. Outbreaks of arboviral diseases such as West Nile encephalitis and Chikungunya fever have been reported in recent years. In May 2015, the Pan American Health Organization (PAHO) issued an alert regarding the first confirmed Zika virus infection in Brazil and on February 1, 2016, the World Health Organization (WHO) declared Zika virus a public health emergency of international concern. Local transmission has been reported in many other countries and territories. Less common, but often deadly threats such as *Yersinia pestis* causes the ancient disease plague. Local plague outbreaks occur in the southwestern U.S., and it is a significant health threat in Africa and Asia.

Specific Research Areas of Interest: The goal of this project is to encourage research that will enhance prevention, detection, diagnosis and response capabilities to vector borne diseases through funding innovative solutions that address the following:

1. Mitigate the spread and impact of vector borne diseases
2. Improve our ability to prevent, detect and respond to outbreaks of vector borne diseases
3. Develop diagnostic tests to differentiate among vector borne diseases
4. Develop vaccines effective against vector borne diseases

Examples of specific research areas of interest include, but are not limited to:

- Development of improved laboratory tests to diagnose vector borne diseases in the field or in healthcare settings (e.g., new diagnostics to detect and differentiate among vector borne diseases after infection, etc.)
- Development of tools to improve monitoring and reporting cases of vector borne disease infection and sequelae
- Development of tools to improve surveillance for vector borne diseases in the US and elsewhere (e.g., better surveillance applications, improved clinical, laboratory, and epidemiological data linkage, interchange, analysis, and visualization, etc.)
- Development of tools to improve linkage to and monitoring of services for vector borne disease-affected families
- Development of tools to improve mosquito, tick and flea control in and around individual houses and in the exterior environment

Impact and Commercialization Potential: Vector-borne diseases continue to cause morbidity and mortality in endemic areas where the threat from these diseases is recurrent. In addition, these diseases can emerge rapidly and unpredictably causing wide-spread outbreaks. Similar symptoms to other diseases can make diagnosis based on symptoms alone difficult and current diagnostic tests can cross-react among different causative agents (e.g., dengue and Zika virus infections). Effective vaccines are not available and environmental control is in need of improvement. Given the large number of individuals affected by these diseases, and the challenges to public health for their containment, improved detection through better diagnostic tests and improved prevention through vaccination would have a great impact on the health of the nation. The proposed research should lead to the development of practical solutions for the detection, prevention and diagnosis of vector-borne diseases. The products and innovations developed through this process will have significant commercial potential and will improve public health and the healthcare system's response to vector-borne diseases.

(14) Biologic Strategies to Address Pathogenic Bacterial Contamination of Healthcare Environments

Background: Antibiotic resistance is one of the most important public health threats of our time, accounting for millions of infections every year in the U.S. with thousands of deaths. The healthcare environment plays a major role in transmission of multidrug resistant organisms (MDROs), as well as other environmentally- or human microbiota- derived pathogens such as *Clostridium*, *Staphylococcus*, *Mycobacterium*, *Pseudomonas*, *Acinetobacter* species etc. As an example, a number of studies have recently reported the role of hand-washing station sinks, sink drains, and other plumbing system components as sources of outbreaks of carbapenem-resistant *Enterobacteriaceae* (CRE) in healthcare facilities. Meanwhile, transient and sometimes persistent contamination of high-touch surfaces in the immediate patient care area (e.g. bed rails, over bed tables, blood pressure cuffs) are regular contributors to transmission. These sources can be difficult to eradicate using traditional cleaning and disinfection strategies. This is likely due to formation of microbial biofilms, which provide protection from antimicrobial agents in disinfectants and biocides. Environmental biofilms are microbial communities composed of diverse organisms in a complex extracellular matrix, and can develop on surfaces and in the premise plumbing and wastewater systems in healthcare facilities. With the latter (as example), contaminated sink drains represent a potential reservoir in close proximity to patients that can persist despite other control measures that reduce patient-to-patient transmission. Novel strategies are needed that can prevent or

eradicate healthcare-associated pathogens, with particular emphasis on MDROs such as CRE in healthcare environments. This research topic intends to address novel approaches using biologic-based applications aimed at controlling environmental microbiota to prevent healthcare-associated infections.

Specific Research Areas of Interest: The goal of this project is to develop novel microbiologic-based strategies that can prevent or control contamination of healthcare environments. The application may be focused or tailored to specific aspects of the healthcare setting such as sinks and other plumbing components or high-touch surfaces in the patient care environment. Examples of specific research areas could include (but are not limited to): 1) using biologic agents such as bacteriophages or live microbial agents to target, lyse, or otherwise control specific organisms within biofilms, 2) developing strategies to sensitize microorganisms on contaminated surfaces to antibiotics or broadly to disinfectants such as, for example, using temperate bacteriophages to deliver the CRISPR-cas systems to antibiotic-resistant organisms on surfaces or in biofilms, or 3) designing approaches to disrupt or alter the microbial communities of the built environment through microbiome-based principles involving live microbial interventions. The technical merit or feasibility of the proposed technology should be assessed through initial bench- top (in vitro) studies. These studies should be designed to provide a proof of concept, and expected deliverables would include a determination of the efficacy of the approach towards microbial strains of the biofilm- associated MDROs as an example. Other approaches might include employing mock surface communities with efficacy studies using developed biocontrol agents under appropriate conditions encountered in the healthcare setting. Methods and metrics to manipulate/recapitulate environmental communities of the built environment would also be considered.

Impact and Commercialization Potential: An effective novel strategy for the prevention or control of CRE or other MDROs on environmental surfaces in the healthcare environment, particularly in healthcare premise plumbing systems, can substantially reduce dispersal of these microorganisms in the patient care environment, with the potential to reduce transmission of antimicrobial resistance and healthcare-associated infections in susceptible patient populations. In addition, beneficial strains or cocktails thereof that have a particular efficacy for colonizing and preventing or precluding healthcare-associated pathogens in the microbiome of the built healthcare environment would make significant strides over and above terminal cleaning strategies. Such approaches could be further used in the future in decontamination of surfaces in other settings, beyond healthcare, or on medical devices, with even wider public health impact. The commercialization potential of such biologic-based technologies is quite high. Designing novel approaches that modulate microorganism communities in environmental biofilms or selectively target MDROs in contaminated healthcare surfaces such as premise plumbing, can have wide applications beyond healthcare- associated situations. Other settings, involving potentially child care, elderly care, industry or food preparation settings could benefit from biocontrol technology with IP rights extended to defined protective microbial community formulations. Alternatively or in addition, bacteriophages specific for antimicrobial-resistant bacteria are readily available and can be isolated from untreated domestic wastewater or other environmental sources, the unique combination and application of which can produce a marketable and potentially valuable product. With appropriate commercialization strategies, using temperate bacteriophages to sensitize antimicrobial resistant bacteria using the CRISPR-cas system could benefit from the ability to secure IP rights for this technology.

Visit the NCEZID homepage for more information on NCEZID's research program areas
<http://www.cdc.gov/ncezid>

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NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH)

National Center for Environmental Health (NCEH) plans, directs, and coordinates a program to protect the American people from environmental hazards. We promote a healthy environment and prevent premature death, avoidable illness and disability caused by non-infectious, non-occupational environmental and related factors. We are especially committed to safeguarding the health of vulnerable populations – such as children, the elderly, and people with disabilities – from certain environmental hazards.

Please visit their web site at: <https://www.cdc.gov/nceh/>

(15) Technology to Develop a Monitor to Detect Iodine Deficiency

Background: Iodine deficiency (IdD) is linked to many neurodevelopmental disorders and is the world's leading cause of intellectual deficits. While IdD is well known in Africa, India, and central Asia, IdD also exists in the US. Although the overall U.S. population is not iodine deficient, CDC National Health and Nutrition Examination Survey (NHANES) data suggests that a significant fraction of the U.S. population may be iodine-deficient. Lack of quality iodine nutrition in pregnant and lactating women places the fetus/infant at risk of impaired neurodevelopment.

Although IdD spot checks in pregnant and lactating women can indicate a problem in a population, epidemiological investigations suggest that 24h urinary iodine anion samples corrected for creatinine are better for case identification, since much of the iodine is quickly excreted in the urine (along with potassium and sodium). Although randomized sampling and spectrometry also show promise in accurately detecting IdD, analysis is best determined by catalytic reduction of cerium ammonium sulfate in the presence of arsenic acid after the urine is acid digested under mild conditions. Such methodology is complicated, time consuming and is not readily available to physicians to aid in diagnosis.

While rapid strip tests based on the iodide-catalyzed oxidation of 3,3',5,5'-tetramethylbenzidine by peracetic acid/H₂O₂ yield a colorimetric output to determine uncorrected iodine ranges, these strip tests are not sensitive and lack the specificity of the laboratory methods in that they provide only aggregate data and cannot probe with specificity for iodine levels below 100 ug/L. An affordable, reliable, sensitive method for IdD detection (at least to 33 ug/L) is needed. Ideally, the method should be capable of being carried out in a physician's office as part of a routine checkup.

Specific Research Areas of Interest: The goal of this research is to develop technology that will provide a simple sensitive IdD detection method for OBGYNs and pediatricians to use in their offices to identify urinary iodine at <33 ug/L. The ideal device would screen multiple samples with clearly quantified measurements. Phase I (6 months): The awardee should conduct a feasibility study to develop a prototype IdD monitor capable of detecting urinary iodine at <33 ug/L. The awardee should provide research data regarding the sensitivity and specificity of the IdD monitor. Phase II (24 months): The

awardee should develop a prototype for pilot testing, validation, scaling up from design to production, and performance evaluation.

Impact and Commercialization Potential: While there are several methods to identify IdD in pregnant and lactating women, high tech laboratory methods are expensive and time-consuming, and strip tests, while inexpensive, are too insensitive to measure levels of iodine that are expected to be harmful. Successful development and subsequent use of an IdD monitor capable of detecting iodine at levels <33 ug/L will improve identification of IdD in expectant and lactating mothers, and in infants. IdD monitoring technology developed from research funded under this topic has the potential to prevent new cases neurological disorders resulting from IdD. There is an approximate need for 15,000 devices in the US and multiples more worldwide as extreme IdD is found in 54 countries. This product has commercial appeal to hospitals, clinics, public health departments, and physician practices in which IdD monitoring is conducted

Links to associated patents:

Photometric detection with complex sample prep:
<https://patents.google.com/patent/RU2265847C2/en>

Strip method detection is patented here: <https://patents.google.com/patent/US6689618>

Colorimetric reaction is described here:
<https://academic.oup.com/jcem/article/83/3/1007/2865523>

The ICP-MS method is discussed here: https://file.scirp.org/pdf/AJAC_2017041415342563.pdf

Visit the NCEH homepage for more information on NCEH's research program areas
<http://www.cdc.gov/nceh/>

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NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS, STD, AND TB PREVENTION (NCHHSTP)

The National Center is committed to our vision of a future free of HIV/AIDS, viral hepatitis, STDs, and TB. NCHHSTP is responsible for public health surveillance, prevention research, and programs to prevent and control HIV and AIDS, other STDs, viral hepatitis, and TB. CDC's National Center for HIV, Viral Hepatitis, STD, and TB Prevention's (NCHHSTP) Strategic Plan Through 2020 articulates a vision, guiding principle, and overarching goals and strategies through 2020 to influence and enhance our programs. The three overarching goals highlighted in this plan are to decrease:

- Incidence of infection,
- Morbidity and mortality, and
- Health disparities.

Every year, millions of Americans are infected with HIV, viral hepatitis, STDs, or TB and tens of thousands die from their infection. Most of these infections share commonalities, from modes of transmission to demographic, social, and economic conditions that increase risk. As a prevention leader, NCHHSTP focuses on high impact prevention and control efforts to reduce incidence, morbidity, mortality, and health disparities due to these infections.

Please visit their web site at: <http://www.cdc.gov/nchhstp/>

(16) Improved Diagnostic Tests for HIV, STDs, Hepatitis and TB

Background: It is estimated that just over 1.2 million people in the United States are living with HIV infection, and almost 1 in 8 (12.8%) are unaware of their infection. Because there are several treatment and prevention options for HIV, a major goal of CDC, other public health agencies and our public and private partners is to further improve the percentage of people that know their HIV status. For individuals that are at risk and uninfected, it allows them to focus on prevention. For those that are infected, there is growing evidence that the sooner a person knows they are infected and can start treatment, the better their overall health can be maintained. There is also emerging evidence that early diagnosis leads to preventing further spread of the virus due to changes in behavior by those who know their status.

Whereas there are specific benefits for HIV testing and treatment, testing and treatment for comorbid pathogens such as TB, hepatitis (B and C), gonorrhea and syphilis are also of great benefit in populations at risk for HIV. These diseases (STDs, TB and hepatitis) can all lead to worse health outcomes for HIV infected individuals. Furthermore, having diseases such as syphilis and gonorrhea can increase the chances of someone acquiring HIV. Because there is an effective vaccine for hepatitis B and effective therapy for hepatitis C, syphilis, gonorrhea and TB, improving tests and testing for these pathogens can lead to a further decrease in HIV transmission or morbidity.

Whereas there is tremendous value in testing and diagnosis for each of the described diseases, some at risk individuals are never tested or do not receive their tests results and often times are only tested for one of the diseases when testing for a combination of the diseases would be more beneficial both for the individual and for public health.

Prognostic tests (e.g. viral load, drug resistance monitoring) also play an important role in improving health outcomes for individuals infected with HIV and the ability to predict recent or long term HIV infection can be used for public health action.

Specific Research Areas of Interest: The major goal of the project is development of diagnostic reagents, tests or testing platforms, that will further improve diagnosis or monitoring of HIV or comorbid pathogens such as hepatitis (B and C), syphilis, gonorrhea or TB. The specific area of interest is innovative approaches or novel technology that would allow for diagnosis of HIV and other comorbid pathogens such as hepatitis (B and C), syphilis, gonorrhea and TB alone or in any combination using a

single test device or platform. The preferred reagents, test format or technology would facilitate testing that allows for rapid results (preferably less than one hour), is affordable (comparable to currently available tests) and can be performed at the point of care or in a laboratory capable of performing moderately complex tests.

Consideration will also be given to innovative technology that provides prognostic (monitoring) results such as viral load (HIV, HCV, HBV), drug resistance detection (HIV, syphilis, gonorrhea, TB), or disease staging (i.e., acute/recent, longstanding or latent infection).

Impact and Commercialization Potential: It is known that early diagnosis and treatment of HIV infection as well as diagnosis and treatment of comorbid pathogens can improve health outcomes for individuals infected with HIV. Furthermore, such testing has the potential for decreasing transmission of HIV and better health outcomes and optimal treatment for the comorbid pathogens. Estimations show that 1.2 million people living in the United States are living with HIV infections, and out of those, 1 in 8 are unaware of their infection. Faster turnaround times, lower cost, and more efficient detection would be highly impactful for these individuals, their partners and the community. Diagnostic reagents, tests or testing platforms, that will further improve diagnosis or monitoring of HIV or comorbid pathogens such as hepatitis (B and C), syphilis, gonorrhea or TB, would be in great demand by the health-care and public health systems as well as other sectors engaged in using diagnostics to treat this patient population.

Visit the NCHHSTP homepage for more information on NCHHSTP's research program areas
<http://www.cdc.gov/nchhstp/>

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NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (NCIRD)

The mission of the National Center for Immunization and Respiratory Diseases (NCIRD) is the prevention of disease, disability, and death through immunization and by control of respiratory and related diseases. NCIRD balances its efforts in the domestic and global arenas as well as accommodates the specific needs of all populations at risk of vaccine preventable diseases from children to older adults.

Please visit their web site at: <http://www.cdc.gov/ncird/>

(17) Prevention and Diagnosis of Acute Respiratory Infections in the US and Globally

Background: Acute respiratory infections kill an estimated 3.9 million people annually and in developing countries are the leading cause of mortality in children under 5 years of age. Specific respiratory virus infections such as influenza and respiratory syncytial virus, are major contributors to this burden of disease, as are other respiratory bacterial and viral pathogens. Respiratory virus infections are frequent events in all age groups and impose a substantial burden on social and healthcare delivery systems.

Specific Research Areas of Interest: The goal of this research includes, but is not limited to activities that support the development and evaluation of tools for: 1) the prevention of acute respiratory infections such as pneumonia, influenza, and Legionnaire's disease; 2) rapid recognition and containment of outbreaks; and 3) advanced diagnostic technologies including point-of-care testing, advanced molecular detection and whole genome sequencing.

Impact and Commercialization Potential: This research will lead to the development of practical solutions for the prevention and diagnosis of vaccine preventable diseases that have a substantial impact on the economy, health and wellbeing of society. The goal of the research supported through this mechanism is expected to begin shifting viral and bacterial infections from common occurrences to rare events. The innovative technologies and solutions developed through this process will make it possible to improve the public health and healthcare system's response in a variety of settings, thus making the commercialization potential unlimited.

Visit the NCIRD homepage for more information on NCIRD's research program areas
<http://www.cdc.gov/ncird/>

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NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL (NCIPC)

For more than 20 years, CDC's National Center for Injury Prevention and Control (the Injury Center) has helped protect Americans from injuries and violence. We are the nation's leading authority on injury and violence. We study violence and injuries and research the best ways to prevent them, applying science and creating real-world solutions to keep people safe, healthy, and productive. NCIPC will prioritize

funding meritorious applications that address the NCIPC program topics listed in this program announcement. NCIPC may also consider meritorious applications that address current NCIPC research priorities. To learn more about NCIPC research priorities, please visit our web site at: <https://www.cdc.gov/injury/researchpriorities/index.html>

Please visit their web site at: <http://www.cdc.gov/injury/index.html>

(18) Technological Innovations to Reduce Deaths and Injuries from Motor Vehicle Crashes

Background: Motor vehicle crashes are a leading cause of death among those aged 1-54 years in the United States, killing over 37,000 people every year and injuring over 3 million more. The cost of medical care and productivity losses associated with motor vehicle-related injuries in the United States can exceed \$63 billion annually. In 2017, 10,874 people died in alcohol-impaired driving crashes. Among passenger vehicle occupants killed in 2017, almost half (47%) were known to be unrestrained (i.e., not buckled up) at the time of the crash. Speed is a known risk factor for injury and death in a crash. In 2017, there were 9,717 speeding-related deaths. In 2017, there were 3,166 deaths in distraction-affected crashes (8.5% of the total fatalities).

Motor vehicle crashes can result from a single or combination of environmental, human behavioral, and vehicle-related risk factors including hazardous road conditions, driving too fast for the environment, driver perception deficits, non-compliance with vehicle safety devices, impaired driving, lack of seat belt use, lack of helmet use, distracted or drowsy driving, and sub-optimal vehicle performance. Reducing any of these risk factors can lower the likelihood of a crash and increase the chance of survival in the event of a crash.

Adaptive technologies can generate feedback loops about the road and environment, driver fitness, and vehicle performance, and applications of these adaptive technologies in both private and commercial vehicles can reduce risks associated with motor vehicle crashes. Currently, there are a limited number of adaptive technologies to warn drivers of potential dangers associated with driving; most of these technologies focus on vehicle related performance (e.g., collision warning, electronic stability control, lane departure warning, adaptive headlights, etc.). Innovative adaptive technologies that can assist in alerting drivers to risks associated with the road or environment and vehicle performance, and that can facilitate drivers to modify personal risk behavior, including impaired or drowsy driving, are sought. These adaptive technologies can result in the development of tools or systems that will reduce the likelihood and severity of motor vehicle crashes and assist drivers in making potentially life-saving decisions more quickly and more intuitively.

Specific Research Area of Interest: The goal of this project is the development of improved technologies that have the potential to further reduce motor vehicle crashes and resulting injuries. These technologies will address risks such as distracted driving, impaired driving, non-compliance with use of vehicle safety equipment (e.g., seat belts), environmental conditions (including road quality), vehicle performance and other factors that may impact driving. A successful awardee would be one that would be able to develop and pilot test new technology designed to reduce motor vehicle crashes and resulting injuries.

Impact and Commercialization Potential: The availability of technologies to reduce motor vehicle crashes and resulting injuries can reduce the related public health burden and save lives. Development of these technologies has commercial viability. Commercial applications of this technology might be of interest to drivers, motor vehicle manufacturers, insurance companies, patients, clinicians, and health systems.

(19) Innovative Technology or Media to Prevent Violence Affecting Children/youth

Background: Violence is a significant public health problem in the United States. In 2017, more than 67,000 people in the United States died as a result of violence. Nearly 20,000 people died from homicide and more than 47,000 died from suicide. Far more people experienced nonfatal violence. For example, more than 1.7 million people were treated for nonfatal injuries from assaults and nearly 500,000 people were treated for self-harm injuries in U.S. emergency departments in 2017. Violence starts early in life. In 2017, there were 4.1 million referrals to child protective services for child abuse and neglect involving an estimated 7.5 million children. Exposure to violence in childhood and adolescence can increase risk for later violent experiences and can have a cumulative and compounding impact on health and well-being across the lifespan. Adverse Childhood Experiences (ACEs) are a collection of experiences that may be traumatic to children and youth, and include exposure to violence and household challenges (e.g., parental mental illness, separation/divorce, substance abuse, and incarceration) that occur during the first 18 years of life. The different forms of violence impacting children and youth, include child abuse and neglect, sexual violence, teen dating violence, youth peer violence, youth/parent suicidal behavior, and exposure to adult intimate partner violence. These forms of violence often share common risk and protective factors. These factors can start in early childhood and continue throughout the lifespan. They go beyond individual-level factors to include family and peer relationships and other influences from schools, the community, and society. Many effective violence prevention strategies have been developed, and broader benefits could be achieved from wider dissemination through innovative media and communication technology (e.g., mobile applications, social media, games, Internet-based interventions). To help communities make decisions about violence prevention strategies, the CDC has released a series of technical packages that describe the best available evidence (see <https://www.cdc.gov/violenceprevention/pub/technical-packages.html>). Media and communication technology also create the opportunity for the development of new prevention approaches based on what is known about violence risk and protective factors and strategies that work in traditional settings.

The strategic vision for CDC's violence prevention work includes a focus on: 1. children and youth to achieve long-term impacts, 2. populations and communities at highest risk for experiencing or perpetrating violence, 3. shared risk and protective factors that are most important for reducing multiple forms of violence, and 4. facilitating the identification, implementation, and scale-up of approaches that have cross-cutting impact (see: https://www.cdc.gov/violenceprevention/pdf/Strategic_Vision.pdf).

By focusing on activities that prevent multiple forms of violence, communities can achieve the greatest impact and increase scalability of their prevention strategies. Additionally, these prevention efforts are ideally designed to use resources more effectively and to better address disparities by focusing on the populations at greatest risk. Innovative media and communication technology can play an important role in effectively reaching populations at greatest risk for multiple forms of violence. Research is needed to guide the development of technological applications for prevention strategies that can effectively protect children and youth who are most at risk for experiencing multiple forms of violence.

Specific Research Areas of Interest: The goal of the project is to develop innovative technology or media, such as applications for mobile devices, social media, games, or Internet-based interventions to prevent multiple forms of violence and other ACEs affecting children or youth. Multiple topics in the violence prevention sections of the NCIPC research priorities emphasize the need for research on the innovative use of new media and communication technology (see <https://www.cdc.gov/injury/researchpriorities/index.html>). For example, the cross-cutting violence prevention research priorities describe specific gaps related to understanding the potential of new media and communication technology to do the following: increase the accessibility of prevention approaches, modify norms about violence and bystander behavior, enhance education and support for young children and their families, reduce stigma and barriers to help seeking, and enhance young people's skills and relationships to reduce risk for multiple forms of violence. The widespread use of smartphone applications, social media, and wearable technology also provides unique opportunities for the broader

dissemination, implementation and evaluation of evidence-based prevention strategies to significantly reduce violence, such as strategies identified in DVP's technical packages, within real world settings.

The prototype (e.g., developing innovative technology or media) should be informed by prior research about violence risk and protective factors and/or evidence-based prevention strategies and through consultation with subject matter experts in the form(s) of violence and the technology or media selected. The awardee should describe the target audience, the type(s) of violence addressed, the process through which the technology or media is expected to work, goals for the product, the functionality and actions for users to take, the measurements and key performance indicators for tracking progress toward the goals, the estimated costs and logistics of scalability, a description of potential barriers to implementation, and any evidence for the potential benefits from prior research.

Impact and Commercialization Potential: The results from this research will have substantial implications for innovative prevention approaches or enhanced opportunities to disseminate existing evidence-based prevention strategies to substantially reduce multiple forms of violence and other ACEs affecting children and youth. Technological or media innovations that show effectiveness in preventing violence affecting children and youth would have the potential for a range of commercial applications. Depending on the nature of the strategy, the target audience, and the costs/logistics of scalability, the product could be in demand by school systems, colleges and universities, youth serving organizations, law enforcement, public health agencies, community groups, parents, and their children.

(20) Developing Tools for Patients and Clinicians to Address Opioid Overdose

Background: The United States is in the midst of an opioid overdose epidemic. Overdose deaths from opioids, including prescription opioids, heroin, and synthetic opioids such as fentanyl have increased almost six times since 1999. In 2017 more than 47,000 people died from overdoses involving opioids and 36% of those deaths involved prescription opioids. Providers, and the health systems they work in, are crucial in promoting safer and more effective opioid prescribing for pain management. Use of the CDC Guideline for Prescribing Opioids for Chronic Pain by providers and health systems can improve the way that opioids are prescribed (see <https://www.cdc.gov/drugoverdose/prescribing/resources.html>). For example, health systems can implement quality improvement measures informed by the guideline to track their efforts and integrate these measures into their electronic health records. Patients, including those with opioid use disorder and in need of opioid treatment services, can benefit from technology to assist them in accessing opioid treatment services and supports that are available in their communities. To support awareness by clinicians of evidence-based opioid prescribing practices, and better linkage to treatment for patients with opioid use disorder, we are also soliciting proposals to create user friendly, helpful electronic tools, apps, or technologies for health care providers or patients.

Specific Research Areas of Interest: CDC is interested in research to develop innovative technologies that will support the prevention of opioid overdose by focusing on one of two important end users: clinicians engaged in pain management or patients in need of treatment for opioid use disorder.

Impact and Commercialization Potential: The availability of technological tools to assist clinicians track their performance on the quality improvement measures can advance guideline-concordant care which will in turn lead to the expected public health benefit of improved patient safety and pain management.

The availability of technological tools to assist those at risk for opioid overdose can better ensure that needed referrals, services, and follow-up care are received. By improving access to medical and non-medical support services, the expected public health benefit is increased linkage to support services that can reduce the risk of opioid overdose. Development of technological tools to assist health systems and clinics implementing quality improvement measures has commercial viability. Commercial applications of this technology may be of interest to health systems, clinics, clinicians and other stakeholders invested in preventing opioid overdose.

Development of technological tools that links people at risk for opioid overdose to support services has commercial viability. Commercial applications of this technology may be of interest to those at risk and their families, healthcare providers, treatment providers, community support programs and staff, and other stakeholders invested in preventing opioid overdose.

(21) Electronic Tools to Assist Older Adults at Risk for Falls

Background: Unintentional falls are the leading cause of fatal and nonfatal injuries in older adults aged 65 years and older. In 2016, falls resulted in more than 3 million emergency department visits and more than 800,000 hospitalizations. About 30,000 older adult deaths occurred because of a fall in 2016, representing an increase of 31% between 2007 and 2016. The older adult population is rapidly growing and is projected to include approximately 74 million Americans aged 65 and older by the year 2030. Given this, a continued increase in the rate of falls could lead to an estimated 59,000 fall-related deaths among those aged 65 and older by 2030. Falls are among the 20 most expensive medical conditions in the US. In 2015, these injuries were estimated to cost nearly \$50 billion dollars, and the amount is projected to climb with the anticipated increase in the older adult population.

Falls often lead to reduced mobility and loss of independence; therefore, reducing fall risk is conducive to maintaining independence. An example of a resource for information about falls prevention is CDC's Stopping Elderly Accidents, Deaths, and Injuries (STeADI) initiative. STeADI includes information on modifiable fall risk factors and evidence-based interventions. Evidenced-based interventions include referral to physical therapy or community-based exercise programs (Tai-chi and Stepping On program); removal of home hazards; stopping, switching, or reducing the use of medications that increase fall risk; increasing vitamin D if deficient; and improving vision impairment. Older adults prescribed with at least one of these fall prevention strategies are 40% less likely to be hospitalized due to a fall. They are more likely to follow these recommendations when advised by their healthcare provider and when receiving reminders and continuous ongoing support and monitoring. Older adults are also more likely to follow recommended fall prevention activities when the activities are affordable and easily accessible. Barriers to following through with fall prevention recommendations include the inability to remember instructions and lack of information about fall prevention programs.

Specific Research Areas of Interest: The goal of this research is to develop technology that will help older adults follow their healthcare provider's recommendations for reducing their fall risk. One way this can be accomplished is through technology that incorporates elements of an evidence-based program, such as those described in CDC's STeADI tools and resources. For example, the technology could use STeADI's patient education materials to educate older adults about falls and how to prevent them. The technology could screen older adults for fall risk (e.g., by using the Stay Independent 12-item survey). The technology could also record the medications used by the older adult and allow for development of an individualized fall prevention care plan as recommended by the older adult's healthcare provider. The technology could then periodically remind the older adult to follow through with the care plan. The technology could prompt the older adult to attend their physical therapy session or remind them to schedule an eye exam, as well as locate local fall prevention programs (e.g., Tai Chi program). Other potential functions include identifying local pharmacies to review the older adult's medications for fall risk and supporting communication with their healthcare provider either in real-time or via a summary format for review at provider visits.

Impact and Commercialization Potential: The availability of a technological tool to assist older adults who are at risk for falls can better ensure that provider recommendations are followed and that needed referrals, services, and follow-up care are received. By facilitating fidelity to recommendations and improving communication about fall risk and prevention between patients and providers, the expected public health benefit is increased linkage to support services that can reduce the risk of older adult falls. Development of a technological tool that reduces risk for older adult falls has commercial viability. Commercial applications of this technology may be of interest to those at risk and their families, healthcare providers, community support staff, and other stakeholders invested in preventing older adult falls.

(22) Prevention and Management of Traumatic Brain Injury Among Youth

Background: As attention to concussion and traumatic brain injury (TBI) has grown in recent years, there has been an increase in the number of pediatric patients with concussion (also known as mild TBI, or mTBI) seen in healthcare settings including emergency departments, urgent care settings and primary care practices. Many healthcare providers have insufficient time and training to systematically assess and manage patients with suspected mTBI, thus limiting adoption of best practices to ensure diagnosis and management consistency. Falls are the leading cause of non-fatal emergency department (ED) visits among children aged birth to 14 years, accounting for 2.4 million visits annually, and the leading cause of TBI ED visits for children in the 0 to 4 year age group. Studies examining injury circumstances and location of the injury in younger children report that although almost twice as many children are hospitalized due to falls from furniture than from stairs, children who fall from stairs are more likely to sustain head injuries. Previous reports on injuries in the youngest children indicate many injuries are related to nursery and infant products (e.g., cribs); furniture; stairs; and surfaces (e.g., carpet, tile floor). Children with TBI navigate two systems of care - health systems and school systems. There are challenges, inconsistencies, and gaps in current systems of care for children with TBI, particularly for children who are transitioning to school after acute care. Communication of medical information to parents and school personnel is inconsistent, which contributes to gaps in care and potentially poorer health, education, and social outcomes for children. Following TBI diagnosis, it is especially important for children and youth to monitor their symptoms (e.g., fatigue, headaches, changes in thinking) when they return to school and sports and recreational activities. Often healthcare providers do not receive follow-up information once the child has returned to school and activities, a critical component of follow-up.

Specific Research Areas of Interest: CDC is interested in research to develop technology that can assist caregivers with prevention of traumatic brain injuries (TBIs) among young children. The technology could support caregivers of young children in making their home safer with respect to TBI among young children by helping them to evaluate opportunities for increased safety in their homes and implementing safe-home strategies. We are also interested in technology that can aid adolescents and young adults with management of TBIs. The technology could support adolescents and young adults who have experienced a TBI by helping them to understand, record and communicate their symptoms in the acute phase as well as after the initial diagnosis. Knowledge of persistent symptoms following diagnosis would help them inform healthcare providers about their health and well-being.

Goal 1: Provide injury prevention information for parents of young children, including information on environmental structuring.

Goal 2: Improve understanding of TBI among adolescents and young adults, and help them to monitor and communicate about their symptoms in order to improve post injury management.

Impact and Commercialization Potential: The availability of technology that can assist caregivers in making their home safer with respect to traumatic brain injury among young children can help to reduce the burden of traumatic brain injury in this population. The technology would also help adolescents and young adults understand, track and manage their traumatic brain injury symptoms, which would aid in older children recovering from traumatic brain injury as well as potentially prevent them from experiencing future injuries. Development of this technology has commercial viability. Commercial applications of this technology may be of interest to adolescents, young adults, caregivers, healthcare providers and youth sports personnel.

Visit the NCIPC homepage for more information on NCIPC's research program areas

<http://www.cdc.gov/injury/index.html>

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NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

The National Institute for Occupational Safety and Health (NIOSH) is part of the U.S. Centers for Disease Control and Prevention. It has the mandate to assure “every man and woman in the Nation safe and healthful working conditions and to preserve our human resources.” NIOSH has more than 1,300 employees from a diverse set of fields including epidemiology, medicine, nursing, industrial hygiene, safety, psychology, chemistry, statistics, economics, and many branches of engineering. NIOSH works closely with the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration in the U.S. Department of Labor to protect American workers.

For additional information about NIOSH, please visit their web site at:
<http://www.cdc.gov/niosh/programs>.

(23) Control Technology and Personal Protective Equipment for High Risk Occupations

Background: Personal protective equipment (PPE) protects workers from death and disabling injuries and illnesses as well as from the specific threats of exposures to certain airborne biological particles, chemical agents, nanomaterials, splashes, noise exposures, fall hazards, head hazards, and fires. It is estimated that 20 million workers use PPE on a regular basis to protect them from job hazards and a total of 135,000 workers potentially could benefit from the use of PPE ([Worker Health Chartbook 2004](#)). Engineering controls include substitution of a safe material for a hazardous one, design changes to equipment, or modification of work methods to eliminate or reduce hazards. Research is needed to develop and evaluate control strategies and personal protective equipment for specific hazards and to assure their practicality and usability in workplaces in all of the high risk industrial sectors.

For additional information about NIOSH PPE and Engineering control programs, please visit their web site at: <http://www.cdc.gov/niosh/programs/ppt/> and <http://www.cdc.gov/niosh/programs/eng/>.

Examples of specific research areas of interest include, but are not limited to:

Conduct research on the ability of existing containment and control strategies to prevent releases and potential human exposures to engineered nanomaterials.

Conduct research to evaluate the effectiveness of personal protective equipment in protecting workers against exposure to engineered nanomaterials. Provide data to fill knowledge gaps and

support guidance for the selection and use of gloves and protective garments to prevent exposures. Respiratory protection research needs to be extended to a broad range of engineered nanomaterials.

Develop a heads-up display coupled with a personal noise exposure monitoring system. Personal noise alert “badges” and personal noise dosimeters exist, but do not have an effective way to alert the user immediately when a noise hazard occurs. A system that displays a warning within the user’s visual field (via lights on protective eyewear, hardhat, etc.) would facilitate hazard recognition.

Develop an inexpensive hand-held earplug test device based on the NIOSH QuickFit concept. Studies of hearing protector users have shown repeatedly that average protection values are much lower than the labeled Noise Reduction Ratings (NRR) determined in laboratories. A QuickFit test system would help workers determine if their hearing protection is giving them at least 15 decibels of attenuation.

Develop innovative engineering control approaches and technologies for reducing asphalt exposures in roofing, and skin exposures and disease in construction workers.

Conduct research to understand PPE integration and interoperability issues. In most cases, individual PPE are currently used without consideration for their ability to function together. Research is needed to test interfaces among different PPE and components. Current interfaces do not provide seamless integration of PPE components resulting in reduced comfort, fit, usability, and protection for the wearer as well as logistical challenges for safety managers and employers.

Develop innovative educational and professional training materials suitable for today’s diverse workplace on the role of PPE in occupational safety and health. This is especially critical for high risk occupations. Innovative methodologies, including social media, should be explored and evaluated to demonstrate their effectiveness at improving workplace safety and health. For example, to what extent can mobile application media be focused on worker safety and health to provide up-to-date PPE information to a diverse range of employers and employees through portable communication devices?

Impact and Commercialization Potential: The impact of the proposed research will prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective equipment. Potential products include technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment worn by individuals to reduce the effects of their exposure to a hazard.

(24) Exposure Assessment Methods for High Risk Occupations

Background: Exposure assessment provides multi-disciplinary strategies and methods to anticipate, recognize, evaluate, control, and confirm effective management of occupational health stressors, exposures to those stressors, and resulting health risks. Major gaps in current approaches include: (1) the lack of practical methods for hazard identification and measurement that can be applied at reasonable cost in many workplaces where health stressors may exist, (2) the lack of validated, noninvasive biological methods for monitoring relevant exposure and resulting dose, and (3) the lack of strategies and methods for epidemiologic studies to demonstrate either a dose-response effect or a conclusion of no association between the agent and disease in the complex environments of today’s workplaces.

For additional information about NIOSH Exposure Assessment programs, please visit their web site at: <http://www.cdc.gov/niosh/programs/expa/>.

Examples of specific research areas of interest include, but are not limited to:

Two areas of research are needed to support effective assessment of worker exposure to engineered nanomaterials. 1) Real-time sensors capable of reliably detecting nanoparticles and providing information on size distribution and count, that can be used for personal monitoring; and 2) Development of methods that can detect and quantify the presence of engineered nanomaterials in samples collected for the purpose of characterizing exposures. These methods need to be cost-effective and available to the OS&H practitioner community. Broader application to general public health assessments should be factored into the research.

Develop new or improved methods to measure occupational health stressors such as psychological and ergonomic factors, noise, chemicals, particles and fibers, physical agents, non-ionizing radiation, or mixtures of stressors in the work environment. Enhanced measurement performance and functionality can include sensitivity, selectivity, size and weight considerations, ease of use, and capabilities to measure multiple analyses simultaneously.

Develop or adapt easy-to-use, direct-reading instruments and test kits to rapidly and inexpensively measure exposures in a variety of workplaces. Critical applications include routine monitoring, evaluating the success of control technologies, and supporting epidemiological studies. For example, developing a sound level meter to monitor worker noise exposure that can be used in underground coal mines.

Improve the measurement of low concentrations of chemicals and biomarkers in biological specimens such as blood, urine, saliva and sweat so that such concentrations can be linked to internal dose at the target organs, work tasks and workers can be categorized according to hazard bands and exposure bands, and at-risk workers can be identified and protected.

Develop a computerized system that can be used to predict worker noise exposure from mining machine noise emissions. The system would include an acoustic model of mining environments and algorithms to characterize exposure based on noise source characteristics. The main application for this technology would be for mining machine manufacturers to evaluate the potential effects of noise controls during the design process. If the impact of design changes on exposure reduction can be accurately predicted without the need for extensive field measurements, innovative noise controls can reach implementation much more quickly.

Impact and Commercialization Potential: This research will lead to the development of practical solutions and prevention activities to address complex problems that cause occupational diseases, injuries, and fatalities and that will lead to reductions in occupational injuries and illnesses among all workers. This research will lead to the development and translation of exposure assessment methods and research findings into prevention practices and products that will be adopted in occupational settings. Potential products include technical methods, processes, techniques, tools, and materials that support the assessment of exposure to physical, chemical and biological hazards in the work environment.

(25) Work-related Injuries from Motor Vehicle Crashes

Background: The risk of injury associated with on-the-job operation of motor vehicles affects millions of U.S. workers who work in all industries and drive all types of vehicles, and for whom driving may be a primary or incidental job task. Motor vehicle-related incidents are consistently the leading cause of work-related fatalities in the United States. Between 2003 and 2017, the Bureau of Labor Statistics reported 25,704 work-related fatalities due to motor vehicle incidents, about 35% of all fatalities at work. Over the same period, workers incurred nearly 400,000 lost-workday injuries due to these incidents. Crash-related fatalities and serious injuries have a devastating impact on workers and their families, and on the economic health and productivity of American businesses. Work vehicles such as large trucks also have an impact on the safety of the motoring public.

The [NIOSH Center for Motor Vehicle Safety](#) coordinates the CDC/NIOSH response to this pressing worker safety issue. Many NIOSH programs include motor vehicle crashes among their top injury prevention priorities: Traumatic Injury; Transportation, Warehousing, and Utilities; Wholesale and Retail Trade; Oil and Gas Extraction; and Public Safety.

Examples of specific research areas of interest include, but are not limited to:

The highest priority is to develop, implement, and evaluate interventions in an effort to build the scientific evidence base to guide prevention of work-related motor vehicle crashes and resulting injuries. This may be achieved by:

- Developing and testing new design concepts and applications with potential for commercialization and diffusion to employers and fleet managers
- Developing and testing novel approaches for driver training and assessment to reduce work-related motor vehicle crashes, including training on the operation of vehicles with Advanced Driver Assistance Systems (ADAS) or other forms of automation
- Developing and evaluating the effectiveness of technology- or management-based intervention strategies to reduce the incidence or severity of work-related motor vehicle crashes
- Developing and evaluating engineering controls for preventing work-related crashes and injuries, with emphasis on specialized work vehicles such as large trucks and fire apparatus

Developing and evaluating an easy-to-use computerized system based on readily available technology that can automate a “fatigue detection” system capable of warning the employee driver and supervisor when the driver may be at risk for a work-related motor vehicle crash. The system would include a statistical algorithm capable of using Global Positioning System (GPS) data from cellular phones to characterize potential number of hours awake within the last 24 hour-cycle. The main application for this technology would be to allow supervisors and employee drivers to identify and respond to fatigue, thereby reducing the driver’s risk of a fatigue-related crash. If fatigue detection systems can use readily available technology, intelligent automation may help mediate work-related injury prevalence.

Impact and Commercialization Potential: Application of evidence-based interventions is expected to have a large impact on reducing the incidence and severity of work-related motor vehicle crashes. This will yield substantial public health benefits, and will positively affect workers’ compensation and health insurance premiums and costs. CDC/NIOSH has well-established working relationships with employers, their trade associations, and standards-setting organizations, and is therefore strongly positioned to communicate findings and guidance to potential users. CDC/NIOSH also has strong infrastructure to facilitate the transfer of technology-based interventions to the marketplace. Given the extremely short induction period between exposure and injury occurrence, CDC can make a measurable difference in a very short period of time (< 4 years).

Visit the NIOSH homepage for more information on NIOSH’s research program areas <http://www.cdc.gov/niosh/homepage.html>.

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FOOD AND DRUG ADMINISTRATION (FDA)

FDA will accept SBIR grant applications on September 5, 2019; January 6, 2020; and April 6, 2020 submission dates.

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get accurate, science-based information they need to use medicines and foods to improve their health.

For additional information about areas of interest to the FDA, please visit our home page at

<http://www.fda.gov>.

Limited Amount of Award

FDA will not fund:

- Phase I applications greater than \$168,087
- Phase II applications greater than \$1,120,586

Research Topics of Interest to FDA

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?	X	

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s		X	
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

FDA will not accept SBIR applications that propose clinical trials, and all of the topics listed below must be for projects that do not propose clinical trials.

FDA Non-Clinical Trials Topics:

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

CBER is responsible for ensuring the safety, efficacy, potency and purity of biological and related products intended for use in the treatment, prevention or cure of diseases in humans as well as the safety of the nation's supply of blood and blood products. The primary responsibility of CBER is to review the quality, safety and efficacy of vaccines, blood products, certain diagnostic products and other biological and biotechnology-derived human products.

CBER's activities include: evaluating the quality, safety and effectiveness of biological products before marketing, and monitoring the pre-clinical and clinical testing of new biological products; licensing biological products and manufacturing establishments, including plasmapheresis centers, blood banks, vaccine and biotechnology manufacturers; AIDS program and policy activities, including research on AIDS therapeutic products, diagnostic tests and vaccines; research to establish product standards, develop improved testing methods and assess the safety of biological products; compliance, lot release program and post market surveillance; meeting PDUFA goals, new research programs, and new regulatory initiatives (managed review process for all products).

CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

CDER develops FDA policy with regard to the safety, effectiveness, and labeling of all drugs for human use; evaluates new drug applications and investigational new drug applications; develops standards for

the safety and effectiveness of all over-the-counter drugs; monitors the quality of marketed drugs through product testing (bioavailability/bioequivalence testing), post marketing surveillance, and compliance programs; develops guidelines on good manufacturing practices; conducts research and develops scientific standards on composition, quality, safety, and efficacy of human drugs.

Drug regulatory research as conducted in CDER is directed at the discovery of new knowledge relevant to drug development, post marketing drug experience (patterns of drug use and safety), and drug regulation to enhance FDA regulatory decisions. These drug regulatory decisions impact on the development of regulations, guidelines and guidance for the regulated industry and provide clarity and consistency in application of CDER regulatory requirements. These drug regulatory decisions also impact public health by ensuring that marketing drugs are safe and efficacious and that their risk: benefit profile remains acceptable during the market life of a drug. Specific areas of research conducted by the Center include: Pharmacology/toxicology, microbiology/virology, clinical pharmacology, pediatric issues in drug therapy, post marketing drug safety, evaluation of effectiveness of regulatory actions, patterns of drug use, including off-label, signal detection methodologies (e.g., data mining techniques), epidemiologic studies of therapeutics using population-based data, regulatory compliance, product quality, and active surveillance methods.

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

- A. Develop a system for gathering real-time data on physician prescribing behavior, understanding and compliance with drug product labeling and frequency of off-label prescribing.
- B. Develop and evaluate the effectiveness of new methods and tools for managing the known risks of marketed drug products (e.g., communicating newly identified risks to health care practitioners and patients).
- C. Develop methods for timely active surveillance of newly approved drug products in large populations to identify both expected and unexpected outcomes.
- D. Develop methods for actively collecting information on all cases of classically drug-associated events (e.g., acute liver failure, blood dyscrasias, severe desquamating skin disorders) to augment the FDA's current passive surveillance system.
- E. Develop improved clinical markers and methods with potential for bed-side application for detection of the early onset of adverse drug events.
- F. Develop surrogate potency methods for biotech drug products to replace traditional animal testing.
- G. Development of psychochemical and in-vitro biological tests to evaluate pharmaceutical equivalence of complex drug substances and drug products.
- H. Research into approaches to handle informative missing patient data in clinical trials, including innovations in study designs and statistical methods of analysis.
- I. Statistical and computational methods and strategies for the design, analysis and interpretation of microarray, genomic and proteomic data.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

The FDA is responsible for the safety of the vast range of food Americans eat; about 80 percent of all food sold in the United States. This includes everything except for the meat, poultry, and processed egg products that are regulated by the USDA. Consequently, CFSAN seeks research designed to complement and accelerate efforts aimed at the detection, prevention, and control of contamination that may be responsible for illness or injury conveyed by foods, colors, and cosmetics. CFSAN conducts research, and develops regulations, guidance and standards related to the composition, quality, nutrition,

and safety of food, food additives, colors, and cosmetics. The Center evaluates FDA's surveillance and compliance programs relating to foods, colors, and cosmetics; reviews industry petitions, and develops regulations for food standards to permit the safe use of color and food additives.

CFSAN maintains an active research program that is focused on the following priorities; ensuring the safety of food, dietary supplements and cosmetics; improving nutrition; and promoting the security and integrity of the food supply. The Center's research activities are intended to; support the FDA's regulatory activities; reduce the incidence of foodborne illness by improving our ability to detect and quantify foodborne pathogens, toxins, and chemicals that could jeopardize the safety and security of the food supply; find new and improved ways to control these agents; and safely produce, process, and handle food and food products. FDA is committed to reducing the incidence of foodborne illness to the greatest extent feasible while at the same time protecting the nation's food supply. Mission-critical knowledge gaps are addressed through translation research focused on the risks associated with FDA regulated products throughout their life cycles, from production to consumption. Ideally extramural research is sought that complements the Center's intramural research efforts, and which will enhance the Agency's and the Nation's ability to reduce the incidence of foodborne illness and protect the integrity of the nation's food supply. FDA's mission-critical needs require that the research not simply end with the generation of new knowledge and technologies, but extend to the validation of new approaches by using realistic conditions that accurately reflect the diversity of the food industry and offer potential solutions that can be accepted by appropriate sectors of the food industry.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

CDRH develops FDA policy and solves problems related to public health and safety of medical devices and radiation-emitting electronic products. It evaluates applications for premarket approval of medical devices, approves product development protocols and exemption requests for investigational devices. It classifies devices into regulatory categories, develops safety effectiveness standards and good manufacturing practices regulations, operates post market surveillance and compliance programs, and provides technical, non-financial assistance to small manufacturers. The Center also conducts programs to reduce human exposure to hazardous ionizing and nonionizing radiation, through an electronic product radiation control program and other programs designed to control and limit radiation exposure. The Center develops and conducts research and testing programs in the areas of physical, life, and engineering sciences related to the human health effects of radiation and medical device technologies, provides expertise and analyses for health-risk assessments, and also develops new or improved measurement methods, techniques, instruments and analytical procedures for evaluating product performance and reliability.

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

- A. Examine the setup, documentation and optimization of our Sun Grid Engine (SGE). The architecture of this networking application is particularly suited to managing surge capacity in high performance computing. The modeling of many physiologic functions and bioinformatic analyses can take months or even years to run on a standard desktop computer. The SGE takes the overall problem and distributes it to a cloud of computers on a network so that no user knows, or cares, if a computation is performing in the background on their machine. As FDA rolls out laptops with multi-core CPUs and which are equipped with prodigious amounts memory this experiment in "cloud computing" could become a reality on the Whiteoak Campus. The scope of work would be to develop, document, and provide training systems for developers, network architects, and users on working methodologies for the integration of cloud computing with the existing FISMA compliant conventional networking.
- B. Develop a high-speed, low light spectral CMOS linear imaging system to measure complete spectra of multiple variables from living tissue. Complete spectra of fluorescence signals (including auto-

fluorescence and FRET) could be measured along a line at high speeds (10 kHz) with a rectangular CMOS grid (e.g. 10 x 1,000 pixels -> 10 sites 1000 wavelengths).

- C. Develop bioassays/biosensors to identify injurious levels of nerve stimulation utilizing bioluminescence and neurotransmitter detection technologies. Research capabilities needed include voltage clamp, current clamp and extracellular techniques in peripheral nerves and brain slices to explore stimulation protocols that release neuroactive substances released in injury and inflammation which are not normally evoked under normal physiological conditions.
- D. Design, build, and validate a phantom that is traceable to a national metrology institute (NMI) such as NIST (or any other NMI) to improve the accuracy and clinical utility of bone mineral density measurements made using dual energy X-ray absorptiometry (DXA). The calibration phantom should be constructed using biosurrogate materials with known/tabulated data for body tissue and tissue substitutes.

CENTER FOR VETERINARY MEDICINE (CVM)

CVM is a public health organization that enables the marketing of effective drugs, food additives, feed ingredients, and animal devices that are safe to animals, humans, and the environment. The Center, in partnership with Federal and state agencies and other customers, ensures animal health and the safety of food derived from animals. The Center makes timely, quality decisions and takes regulatory actions to ensure that these products provide for quality health care of animals, minimize the transmission of zoonotic diseases, and increase the efficiency of production of animal-derived food and fiber. Regulatory decisions are supported by research, the monitoring of product safety, and efficacy, and the continual improvement of processes.

Research and development opportunities within the Center for Veterinary Medicine that lend themselves to performance by small businesses include, but are not limited to, the following areas of interest:

- A. Development, for the specific purpose of obtaining approval or conditional approval, of products for the treatment, control or prevention of diseases or conditions occurring in minor species or small numbers of major species.
- B. Development and validation of high throughput/screening quantitative and qualitative analytical methods for analyzing drugs, additives, and contaminants in animal tissues and feeds.
- C. Development of methods to determine absorption, distribution, metabolism, and excretion of drugs, feed additives and contaminants (microbial and chemical) in food animals, including minor species.
- D. Development of new biomarkers and models for determining the safety and effectiveness of veterinary drugs and food additives in domestic animals, including minor species.
- E. Development of methods to determine the effects of drugs, food additives, and contaminants (microbial and chemical) on immunological and physiological functions of domestic animals, including minor species.

OFFICE OF CRITICAL PATH PROGRAMS

The Office of Critical Path Programs, in FDA's Office of the Chief Scientist, coordinates the cross-agency Critical Path Initiative (CPI), FDA's strategy for transforming the way medical products are developed, evaluated, and manufactured. CPI activities are under way throughout the Agency, from the product centers to the Office of the Commissioner. For details, see <http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm>. Collaboration is key to the CPI initiative because bringing safe, effective, and innovative therapies to the American public requires FDA to leverage the resources and expertise of all stakeholders, including other Federal

agencies, academia, healthcare professionals, patient and consumer groups, regulated industry, and health-related organizations. In 2008, CPI collaborations involved 84 government agencies, universities, industry leaders, and patient groups from 28 states and 5 countries on a raft of groundbreaking research projects.

Research and development opportunities within FDA that lend themselves to performance by grantees include, but are not limited to, the following:

- A. Studying the immunological correlates of TB immunity and developing tools to evaluate TB vaccine efficacy.
- B. Developing study models for testing combination-antimicrobials as a strategy to prevent the development of drug resistance.
- C. Developing new approaches to preclinical safety testing.
- D. Identifying biomarkers for safety and efficacy evaluation of medical products.

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT

The Office of Orphan Products Development was established to identify and facilitate the development of orphan products. Orphan products are drugs, biologics, medical devices and foods for medical purposes, which are indicated for a rare disease or condition (i.e., one affecting fewer than 200,000 people in the United States). These products may be useful in a rare disease/disorder but lack commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are those marketed products in which there is evidence suggesting usefulness in a rare disease/disorder but which are not labeled for that disease/disorder because substantial evidence of safety and effectiveness for that use is lacking.

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

- A. Development of products for the treatment of rare diseases or disorders including but not limited to neurological, metabolic, genetic, ophthalmologic, hematologic, and dermatological diseases or disorders for the specific purpose of obtaining marketing licensure.
- B. Development of products for use in diagnosis of rare diseases for which the diagnostic tool would be used in fewer than 200,000 persons annually in the United States.
- C. Development of vaccines for the prevention of rare diseases to be used in fewer than 200,000 persons annually in the United States.

For additional information on research topics and administrative and business information, contact:

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**APPENDIX A: NATIONAL INSTITUTES OF HEALTH SBA-APPROVED SBIR/STTR
TOPICS FOR AWARDS OVER STATUTORY BUDGET LIMITATIONS****National Institutes of Health SBA-Approved SBIR/STTR
Topics for Awards over Statutory Budget Limitations****5/1/2019**

NIH has received approval from SBA for the topics listed within for budgets greater than **\$252,131** for Phase I SBIR/STTR awards and greater than **\$1,680,879** for Phase II SBIR/STTR awards for 2019-2020. Applicants are **strongly encouraged** to contact NIH program officials prior to submitting any award budget in excess of these amounts. Applicants are also required to follow NIH Institute- and Center-specific budget guidance found in all SBIR and STTR funding opportunity announcements.

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NATIONAL CANCER INSTITUTE (NCI)

- A. Therapeutics (e.g. Small Molecules, Biologics, Radiomodulators, and Cell-based Therapies)
- B. *In Vitro* and *In Vivo* Diagnostics (e.g. Companion Diagnostics and Prognostic Technologies)
- C. Imaging Technologies (e.g. Agents, Devices, and Image-Guided Interventions)
- D. Devices for Cancer Therapy (e.g. Interventional Devices, Surgical, Radiation and Ablative Therapies)
- E. Agents for Cancer Prevention (e.g., Vaccines, but not “Technologies for Cancer Prevention”)
- F. Development of Low-Cost Technologies Low-Resource Settings and Cancer for Global Health
- G. Development of Digital Health Tools

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

- A. Innovative platforms for identification and prioritization of targets for therapeutic intervention with clear clinical impact.
- B. Technologies to determine alternative uses for existing therapeutic interventions.
- C. Tools and technologies to allow assaying of activities of compounds on currently “non-druggable” targets.
- D. Phenotypic assay development, including stem cell technology platforms for human “disease in a dish” applications and the evaluation of toxicity.
- E. Co-crystallization high-throughput screening techniques.
- F. Small molecule and biologics analytical characterization.
- G. Tools and technologies that increase the predictivity or efficiency of medicinal chemistry, biologic, or other intervention optimization.
- H. Accelerate bioengineering approaches to the development and clinical application of biomedical materials, devices, therapeutics, and/or diagnostics.
- I. Tools and technologies that increase the efficiency of human subjects research, including development of technologies that facilitate rapid diagnosis and/or clinical trial recruitment and subject tracking, IRB evaluation, and/or regulatory processes.
- J. Novel platforms, technologies and tools for: (1) enabling clinical and translational research, particularly those with mechanisms for inclusion of patient reported data and (2) integration of patient data collected from multiple devices and multiple/diverse clinical studies.
- K. Searchable access to information about researchers and their expertise, including but not limited to their publications, published data sets, methods, patents, clinical trials, partnerships, collaborators, and clinical specialty/expertise (if applicable).
- L. Tools for meaningful sharing of research data with low barrier for provision and user friendly access.
- M. Microphysiological Systems (MPS)/Tissue Chips.

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH (NCCIH)

- A. Development and validation of biomarkers which correlate with efficacy of complementary health approaches.
- B. Formulation, development, and clinical testing of complementary health approaches and natural products that would permit FDA approval of a natural product for a specific indication.
- C. Identification and validation of biological targets associated with complementary health approaches.
- D. Development of innovated technologies and methods to assess natural product-drug interactions in humans.
- E. Studies of the mechanistic effects of mind and body interventions that will allow for optimization of the efficacy and safety of the mind and body approach for commercialization.
- F. Non-traditional phenotypic assay development for complex natural product mixtures.
- G. Integrated *in silico* tools for exploiting natural product bioactivity.
- H. Development and clinical testing of innovative technologies and methods for mind and body approaches. Examples include the use of mobile health technologies such as smart phone apps, sensors, on-line delivery, phone-based delivery, etc.
- I. Design, development, evaluation and validation of devices or systems related to complementary health approaches.

NATIONAL EYE INSTITUTE (NEI)

General Research and Development Topics

- A. New or improved ophthalmic or surgical instruments for diagnosis and treatment of eye disorders.
- B. Drug delivery systems; gene therapy, cell-based therapy or regenerative medicine.

Retinal Diseases

- A. New therapeutic approaches for inflammatory and degenerative diseases and for inhibition of abnormal angiogenesis in the retina and choroid.

Corneal Diseases

- A. New therapeutic approaches, artificial corneas, and drug delivery methods for the treatment of corneal injury, infection, dry eye, ocular pain, and other ocular surface disorders.

Lens and Cataract

- A. New approaches in the management of cataracts.

Glaucoma and Optic Neuropathies

- A. New therapeutic agents for treatment of glaucoma.

Visual Impairment and Blindness

- A. New or improved devices, systems, or programs that meet the rehabilitative and everyday living needs of blind or visually-impaired persons.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

- A. Biomedical technologies (medical devices, instruments, pharmaceuticals, drugs, therapeutics, vaccines, diagnostics and biologics) for heart, lung, blood, and sleep related diseases and disorders requiring Federal regulatory approval (FDA) or clearance to be commercialized.
- B. Small and large animal testing of products of tissue engineering and regenerative medicine, drugs, medical devices, therapeutics, and biologics and studies involving *in vivo* animal experiments for heart, lung, blood, and sleep related diseases and disorders.
- C. Clinical trials and other experiments involving human subjects for heart, lung, blood, and sleep related diseases and disorders.
- D. Therapeutics (drugs, devices, or biologics) development for heart, lung, blood, and sleep related diseases and disorders.
- E. Device development for heart, lung, blood, and sleep related diseases and disorders
- F. Diagnostics development for heart, lung, blood, and sleep related diseases and disorders.
- G. Investigation of biomarkers and biosignatures of heart, lung, blood, and sleep related diseases and disorders.
- H. Technologies to enhance clinical research for heart, lung, blood, and sleep related diseases and disorders.
- I. Advanced instrumentation and high throughput tools for biomedical research in heart, lung, blood, and sleep related diseases and disorders.
- J. Tools and platforms to improve the dissemination and implementation of evidence-based interventions for heart, lung, blood, and sleep related diseases and disorders.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

- A. Development of novel or significant improvements for nucleic acid sequencing technology.
- B. Development of novel or significant improvements for functional genomics technology.
- C. Genomics tools ranging from new instruments to sophisticated molecular biology kits.
- D. Bioinformatics software for genomic, genetic and sequence data analysis, functional genomics, associations between genomic data and diseases or phenotypes, interpretation of variants, and genomic data integration.
- E. Databases and data management for genomics research and application including sequences, functional data, annotation of variants, and phenotypes.
- F. Incorporating genomic results into electronic medical records.
- G. Informatics tools that assist in delivering genomic medicine to patients.
- H. Development and application of methods for machine learning, pattern detection, and knowledge networks for genomics and translation to genomic medicine.
- I. Informatics methods and platforms to enhance privacy, data standards, and data exchange in genomics and translation to genomic medicine.
- J. Use of cloud and other computing models to improve scale, reproducibility, interoperability, cost-effectiveness, and utility of genomic and clinical data in genomics and translation to genomic medicine.
- K. Single cell genomic analysis.

NATIONAL INSTITUTE ON AGING (NIA)

NIH has received approval from SBA for the topics listed within (but not limited to), for budgets greater than \$300,000 for Phase I SBIR/STTR awards and greater than \$2,000,000 for Phase II SBIR/STTR awards for 2019-2020. Applicants are strongly encouraged to contact NIH program officials prior to submitting any award budget in excess of these amounts. Applicants are also required to follow NIH Institute- and Center-specific budget guidance found in all SBIR and STTR funding opportunity announcements.

Division of Neuroscience (DN)

The Division of Neuroscience (DN) fosters and supports extramural research and training to further the understanding of the dementias of old age, as well as neural and behavioral processes associated with the normally aging brain. An area of special emphasis is brain-behavior relationships. An important component of this Division is the support of basic, clinical, and epidemiological studies of AD and related dementias of aging.

- A. Development of new and/or validation of existing sensitive, specific, and standardized tests for diagnostic screening and the development of biomarkers.
- B. Target discovery and validation through the application of systems biology and systems pharmacology approaches of MCI, AD, ADRD, or other dysfunctions of the central nervous system.
- C. Preclinical and/or clinical discovery, development, and/or evaluation of drug, nutritional, behavioral, cognitive, sensory, environmental, or other types of interventions to remediate age-related cognitive decline and/or other dysfunctions of the central nervous system.
- D. Development of new technologies for in-home use or for coordination or delivery of services to sustain in-home living for individuals with MCI, AD, ADRD, or that may prolong functional independence when there are dysfunctions of the central nervous system.
- E. Development of biosensors and prosthetic devices, technologies, and related software development to aid in the assessment, diagnosis, and remediation of age-related cognitive decline and/or other dysfunctions of the central nervous system.
- F. Development of technology and analysis tools to examine genetic, epigenetic, transcriptomic, proteomic, metabolomic, and cell stress pathways in neurons and glia of the aging and AD/ADRD brain.
- G. Improvement of technology to analyze structural and functional brain connectivity at the cell, neural circuitry, and global-network levels to define the normal trajectory of brain structure and function over the adult lifespan.
- H. Development of technology, including non-invasive methods and novel probes, to monitor and manipulate the plasticity of neural circuits in the adult and aged nervous system.
- I. Development of novel markers of neural stem cell function and novel approaches for analysis of next-generation sequence data.

Division of Aging Biology (DAB)

The Division of Aging Biology promotes and supports research and training on the molecular, cellular, genetic, and physiological mechanisms underlying normal aging and age-related pathologies. The

objective of DAB-funded research is to elucidate the basic biochemical, genetic, and physiological mechanisms underlying the process of aging and age-related changes in humans and in animal models of human aging. This includes investigations of the gradual or programmed alterations of structure and function that characterize normal aging and investigations of how these adverse changes become risk factors for, or accompany, age-related conditions and disease states.

- A. Development of interventions to 1) reduce oxidative or other stresses and aging-related diseases; 2) improve the immune response to foreign molecules or reduce the response to self or suppress age-induced inflammation; 3) enhance longevity or slow aging and may affect other age-related conditions or diseases; 4) reduce the level of damage to nucleic acids, proteins and lipids and the macromolecular complexes formed from these molecules, and improve the damage surveillance and repair potential of cells.
- B. Development of minimally-perturbing techniques for collecting blood old non-human animals and the development of non-invasive research and test methods for use in non-human animals.
- C. Development of novel strategies for treating age-related renal, pulmonary, urology, reproductive disorders, and age-related changes in hormone production and function.
- D. Development of novel methodology for treating osteoarthritis, including devices, processes and pharmacological agents with the potential to: (1) slow the rate of joint deterioration, (2) promote the remodeling of damaged joints, (3) reduce the likelihood of progression to osteoarthritis, and/or (4) improve outcomes for patients with active osteoarthritis.
- E. Development of tools and resources in genetics and genomics to study molecular mechanisms of normal aging or aging-related diseases.
- F. Development of novel methodology for treating chronic wound healing, including devices, processes and pharmacological agents with the potential to: (1) improve the rate and or quality of wound healing, and/or (2) improve outcomes for patients with chronic wounds.
- G. Development of biomarkers for prognosis, diagnosis, or treatment monitoring of aging or aging-related diseases; and analysis or integration of large data sets for developing biomarkers or biomarker signatures of aging or age-related diseases.

Division of Behavioral and Social Science (DBSR)

- A. Behavioral-economics approaches (incentives or disincentives) to motivate sustainable behavior change to improve health and well-being.
- B. Social, behavioral, environmental and or/technical interventions (including robotics) on the individual, institutional, family, or community level to promote older adult independence, increase well-being and prevent disease and/or disability (across home, work and institutional settings), including age-related cognitive impairment.
- C. Evidence-based methods, technologies, and interventions to reduce the burden of caregiving for persons with Alzheimer's disease and AD-related dementia, including training materials/resources appropriate for use by informal caregivers, or professional caregivers within health-care systems or community-based organizations.
- D. New sampling and data-collection methodologies for use in large population-based household surveys and behavioral interventions of relevance to aging, including blood-spot technology for

biological data collection, genetics and Genome Wide Association approaches and survey and archiving/database-support technology and resources for integrating big data and utilizing artificial intelligence and machine learning for assessing/diagnosing aging-related illnesses.

- E. Risk-reduction programs for improving the health of older workers, lowering the rate of health-care utilization, and improving the cost effectiveness of employer-based insurance plans.

Division of Geriatrics and Clinical Gerontology (DGCG)

- A. Development and validation of human aging mechanistic markers predictive for various age-related conditions or responses to interventions. Products of interest include the development and validation of commercial assays which could be used in clinical/epidemiologic research to assess mechanisms of aging (e.g., cell senescence, autophagy, DNA damage and repair) in human blood, tissues or cells and markers of age-related chronic inflammation. This may involve refinement of existing assays (e.g., conversion of lab assay to high-throughput screening) and/or de novo assay development for use in clinical research. Novel molecular imaging techniques (in vitro and in vivo) to study aging mechanisms in humans are also encouraged.
- B. Potential new therapeutics and/or interventions targeting fundamental mechanisms of aging and that influence the risk or progression of multiple age-related conditions. This may include identification of new therapeutic targets or repurposing of existing FDA-approved medications.
- C. Development of high throughput drug screening platforms to identify small molecules for enhancing the functions of protective genetic/metabolic factors associated with exceptional longevity or health span in humans.
- D. Development of clinical decision-support tools able to broadly integrate into the electronic health record to help physicians/providers caring for patients with multiple (3 or more) chronic conditions prioritize, coordinate, and deliver the interventions that are most beneficial and relevant within the context of these patients' lives and the health-care-delivery system.
- E. Development of assistive technologies/robotics to enable and support older persons to live independently and safely at home; socially-assistive robots; robots for caregiver and mobility assistance; robots for exercise and rehabilitation assistance.
- F. Development of technologies/robotics/sensors to assist in the improvement of physical function and mobility in older persons prior to (pre-habilitation) or following (rehabilitation) elective/planned surgery.
- G. Development and validation of improved approaches for evaluation, monitoring or treatment of diastolic dysfunction in older adults.
- H. Development of improved instrumentation/ imaging and sensor technology for measuring ambulation and biomechanics of movement including balance, sway, gait, and postural control to identify stable and unstable patterns of movement during activities of daily living.
- I. Development of methods and technology to accurately determine the renal glomerular filtration rate (GFR) in older persons and patients with chronic kidney disease; new methods and technology should accommodate the effects of age-related changes in muscle mass, levels of serum creatinine, renal blood flow and renal concentrating ability.

- J. Development and validation of non-invasive methods of examining bone quality (density, architecture, and strength of bone).
- K. Development and validation of instruments and/or methods to evaluate fatigability—the level of fatigue related to the intensity, duration, and/or frequency of activity (in contrast to measures of fatigue), particularly in adults with or at-risk of developing age-related conditions or diseases leading to physical disability.
- L. Development and validation of innovative approaches to pain control that considers age-related physiologic changes such as gastrointestinal absorption, cutaneous integrity, and musculoskeletal structure and function.
- M. Development and validation of new technology such as non-invasive methods to examine blood-flow velocity in arteries, individual coronary arteries, renal arteries, and cerebral arteries.
- N. Development of clinical decision support tools that help physicians caring for patients with multiple chronic conditions to prioritize the interventions that are most beneficial and relevant within the context of these patients' lives; or tools for patient self-management of multiple chronic conditions. Development of patient-focused tools for prioritizing and making decisions about the most significant health concerns to help select and order their self-management behaviors related to 3 or more chronic conditions.
- O. Development of new therapeutic interventions to promote wound healing, including improved post-surgical treatments/technologies promoting wound healing, prevention of chronic wounds, or reduced scar formation.
- P. Development of vaccines and other agents for preventing and treating infections in older persons, including development of new vaccines or preventive interventions, and new methods using currently available vaccines or preventive medications. Improve vaccine response/immune function, and for physical functional problems in old age.
- Q. Development of devices and/or techniques for preventing or treating urinary incontinence.
- R. Development and effectiveness testing of innovative, practical, cost-effective technologies, data collection and extraction systems and devices that could enhance the participation in clinical trials of older vulnerable people who are typically under-represented in clinical trials.
- S. Development of new diagnostic tests to predict adverse and/or costly, or favorable, health outcomes with aging or in the setting of chronic diseases, injuries, surgery, hospitalization, or other health-related conditions.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

- A. Treatment of alcoholism.
 - Pharmacological discovery, strategies, and development
 - Innovative therapeutic approaches
 - Prevention strategies
 - Therapies for co-morbid conditions, including organ damage
- B. Technology development to support screening, brief intervention, and referral to treatment for alcohol-involved patients in medical settings.
- C. Development of novel technologies or methods.
 - To detect the effects of alcohol on CNS structure and activities
 - To prevent harmful drinking during pregnancy, to identify prenatal alcohol exposure, and to enhance outcomes of individuals with Fetal Alcohol Spectrum Disorder
 - Tools for alcohol-related laboratory studies, such as animal strains, cell lines, stem cells, in vitro techniques, neuroimaging, ligands, in vivo detection of neuromodulators, or computational tools
 - Stem cell generation, dissemination, and model development
 - Voice technology, cell phones, and other
- D. Development of Biomolecular Signatures of Alcohol Exposure and Alcohol-induced Tissue Injury.
- E. Development, Optimization, and Validation of Novel Tools and Technologies for Neuroscience Research.
- F. Design, Development, and Improvement of Alcohol Biosensors.
- G. Investigational New Drug (IND)-enabling Development of Medications or Devices to Treat Alcohol Use Disorder and Alcohol-related Disorders.
- H. Genotyping of DNA samples from subjects with addiction and substance use disorders.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

Division of AIDS (DAIDS)

- A. Development of anti-HIV agents directed at new viral or cellular targets, including development and *in vivo* evaluation of sustained release formulations for treatment and prevention of HIV infection.
- B. Development and evaluation of therapeutic vaccines and other immune-based therapies to attenuate HIV disease progression or reduce HIV infectiousness.
- C. Development of therapeutic strategies for curing HIV infection or effecting a sustained remission in the absence of daily antiretroviral drug therapy.
- D. Development of methods for detecting and quantifying persistent reservoirs of replication competent latent HIV in blood and tissues, including bio-imaging.
- E. Development and evaluation of practical and affordable tests (e.g., viral load, drug toxicities, drug resistance) to monitor populations infected with HIV and associated infectious agents. Development of tests to detect early infection or viral rebound in HIV-infected individuals and to determine HIV incidence (HIV infection before seroconversion).
- F. Development of long-acting (minimum 30 days) sustained/extended release pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and multipurpose prevention technologies (MPT) products that can provide systemic protection from HIV infection.
- G. Development of rapid tests for the detection of antiretroviral drugs in various human matrices (e.g., blood, urine, hair).
- H. Development of processes suitable for HIV-1 vaccine product design, development and cGMP manufacturing, formulation, analytics and characterization of (a) HIV Env immunogens and related constructs/products; (b) fabrication, and development of nanoparticle-based delivery modalities, such as self-assembling proteins, surface conjugated/adsorbed nanoparticles, synthetic, lipid and polymer-based nanoparticles; (c) antigen-adjuvant formulations and/or combination-adjuvant(s) and dosage forms (e.g., suspension, lyophilized and aerosolized) for co-delivery/co-administration, (d) production of monoclonal antibodies (neutralizing and/or non-neutralizing); (e) delivery of antibodies as vectored or by nucleic acid technologies, (f) VLPs and viral vectors, and (g) DNA and RNA vaccine platforms.
- I. Improving cell line development process (transient, stable pools, stable clones, etc.) by using existing and novel cell lines, cultures, and supporting/customized technologies to expedite and increase Env expression, production, quality, and yield, novel chromatography purification platforms for viral vectors and Env proteins for HIV vaccine manufacturing.
- J. Development of formulation and dosage form technologies to prevent or treat HIV and HIV-associated co-infections.

Division of Allergy, Immunology, and Transplantation (DAIT)

- A. **Allergy, Asthma and Airway Biology Branch** will consider preclinical and clinical research for conditions of interest: asthma, food allergy, eosinophilic esophagitis and gastroenteritis in relation to food allergy, atopic dermatitis, urticaria, rhinitis, rhinosinusitis, drug allergy, and sepsis. This includes but is not limited to the development of methodologies to manage, and analyze clinical and epidemiologic research in the above conditions and the development of biomarkers as diagnostic markers, markers of disease severity, predictive markers for treatment effectiveness, particularly of immunologic interventions such as allergen immunotherapy for food and respiratory allergy; novel

approaches for detecting infants at risk for developing asthma and other allergic diseases; immune targets for asthma and allergic disease interventions; development of immunotherapies to prevent or treat allergic diseases.

- B. **Basic Immunology Branch** will consider preclinical and clinical research to study the origin, maturation, and interactions of immune cells, immune cell receptors, ligands, cytokine biology, molecular basis of activation, antigen recognition, immune tolerance, immune response regulation, hematopoiesis and stem cell biology, enhancement of vaccine effectiveness in neonates and adults, and basic immunology of vaccines and immunotherapeutics as medical countermeasures for biodefense. This research includes but is not limited to development of novel vaccine adjuvants; single cell assays to isolate and study antigen-specific lymphocytes; immunotherapeutic antibodies; biomarkers of host immune defense; single cell and other sample-sparing assays for study of human immunology.
- C. **Autoimmunity and Mucosal Immunology Branch** will consider preclinical and clinical research to develop and improve therapies for the treatment of autoimmune diseases and primary immune deficiencies (not HIV), basic research of autoimmune disease mechanisms, and biomarkers, immunotherapy of disease processes, disorders mediated by lymphocyte products, and mucosal immunity. This includes but is not limited to innovative treatments for autoimmune diseases; standardized validated diagnostic criteria and outcome measures for autoimmune diseases correlated with disease activity; high throughput assay of T-cell activity in autoimmune diseases; biomarkers to measure risk, disease activity, and therapeutic response in autoimmune diseases; innovative treatments for autoimmune diseases; mucosal immunity.
- D. **Transplantation Branch** will consider preclinical and clinical research in organ, vascularized composite tissue and cellular transplantation: acute and chronic graft rejection, allogeneic and xenogeneic transplantation, development of immunomodulatory agents to prevent and treat graft rejection and to promote acute and long term graft acceptance and immunologic tolerance, genomics of the alloimmune response, graft versus host disease for hematopoietic stem cell transplantation, minor histocompatibility antigens, complications of immunosuppression in transplantation, and major histocompatibility complex (MHC) region genomics and technologies for MHC typing. This includes but is not limited to methods and analysis tools to facilitate high throughput, high-resolution MHC typing in humans and non-human primates.
- E. **Radiation Countermeasures Program** will consider preclinical research on the identification and evaluation of medical countermeasures (MCMs) for public health emergencies involving ionizing radiation, through: 1) development of mitigators and therapeutics for acute radiation syndrome, delayed effects of acute radiation exposure, and/or radiation combined injury; 2) advancement of radionuclide-specific therapies, including chelating, blocking, or other novel decorporation agents; 3) improved methods of accurate, high-throughput radiation biodosimetry; 4) identification of biomarkers of organ-specific radiation injury; and 5) assessment of biomarkers of radiation injury in special populations and formulation of MCMs for administration to these affected groups.

Division of Microbiology and Infectious Diseases (DMID)

- A. Identify and qualify infectious disease-related biomarkers, including:
1. Biomarkers to predict susceptibility to infection and/or diagnose an infectious disease.
 2. Biomarkers to predict or monitor a subject's response to therapeutics or vaccinations.
 3. Biomarkers from natural history studies that could be used to assess disease progression in acute and chronic diseases.
- B. Development of rapid, highly sensitive and specific clinical diagnostics, including point-of-care diagnostics, that are easy to use, cost-effective and can diagnose individuals infected with pathogens or individuals that have been exposed to toxins.

- C. Discovery and development of vaccines or other immunoprophylaxis tools for infectious diseases.
- D. Development of vaccine enhancement and formulation technologies with the goal of providing protection against infectious disease agents, providing accelerated immune responses (more rapid schedules or reduced number of immunizations), increasing ease of administration (i.e., self-administration), increasing product stability to minimize cold chain requirements, and enhancing cost-effectiveness of vaccine manufacturing.
- E. Discovery and development of therapeutics for infectious diseases.
- F. Development of technologies or approaches that address arthropod vector monitoring, management, and control to prevent transmission of vector-borne pathogens to humans.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

- A. Research and development of new therapies using small molecules or biologics for arthritis, musculoskeletal and skin diseases.
- B. Research and development of novel biomedical devices or tissue engineered products for arthritis, musculoskeletal and skin diseases.
- C. Research and development of new biomarkers or novel imaging technologies for arthritis, musculoskeletal and skin diseases.
- D. Research and development of innovative internet-based technologies to manage arthritis, musculoskeletal and skin diseases.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

- A. **Connected Health-Mobile Health and Telehealth.** Development of enabling technologies that emphasize the integration of wireless technologies with human and biological interfaces. This program includes the development of software and hardware for telehealth and mobile health studies. This program includes the input and delivery of healthcare information digitally for the analysis or monitoring of health or disease status. The emphasis is on developing mobile health technologies driven by clinical needs and integrating these technologies in healthcare delivery, wellness, and daily living.
- B. **Engineered Cells.** Development of engineered cells to elicit a broadly applied biomedically relevant effect across a spectrum of diagnostic, therapeutic, imaging, and interventional applications. Emphasis is on engineering functionality and issues surrounding biocompatibility of engineered cells. Functionality could be derived from controlling natural or artificial attributes of an engineered cell and based on biochemical, optical, and/or mechanical properties, for example.
- C. **Engineered Tissues.** Development of technologies to enable the *in vivo* and *in vitro* engineering of human tissue constructs for biomedical applications. Emphasis is on the design and construction of tools for analyzing and controlling the function of engineered human tissues. Outcomes include but are not limited to: real-time, non-invasive monitoring of tissue function and cell-environment interactions; control of spatiotemporal tissue growth through cell viability, guiding, differentiation, and migration; design, 3D printing, and assembly of human tissues for and biomedical applications; preservation of biological specimens, from protein solutions and cell suspensions to tissues and organs, for a variety of biomedical applications, including transplantation.
- D. **Image-Guided Interventions.** Development of novel image-directed technologies for guidance, navigation, tissue differentiation, and disease identification for reaching specified targets during therapeutic procedures, which may range along the continuum from non-invasive to minimally invasive to open surgical interventions. These technologies may range from molecular to macroscopic scale levels. In addition, emphasis includes technologies that expand needed procedural access for individuals otherwise excluded by disease characteristics, co-morbidities, and other parameters.
- E. **Magnetic Resonance Imaging.** Development of *in vivo* MR imaging and MR spectroscopy, for both animal and human research and potential clinical applications. The emphasis is on the development of MRI hardware and methodologies, including image acquisition and reconstruction techniques, that would improve the speed, spatial resolution, information content, efficiency, robustness, quality, patient experience, and safety. The emphasis should be on technological development rather than detailed applications to specific diseases or organs.
- F. **Mathematical Modeling, Simulation and Analysis.** Development of novel mathematical modeling, simulation and analysis tools that can be broadly applied across a wide spectrum of diagnostic, therapeutic, imaging, and interventional applications. Emphasis is on engineering solutions for theory-driven, physics-based, physiologically realistic, virtual representations of biomedical systems, with a particular weight on multiscale modeling. Interests include, but are not limited to: multiscale modeling, predictive modeling frameworks, non-standard methodologies, and methods to address model credibility, reproducibility, and reuse.
- G. **Nuclear Medicine.** Research and development of technologies that create images out of the gamma-ray or positron emissions from radioactive agents that are injected, inhaled, or ingested into the body. The emphasis is on: simulation and development of new detectors, collimators, and

readout methods that enhance the signal quality of detecting isotope emissions; designs of novel camera geometries; and correction methods that compensate for the radiation physics properties to improve the clinical reliability of the image. Of interest are improvements and corrections for interaction events in PET detectors and enhancement to time of flight (TOF) image generation methods (reconstruction algorithms); as well as new collimator and camera designs for SPECT.

- H. **Optical Imaging and Spectroscopy.** Development and application of optical imaging, microscopy, and spectroscopy techniques for improving disease prevention, diagnosis, and treatment in the medical office, at the bedside, or in the operating room. Examples of research areas include fluorescence imaging, bioluminescence imaging, OCT, SHG, IR imaging, diffuse optical tomography, optical microscopy and spectroscopy, confocal microscopy, and multiphoton microscopy. The emphasis is on development of cost effective, portable, safe, and non-invasive or minimally invasive devices, systems, and technologies.
- I. **Technologies for Tissue Chips.** Development of technologies to enable the engineering of tissue chips/microphysiological systems for biomedical applications. Emphasis is on the design and construction of in vitro tools for analyzing and controlling the function of engineered human tissues. Examples include but are not limited to: microfluidics to control spatiotemporal tissue growth, 3D bioprinting systems for tissue assembly, high-throughput assays and instruments to reduce the cost, time, and complexity of tissue engineering, and bioreactors to produce tissues at scale.
- J. **Therapeutic Medical Devices.** Design and development of non-imaging devices intended for therapeutic interventions. Emphasis is on engineering non-imaging devices, components, and control systems for in vivo therapeutic interventions directed toward overcoming a technological challenge that limits biomedical application. Devices may be, but are not limited to: rehabilitative or curative; assistive; or preventative.
- K. **Ultrasound: Diagnostic and Interventional.** Improvement of technologies for diagnostic or therapeutic uses of ultrasound. The diagnostic ultrasound program includes, but is not limited to the design, development and construction of transducers, transducer arrays, and transducer materials, innovative image acquisition and display methods, innovative signal processing methods and devices, and optoacoustic and thermoacoustic technology. It also includes the development of image-enhancement devices and methods, such as contrast agents, image and data presentation and mapping methods, such as functional imaging and image fusion. The therapeutic ultrasound program includes, but is not limited to the design, development, and construction of transducers, transducer arrays, interventional technologies, adjunct enhancement of non-ultrasound therapy applications, high-intensity focused ultrasound (HIFU), or hyperthermia applications. It also includes non-invasive or minimally invasive interventional surgical or therapy tools, ultrasound contrast agents for therapy, targeted drug delivery, neuromodulation, and biopsy.
- L. **X-ray, Electron, and Ion Beam.** Simulation, design and development of new detector systems; new readout methods that enhance the signal quality for x-ray image generation; designs of novel imaging geometries; algorithms that compensate for the physical properties of the detection system to improve the clinical reliability of the image (reconstruction algorithms); and approaches to radiation dose reduction, especially in CT. Of interest are diagnostic image enhancements via photon counting, dual energy, and new applications of cone-beam tomography.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

Child Development and Behavior Branch

- A. Real time Human Interactive Data Acquisition and Analysis Technologies: Development and research testing of new or adaptation of existing devices and innovative technologies to improve the collection, analysis, and automated coding of audio and video recordings in real world settings (e.g., homes, childcare centers, schools, and primary care offices) over prolonged periods of time (i.e., days, weeks, or longer) to allow for (1) rapid analysis of interactions, including those involving one or more languages, and (2) simultaneous analysis of nonverbal and verbal behaviors during interactions. Incorporation of data from sensors capable of simultaneously recording real time physiological signals (e.g., pulse, heart rate, skin conductance response, temperature, accelerometer, etc.) time-locked to audio and video data and analyses is also highly desired.

Contraception Research Branch

- A. Development of innovative contraceptive approaches for both males and females.

Developmental Biology and Structural Variation Branch

- A. Innovative technologies for imaging developmental processes and gene expression; technologies for gene manipulations and perturbations; and *in vivo* tools for quantitative measurement of physical properties of cells and tissues contributing to embryonic morphogenesis.

Fertility and Infertility Branch

- A. Development of novel techniques for assessment of gamete quality.

Gynecologic Health and Disease Branch

- A. Development of innovative technologies for the treatment of endometriosis, uterine fibroids, or pelvic floor dysfunction, the latter including pelvic organ prolapse, urinary incontinence or fecal incontinence.

Intellectual and Developmental Disabilities Branch

- A. Technology development to improve screening, diagnosis and treatment of intellectual and developmental disabilities.

Maternal and Pediatric Infectious Disease Branch

- A. New technologies relevant to resource-limited countries for screening, diagnosis, and management of HIV and other infectious diseases, including tuberculosis, viral hepatitis, other congenital infections such as cytomegalovirus, respiratory infections, etc., in infants, children and pregnant/breastfeeding women.
- B. Development and evaluation of vaccines relevant to HIV and other infectious diseases for infants, children, and pregnant/breastfeeding women.

Obstetric and Pediatric Pharmacology and Therapeutics Branch

- A. Development of devices to help diagnose or treat pediatric and pregnancy associated disorders.

Pediatric Growth and Nutrition Branch

- A. Isolation, purification and synthesis of human milk oligosaccharides and peptides with biological activity.
- B. Develop rapid and reliable methods to determine components (both nutritive and non-nutritive) in human milk.

Pediatric Trauma and Critical Illness Branch

- A. The development of devices, innovative therapeutic technologies and behavioral interventions to improve pediatric patient outcomes and minimize the negative sequelae of trauma, injury or critical illness.

Population Dynamics Branch

- A. Developing tools and methods to accurately and reliably measure head circumference in infants and children
- B. Technological innovations or inventions to improve collection of biomarker and anthropometric data in large population-representative surveys
- C. Hardware or software to improve collection of accurate cause of death information in large population-representative surveys or in administrative data sets
- D. Innovative methods to add new reproductive and gynecologic questions and/or sampling frameworks to existing large cohorts and/or longitudinal studies

Pregnancy and Perinatology Branch

- A. Devices, instruments, and tools to minimize bacterial colonization, reduce proclivity for thrombus formation; reduce health-care associated infection risks.
- B. Methods to reduce pain in all of perinatal care (in newborn infants, in mothers in labor, during postpartum after spontaneous delivery and cesarean section
- C. Novel Methods to predict, assess, monitor or treat (when feasible) fetal health, fetal growth, preterm birth, preeclampsia.

National Center for Medical Rehabilitation Research

- A. Development of medical rehabilitation interventions and biomedical technologies to improve rehabilitation treatment for restoration of function.

**NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS
(NIDCD)**

- A. Research and development for biomedical technologies (medical devices, diagnostic instruments, pharmaceuticals, drugs, therapeutics, vaccines, and biologics) that require clearance by the FDA as a regulated product before commercial distribution.
- B. Development of novel open design hardware and software that facilitate rapid dissemination, reconfiguration, and enhancement to enable research beyond what can be performed with existing tools.
- C. Projects proposing clinical trials with a large number of participants.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

Infectious Diseases and Immunity

- A. Develop oral topical formulations with combined microbicidal, analgesic, and anti-inflammatory activities to enhance oral mucosal defenses and prevent and/or control oral infections and lesions in HIV-infected and/or immunosuppressed subjects.

Preclinical Research

- A. Preclinical research and development activities for dental and craniofacial technologies (including devices, diagnostic instruments, reconstructive materials, pharmaceuticals, therapeutics, vaccines and biologics) that require review and approval by the FDA as a regulated product before commercial distribution.

Clinical Research

- A. Develop improved methods to detect and predict progression of dental caries, periodontal disease, reversible and irreversible pulpitis.
- B. Develop new or improve methods or materials to enhance oral and craniofacial surgery. This would include both intraoral and extraoral surgery.
- C. Develop improved methods or materials to mechanically and/or biologically repair or treat tooth structure damaged by dental caries or periodontal disease.
- D. Develop safe and efficacious methods to diagnose caries, pulp vitality and / or periodontal diseases utilizing non-ionizing radiation.
- E. Develop technologies for local delivery of drugs to treat oral and craniofacial diseases or disorders.
- F. Develop novel non-opioid pharmacological medications for management of acute dental pain.

Oral, Oropharyngeal and Salivary Gland Cancers

- A. Develop imaging techniques for the early detection, diagnosis and prognosis of pre-malignant lesions.
- B. Develop genetic animal models of oral cancer premalignancy and oral cancer progression that mimic human oral cancers, including HPV associated oropharyngeal cancers.

Temporomandibular Disorder and Orofacial Pain

- A. Identify and develop novel pharmacologic or biologic agents, including but not limited to small molecules, peptides, recombinant proteins and nucleic acids to prevent, control, and/or treat orofacial pain.

Saliva, Salivary Diagnostics, and Salivary Gland Diseases

- A. Develop viral, non-viral and gene therapy-based approaches to address compromised salivary gland function. Develop cell and tissue-based strategies and technologies for restoration of damaged or destroyed salivary gland function.
- B. Develop novel compounds or materials that protect and preserve salivary glands from head and neck cancer irradiation therapy.

- C. Development of non-invasive methods for the determination of efficacy and safety of artificial saliva, sialogogues, and of their delivery vehicles used in addressing the diminution or lack of saliva (xerostomia) due to Sjögren's Syndrome or head and neck cancer irradiation therapy.
- D. Develop biomarker-based technologies for the identification of Sjögren's Syndrome using blood or saliva as body fluids.

Biotechnology, Biomaterials, and Applications for Regeneration and Restoration of Oral, Dental and Craniofacial Tissues

- A. Develop methods, materials, and devices for orthodontic, prosthetic, periodontic, endodontic and craniofacial applications including those that can be used for craniofacial bone distraction, reconstruction, hard and soft craniofacial tissue healing and regeneration, and scarless craniofacial tissue repair.
- B. Develop imaging diagnostics to accelerate clinical implementation of reliable, reproducible, highly specific and sensitive diagnostic instruments for various applications, including but not limited to dental caries, cracked teeth, pulp vitality, bone quality, and periodontal disease.

Clinical and Behavioral Research

- A. Develop and test for safety, efficacy, and/or effectiveness of measures or materials for diagnosing, preventing, or treating oral, dental, and craniofacial conditions and disorders.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

NIDDK supports the topics below as they pertain to *Diabetes* (Type 1 and Type 2 Diabetes, Metabolic Disorders, and Endocrine Disorders), *Digestive Diseases* (Gastrointestinal Diseases, Liver and Pancreatic Diseases, Obesity, Nutrition, and related diseases), and *Kidney Diseases* (Kidney Diseases, Urologic Diseases, and Hematologic Diseases).

- A. Development or evaluation of pharmacological agents (i.e., drugs, therapeutics), gene therapies, novel formulations, cell-based or other biological technologies for intervention in or prevention of *Diabetes and Digestive and Kidney Diseases*.
- B. Development or evaluation of biomedical devices, tools, techniques, or instrumentation for intervention in or prevention of *Diabetes and Digestive and Kidney Diseases*.
- C. Development of biomarkers, assays, techniques, diagnostic technologies or associated reagents for assessing state or function in normal, developing, or diseased cells or tissues affected by *Diabetes and Digestive and Kidney Diseases*.
- D. Development or evaluation of imaging, screening, or evaluation techniques or technologies for assessing state or function in normal, developing, or diseased cells or tissues affected by *Diabetes and Digestive and Kidney Diseases*.
- E. Development or evaluation of animal or cell models for studying *Diabetes and Digestive and Kidney Diseases*.
- F. Development or evaluation of novel materials or material treatments (e.g., sterilization, coating, etc.) for use in devices or other tools or methods used to prevent, diagnose, or treat *Diabetes and Digestive and Kidney Diseases*.
- G. Development of cell- or data-banks for the biomedical research community.
- H. Development or evaluation of technologies, including software applications, for improving patient adherence in *Diabetes and Digestive and Kidney Diseases*.
- I. Development or evaluation of technologies for improving clinical research in *Diabetes and Digestive and Kidney Diseases*, including technologies for improving data collection and reporting of patient outcomes.
- J. Development or evaluation of –omics, informatics, or internet-based technologies for biomedical research or clinical applications in diagnosing or managing *Diabetes and Digestive and Kidney Diseases*.
- K. Development or evaluation of technologies to prevent or avert cell or tissue injury during other disease states or surgical procedures.

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

NIDA will allow the increase in budget for the applications in two specific technical/scientific areas: (1) SUD Drug Discovery and Development; (2) SUD Medical Devices.

For projects pertaining to Area 1, applicants are expected to propose and conduct activities that will eventually lead to the successful filing of an Investigational New Drug (IND) application, as well as clinical studies to support the filing of a New Drug Application (NDA) and/or Biological License Application (BLA). For projects pertaining to Area 2, applicants are expected to propose activities that will lead to the successful application for FDA clearance/approval.

1. SUD Drug (Medication to treat SUD, and to prevent and reverse overdose) Discovery and Development

Projects proposed under Area 1 may include application of emerging and existing technologies and platforms for SUD medication development with the focus on products with the potential to minimize drug seeking, compulsive behavior, overdose prevention and reversal:

- A. Early therapeutic discovery activities ranging from Target ID and validation through lead development.
- B. Preclinical and/or clinical drug development.
- C. Technologies or formulations to improve medication delivery, longer-acting formulations of existing addiction medications.

2. SUD Medical Devices

Projects proposed under Area 2 may include the development of the following categories of biomedical products:

- A. Imaging technologies for investigating brain function and enhancing disease diagnosis and treatment of SUD;
- B. Devices and technologies that directly diagnose and/or reduce craving;
- C. Innovative methods and tools to identify and treat newborns exposed to opioids, along with other drugs, to improve both short- and long-term developmental outcomes; novel approaches to managing neonatal opioid withdrawal syndrome (NOWS), also referred to as neonatal abstinence syndrome (NAS);
- D. Diagnostic medical devices that identify patients at increased risk for addiction;
- E. Digital health technologies and mobile medical applications focused on behavioral health interventions to alleviate the burden of SUD through prevention and reduced risk;
- F. Therapeutic (e.g., neuromodulation) devices and other advanced methods to improve SUD treatment outcomes and relapse prevention;
- G. Medical devices used to diagnose and treat respiratory depression;
- H. Technologies for physiological monitoring, including remote detection (e.g., wearable sensors, health monitoring/emergency notification systems) — tailored to patients with SUD.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

NIEHS do not have budget waiver topics. Refer to the NIEHS “Limited Amount of Award” for specific budget guidelines.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

Division of Biophysics, Biomedical Technology, and Computational Biosciences

- A. Development of reagents and methods for detecting in real time, analyzing, and separating biologically important compounds, macromolecules, and their interactions.
- B. Development of new methods and materials directed toward the solution of biological macromolecule structures, including membrane proteins, assemblies and complexes by, but not limited to, x-ray diffraction, electron diffraction, cryo-EM, NMR and mass spectroscopy.
- C. Imaging probes and sensors, other reagents and methods, instrumentation, software for microscopy, spectroscopy, and single molecule analysis of molecules, cells, tissues, embryos and small model organisms. Technologies for applications of microscopy, spectroscopy and single molecule analysis in basic biomedical research, including but not limited to light, electron, X-ray, cryo-electron, and scanning probe microscopy and fluorescence, magnetic and electron paramagnetic spectroscopy. NOT included are small animal and preclinical imaging and high throughput platforms for diagnostic and clinical applications.
- D. Development of instrumentation and devices for detection, analysis, separation and/or manipulation of biologically important molecules, cellular components or cells.
- E. Development of instrumentation and devices for elucidating interactions of biologically important molecules *in vitro*, *in vivo*, within cells.
- F. Development of probes for detection of genetic polymorphisms, including disease genes.
- G. Development of valid animal models for genetic diseases and birth defects.
- H. Improvement of methodology (technology) for genetic analysis (e.g., gene expression, probes).
- I. Development of tools and technologies to detect and monitor complex phenotypes or traits.
- J. Development or improvement of methods for high throughput detection of epigenomic changes.
- K. Development of improved technology, reagents and tools to derive, grow, isolate, differentiate and characterize cells.
- L. Development or improvement of methods for characterizing and studying complex communities of microorganisms, including interactions with host organisms.
- M. Development of non-mammalian model systems.
- N. Development of tools and methods for the modeling, simulation, and/or analysis of complex biological systems.
- O. Development and/or enhancement of computational tools and methods to collect, store, interpret, analyze and/or visualize biomedical data.
- P. Development of software and hardware for improving the effectiveness of computational approaches in biomedical research.
- Q. Development of high-throughput and/or computational methods and strategies to define/characterize the function, inhibition, and/or interactions of biological macromolecules and cells.

Division of Pharmacology, Physiology, and Biological Chemistry

- A. Methods for isolation, characterization, and production of natural and bio-engineered products.
- B. Development of methodology to improve the efficiency of discovery, development, and production of bio-medically relevant compounds.

- C. Isolation, characterization, and development of factors and strategies, methods, or treatments involved in tissue repair, wound healing, sepsis, and traumatic injury, emergency, peri-operative, or critical care conditions, and associated pain management.
- D. Research to improve drug design and delivery.
- E. Development of technologies, including instrumentation, reagents, and methods for -omics, including but not limited to robotics, sample preparation and pre-fractionation, analytical separations, mass spectrometry, intelligent automated data acquisition, and improved informatics technologies.
- F. Development of technologies, including instrumentation, software, reagents, and methods for the study of carbohydrates, including but not limited to development of: specific glycan structural databases, methodologies for synthesis of robust glycan libraries, glycan labeling reagents and glyco-enzyme inhibitors, and analytical tools for determining carbohydrate structure and biological function.
- G. Development of tools to study oxidative stress and/or mitochondrial function.

Division of Training, Workforce Development, and Diversity

- A. Development of products or services to enhance diversity of the scientific workforce.

Division for Research Capacity Building

- A. Development of efficient, user-friendly, and culturally appropriate resources to enhance health science literacy

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

All Divisions:

- A. Preclinical drug/device development studies, including pharmacology, efficacy and toxicology.
- B. Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.
- C. Studies in normal healthy volunteers to determine a drug's safety profile, metabolism, etc.
- D. Clinical studies in patient/disease population to assess the drug's effectiveness.
- E. Assessment of devices with regard to performance standards related to the FDA approval process.
- F. Safety and effectiveness studies of novel medical devices.
- G. Evaluation of novel imaging approaches for diagnostic purposes.
- H. Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.
- I. Rapidly develop novel, engaging computer-based cognitive training programs that are based on efficacious neurotherapeutic approaches and which use cognitive training to target a specific neural system/functional domain.
- J. Augment existing computerized cognitive interventions to be personalized, engaging, adaptive, sufficiently challenging, and optimal for maximizing real world functional improvements.
- K. Test the feasibility, efficacy and potential adverse effects of these programs utilizing measures of functional outcomes in an identified clinical population, particularly those with neuropsychiatric disorders, ASD, and/or HAND, at a specified developmental stage, including measurement of the duration of treatment effects.
- L. Rapid development and evaluation of mobile based platforms and applications.

Division of Neuroscience and Basic Behavioral Science (DNBBS)

- A. Novel imaging probes to study brain structure and function at all levels, from the molecular to the whole organ, using any imaging modality (PET, fMRI, optical, etc.).
- B. Drug discovery/drug development of novel compounds which act on molecular pathways (receptors, enzymes, second messengers, etc.) that are not typically targeted with currently available psychiatric drugs, and that have a strong biological justification as a novel mechanism for treatment of psychiatric disorders.
- C. Novel screening assays for high throughput acquisition and analysis of data about behavior and the brain, from the level of genes to the level of behavior.
- D. Novel technologies that would enable researchers to study how populations of neural cells work together within and between brain regions, in order to understand how changes in neural activity contributes to mental disorders.
- E. Complex instrumentation for neuroscience research

- F. Complex brain or cellular imaging or analysis.
- G. Tools to facilitate the detailed analysis of complex circuits and provide insights into cellular interactions that underlie brain function.
- H. Proof-of-concept testing and development of new technologies and novel approaches for large scale recording and manipulation of neural activity, at or near cellular resolution, at multiple spatial and/or temporal scales, in any region and throughout the entire depth of the brain
- I. Iterative refinement of such tools and technologies with the end-user community with an end-goal of scaling manufacture towards reliable, broad, sustainable dissemination and incorporation into regular neuroscience practice.
- J. Novel informatics tools to facilitate the sharing of complex data sets between laboratories.
- K. Novel tools for investigating brain-derived GPCRs in mental health research.
- L. Educational tools/technologies for neuroscience and mental health.
- M. Technologies to support the goals of the BRAIN Initiative: <http://www.braininitiative.nih.gov/>

Division of Translational Research (DTR)

- A. Develop, test and validate reliable and stable biomarkers that can identify at-risk individuals prior to disease onset, improve diagnosis, predict treatment response, or measure disease progression. Biomarkers are also needed in clinical trials to identify dose ranges, to identify a specific subpopulation of subjects to enroll in a treatment trial, or to measure efficacy or toxicity/side effects.
- B. Develop novel and targeted interventions (pharmacological, cognitive, behavioral, computer, or device-based) that affect particular neural circuits and signaling pathways relevant to the developmental trajectory of the disease.
- C. Conduct early stage, proof of concept clinical trials to advance the development of novel therapeutics. The clinical trials are expected to include biological/behavioral data to assess target engagement and to help determine potential success or failure of the compound before moving on to larger clinical trials (see NOT-MH-11-015 <http://grants.nih.gov/grants/guide/notice-files/NOT-MH-11-015.html>).
- D. Based on expanded knowledge of neurobehavioral trajectories, develop novel objective assessment tools that can identify early signs of risk or onset of recurrence of particular mental disorders or in domains of functioning (see MH's RDoC project: <http://www.nimh.nih.gov/research-funding/rdoc/index.shtml>) for pediatric populations.
- E. Develop computational biological/behavioral assessment tools that can be used across ages, species, and cultures to evaluate dysfunction in domains relevant to mental disorders (e.g., mood dysregulation, deficits in executive function).
- F. Develop computational platforms to enable the integration and sharing of data characterizing typical and atypical developmental trajectories in humans and non-human animals.
- G. Clinical research tools.

- H. Develop valid measures of the various constructs in the Research Domain Criteria (RDoC) matrix (see <http://www.nimh.nih.gov/research-funding/rdoc/index.shtml>), e.g., neurocognitive tasks, psychometrically sophisticated questionnaires, measures of behavior, and biomarkers, into a commercial product.
- I. Develop clinical risk assessment instruments that encompass multiple domains (e.g., genetic, neurobiological, and environmental), are sensitive to developmental stage, and have high predictive power for the onset or recurrence of mental illness.
- J. Developing clinical risk assessment instruments for developing particular benefits or harms during treatment for mental disorders, and communicating such probabilistic information to patients and their families in a readily understandable manner.
- K. Develop electronic sensors, monitoring devices and systems, and data analysis software for automated detection and diagnosis of mental disorders and key transdiagnostic dimensions of psychopathology.

Division of AIDS Research (DAR)

- A. Develop and test novel, non-invasive diagnostic approaches (instrumentation, imaging, biomarkers, central nervous system [CNS] cell-based *in vitro* models) to detect neurocognitive dysfunction associated with HIV-1 infection and innovative technologies to study the mechanisms involved in HIV-1 associated neuropathogenesis and persistence of HIV-1 in the CNS or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy.
- B. Design and test novel therapeutic strategies aimed at amelioration of HIV-1 induced CNS dysfunction and/or eradication of HIV-1 from CNS reservoirs or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy.
- C. Discover and develop innovative technologies for targeting therapies to the brain, including antiretroviral drugs, nanotechnology, imaging tools to study HIV-aging interactions or HIV-related neurodegeneration and neuroprotective strategies with improved capability to cross the blood-brain barrier for amelioration of HAND.
- D. Develop evidence-based interventions to reduce risk for HIV among at-risk individuals or improve outcomes along the HIV care continuum for individuals living with HIV which are delivered through mobile devices or other technologies.
- E. Develop technologies, instruments and tools to aid in Improving uptake, adherence, and persistence to biomedical HIV prevention and treatment regimens; Increasing regular HIV testing among those most at risk of acquiring HIV and translating findings from basic behavioral and social science research into processes to improve engagement in HIV care
- F. Develop new tools/ techniques to aid in deciphering the complex neuro-immune interactions at a molecular and cellular level in the context of HIV
- G. Build and optimize informatics tools to aid in analyzing and characterizing the phenotype of CNS disease modalities associated with HIV by using machine learning, big data and systems biology-based approaches

Division of Services and Intervention Research (DSIR)

- A. Randomized clinical trials evaluating the effectiveness of known efficacious interventions.

- B. Analyses of naturalistic databases to evaluate the effectiveness of known efficacious interventions.
- C. Identifying moderators and mediators of intervention effects as a step to design and test personalized interventions.
- D. Evaluating the combined or sequential use of interventions.
- E. Determining the optimal length of intervention, establishing the utility of continuation or maintenance treatment (that is, for prevention of relapse or recurrence).
- F. Evaluating the long-term impact of efficacious interventions on symptoms, functioning, and quality of life.
- G. Developing novel information technology tools designed to improve the delivery and dissemination of evidence-based interventions and assist healthcare providers in identifying, adopting, and implementing proven prevention and treatment interventions.

Services research covers all mental health services research issues across the lifespan and disorders, including but not limited to:

- A. Services organization, delivery (process and receipt of care), and related health economics at the individual, clinical, program, community and systems levels in specialty mental health, general health, and other delivery settings (such as the workplace).
- B. Interventions to improve the quality and outcomes of care.
- C. Enhanced capacity for conducting services research.
- D. The clinical epidemiology of mental disorders across all clinical and service settings.
- E. The dissemination and implementation of evidence-based interventions into service settings.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

- A. Telehealth, telemedicine, and mobile health technologies (e.g., smart phone apps, web-enabled wearable sensors) to improve remote access to prompt diagnosis, early treatment, and clinical management for adult and pediatric patients in minority and health disparity populations, and to improve access to specialty care that would otherwise be inaccessible due to high cost or transportation barriers (e.g., by linking academic tertiary care-oriented health centers with community-based primary care settings).
- B. Products, technologies or services designed to improve accessibility or uptake of existing technologies (e.g., mobile phones, tablets, free WiFi, diabetic glucometers, blood pressure monitors, etc.) within disadvantaged communities and medically underserved areas (including urban, rural, remote, or island regions) to promote healthy lifestyles, enhance patient-clinician communication, provide patient education for self-management of chronic diseases/conditions, or enhance surveillance of communicable and non-communicable diseases in minority and health disparity populations.
- C. Products, technologies or services that take advantage of existing or emerging technologies (e.g., electronic health record systems, biomedical informatics platforms, big data resources and analytics, precision medicine) to improve health services delivery and quality of care, including but not limited to coordination of primary and specialty care, integration of behavioral health services into primary care settings, enhancement of provider-patient communication, and reduction of health literacy barriers in minority and health disparity populations.
- D. Products, technologies or services to enhance early detection of diseases, pre-disease states, or adverse health conditions in minority and health disparity populations through analysis of novel or validated biomarkers in saliva, breath, blood, and other tissues or specimens, including microbiota.
- E. Groundbreaking products or technologies to monitor real-time or cumulative exposures to physical, social and environmental risk factors acting at multiple levels across the life course (“exposome”) to improve understanding and situational awareness of factors that may significantly contribute to population health disparities, and/or to empower individuals or communities to take steps to avoid or mitigate the effects of such exposures.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

The NINDS accepts a broad range of small business applications that are significant, innovative, and relevant to its mission. Examples of research topics within the mission of NINDS are shown below. This list is not all inclusive and some research areas fall into multiple categories.

- A. Therapeutics and Diagnostics Development for Neurological Disorders, including biomarker and diagnostic assays, therapeutics (drugs, biologics, and/or devices) for treatment of neurological disorders, and technologies/methodologies to deliver therapeutics to the nervous system.
- B. Clinical and Rehabilitation Tools, including intraoperative technologies for neurosurgeons, rehabilitation devices and programs for neurological disorders, and brain monitoring systems
- C. Technology and Tools, including technologies to image the nervous system, neural interfaces technologies, and tools for neuroscience research and drug development.

Within these research topics, the following research may require additional funds above the hard budget caps:

- A. *In vivo* animal testing required for therapeutics and diagnostics development.
- B. Drug and biologics preclinical discovery and development activities for regulatory submission, such as lead identification/optimization, preclinical efficacy testing, IND-enabling studies, and manufacturing for clinical trials.
- C. Device preclinical discovery and development activities for regulatory submission, such as hardware prototyping, device/software verification, biocompatibility/sterilization testing, pre-clinical efficacy testing, large animal GLP safety testing, and preparing material/devices for human testing.
- D. Clinical testing of therapeutics (drugs, devices, or biologics), diagnostics, clinical and rehabilitation tools (i.e. intraoperative technologies, rehabilitation devices and programs, and brain monitoring systems), and technologies for clinical research. This would include clinical research studies to test scientific hypothesis that are not feasible or practical to conduct in animal models but would inform a final device design.
- E. *In vivo* animal testing of technologies for animal research and development of animal models for drug development and neuroscience research.
- F. Research that requires special facilities to contain hazardous or infectious materials.

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is a Presidential project aimed at revolutionizing our understanding of the human brain. NIH is one of several federal agencies involved in the BRAIN Initiative. Planning for the NIH component of the BRAIN Initiative is guided by the long-term scientific plan, "BRAIN 2025: A Scientific Vision," which details seven high-priority research areas. This report, as well as a list of the specific BRAIN Initiative funding opportunities, can be found at <http://braininitiative.nih.gov/>.

Based on priority areas identified by the BRAIN 2025, technology areas were identified to be appropriate for commercial development and may require additional funds above the hard budget caps:

- A. Development of research tools and technologies to understand the dynamic activity of neural circuits.
- B. Development of novel tools and technologies to facilitate the detailed analysis of complex circuits to provide insights into cellular interactions that underlie brain function.

- C. Development of invasive and non-invasive devices for recording and modulation in the human central nervous system.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

- A. Development of technologies or devices requiring extensive engineering. Some examples include mobility assistive devices, POC monitors, or monitors of gait or other physiological measures. This does not include projects utilizing only mHealth technology.
- B. Projects proposing large (hundreds of participants) clinical trials.
- C. Technologies to facilitate delivery of prevention interventions across the lifespan.
- D. Development of biological and behavioral monitoring devices for patients in at-risk populations, especially rural populations.
- E. Projects that develop and test tools to address symptoms in caregivers.
- F. Research on non-pharmacologic approaches to reduce the severity of pain and to help individuals manage pain, including behavioral and biopsychosocial-centered approaches, and those that seek to optimize non-pharmacologic intervention timing, dosage and sustainability for pain management.
- G. Innovative web-based information and communication technologies for addressing clinical care and advance care planning specific to hospice and palliative care symptoms, and for those in need of care to improve the effectiveness and efficiency of patient report data and integration into appropriate hospice/palliative health care systems.
- H. Use and integration of Health Information technology within/across “big data” systems, e.g., electronic health records for data collection, management and care integration. Of particular interest is technology that can be used across the spectrum of hospice and palliative care services/health systems.
- I. IT implementation across the spectrum of palliative and hospice settings that highlight the potential of informatics to improve the metrics and standards of palliative and hospice care.

NATIONAL LIBRARY OF MEDICINE (NLM)

- A. Development and applications to improve storage, retrieval, access, management, representation, and use of biomedical knowledge
- B. Development of tools and methods for visualization, modeling, simulation, or analysis of complex biological systems and clinical processes
- C. Innovative approaches for data security and privacy, and technical issues related to other ethical, legal, and social implications of personal health data
- D. Methods for data integration to support discovery, learning, and health care
- E. Informatics tools that assist in delivering precision medicine to patients, or health decisions

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI), OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS (ORIP)

RESEARCH AND DEVELOPMENT IN THE DIVISIONS OF COMPARATIVE MEDICINE AND OF CONSTRUCTION AND INSTRUMENTS

- A. Development of new technologies for rapid characterization and deep phenotyping of large numbers of animals.
- B. Development of technologies to identify biomarkers for clinical diagnostics in well validated disease models.
- C. Development of vaccines and new therapeutic agents to prevent and/or control selected laboratory animal diseases. One high priority need is to develop methods to control and prevent Herpes virus B in nonhuman primates.
- D. Design of specialized equipment and caging for laboratory animals to permit optimal environmental control and operational efficiency, including improvements in caging, identification/tagging of animals and remote monitoring in animal facilities.
- E. Identification, development, and characterization of spontaneous and engineered vertebrate animal models for studies of various human diseases, excluding most random mutagenesis projects performed on rodents.
- F. Development and refinement of high throughput technologies and devices for the effective cryopreservation, long-term maintenance of cells, tissues, and laboratory animal embryos, and gametes.
- G. Development of technologies and devices for the effective monitoring of frozen and cryopreserved cells, biological materials/tissues and laboratory animal embryos, and gametes.
- H. Development of improved reagents, machine learning technologies, devices and high throughput technology to perform, analyze, capture and process data gathered in “omics” studies (genomics, transcriptomics, phenomics, proteomics, glycomics, epigenomics, metabolomics, among others) in normal disease and intervention conditions in animal/biological models.
- I. Development of biological tools and reagents for reconstruction, remodeling, repair and regeneration of tissues damaged by injury or disease. Development of the technologies and procedures to test efficacy and safety of these experiments in animal models. Approaches to detect and track the implanted cells and tissues *in vivo*.
- J. Development of acellular biomaterials, biosensors and reagents to promote, detect and track reconstruction, remodeling, repair and regeneration of tissues damaged by injury or disease.