**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

## APRIL 1, AUGUST 1, AND DECEMBER 1, 2006

**National Institutes of Health (SBIR and STTR)**

**Centers for Disease Control and Prevention (SBIR)**

**Food and Drug Administration (SBIR)**

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# 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 identified in this solicitation.

Applicants are strongly encouraged to query program administrators periodically via email to learn of new or emerging scientific interests of the NIH, CDC, and FDA awarding components.

Additional information on each of the awarding components 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)

The mission of the NIH is to improve human health through biomedical and behavioral research, research training, and communications. The programs of the NIH are oriented principally towards basic and applied scientific inquiry related to the causes, diagnosis, prevention, treatment, and rehabilitation of human diseases and disabilities; the fundamental biological processes of growth, development, and aging; and the biological effects of the environment. In addition, the NIH sponsors training of research personnel; career development of new and established scientists; evaluation and dissemination of new information about medicine and health; construction and renovation of research facilities and provision of other research resources; and improvements in biomedical communications.

To carry out these responsibilities, the NIH is organized into awarding components (Institutes/Centers). Those components that have an extramural element, that is, 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 proposals, including the co-funding of such proposals by one or more awarding components having relevance in the projects.

### TRANS-NIH RESEARCH PROGRAMS

### Phase II Competing Renewal Awards

Some NIH Institutes/Centers (ICs) now offer Phase II SBIR/STTR awardees the opportunity to apply for a Phase II Competing Renewal award. Some ICs have announced this opportunity through the NIH Guide for Grants and Contracts (see list 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 II Competing Renewal award. Moreover, this opportunity is only for Phase II awardees that propose to continue the process of assessing and improving drugs or devices or propose to conduct preclinical studies of drugs or devices that ultimately require: 1) clinical evaluation, 2) approval of a Federal regulatory agency, and/or 3) continuing refinements to durable medical equipment (DME) designs such as cost reduction, testing for safety, durability, and reliability, and meeting or establishing standards. Such products include, but are not limited to, devices, drugs, vaccines, therapeutics, and medical implants related to the mission of the IC. The product being developed must be one for which Federal regulatory approval (e.g., FDA) is a required step toward commercialization. Prospective applicants are strongly encouraged to contact NIH staff prior to submission of a Competing Renewal application. 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 Announcements (http://grants.nih.gov/grants/funding/sbir_announcements.htm). The following NIH ICs will accept applications for Phase II Competing Renewal awards: **NIAAA, NIA, NIAID**, **NICHD, NIDA** (SBIR only), **NIMH** (SBIR only), **NHLBI** (SBIR only and only Competing Renewals of NHLBI-supported Phase II awards), **NIDCD, NIDDK, and NINDS.**

**Bioengineering Nanotechnology Initiative**

See Program Announcement at http://grants.nih.gov/grants/guide/pa-files/PA-06-009.html (SBIR) and http://grants.nih.gov/grants/guide/pa-files/PA-06-008.html (STTR)

The NIH invites grant applications for nanotechnologies useful to biomedicine. Nanotechnology is defined as the creation of functional materials, devices and systems through control of matter at the scale of 1 to 100 nanometers, and the exploitation of novel properties and phenomena at the same scale. Nanotechnology is emerging as a field critical for enabling essential breakthroughs that may have tremendous potential for affecting biomedicine. Moreover, nanotechnologies developed in the next several years may well form the foundation of significant commercial platforms.

The following list describes some of the priority areas for nanoscience and nanotechnology research support at NIH. The list is not exhaustive, nor are the topics mutually exclusive. Their presentation here exemplifies important scientific areas in which research at the nanoscale has the potential to make enormous contributions to solving biomedical problems.

- Nanomaterials (enabling): development of synthetic nanoscale building blocks for the formulation of bottom-up approaches to complex and multi-functional nano materials. These materials are expected to find use in applications towards pharmaceutical delivery, towards the development of contrast and biological agents, and multi-functional medical devices.
- Nano-bio interfaces: science of controlling the interface between biomolecular systems and nanoscale synthetic materials, which involves ability to control the interface architecture and transduction of the control signal through this interface.
- Nanoimaging: real-time imaging of subcellular structure, function, properties and metabolism.
- Cell biology: nano-scale research on cellular processes, including biophysics of molecular assemblies, membranes, organelles, and macromolecules.
- Molecular and cellular sensing/signaling: technologies to detect biological signals and single molecules within and outside cells.
- Prosthetics: mechanical, chemical, and cellular implant nano-technologies to achieve functional replacement tissue architectures.
- Environmental and health impact of nanotechnologies: ramifications of nanomaterial processing, use, and degradation on health and the environment.
- In-vivo therapeutics: development of nanoparticles that enable controlled release of therapeutic agents, antibodies, genes and vaccines into targeted cells.
- Sensor technologies: detection and analysis of biologically relevant molecular and physical targets in samples from blood, saliva and other body fluids, or for use in the research laboratory (purified samples), clinical specimens, and in the living body.
- Nanosystem design and application: fundamental principles and tools to measure and image the biological processes of health and disease and methods to assemble nanosystems.
- Bioinformatics for nanotechnology: algorithms and computer software to enable and support all of the above.

**Manufacturing Processes of Medical, Dental, and Biological Technologies (STTR [R41/R42])**

http://grants.nih.gov/grants/guide/pa-files/PA-06-012.html (SBIR) and http://grants.nih.gov/grants/guide/pa-files/PA-06-013.html (STTR)

The NIH encourages research related to advanced processing in the manufacture of biomedical products and the implementation of new technologies in medical care. New methods, procedures, measures, and controls are needed for manufacturing a broad range of technologies and products with unsurpassed quality and to lower manufacturing costs for existing and/or new processes. Research is also encouraged that can contribute to the containment and reduction of health care costs and that can improve the cost

effectiveness, quality, and accessibility of the health care system.

Because manufacturing-related R&D is extremely broad in scope, the following examples of research topics may be of interest but are not meant to be exhaustive.

Flexible computer-assisted integrated manufacturing equipment and intelligent processing equipment adaptable to the varied needs of biomedical research and medical care device and material production.

Systems engineering and management tools needed for the development of biomedical product manufacturing plants with particular emphasis on the requirements to meet GMP requirements for FDA approvals.

Technology for the manufacture of research instrumentation, such as highly sensitive, high resolution spectrometers, highly selective electrodes, microarray devices, and microfluidic devices.

Technology for the manufacture of clinical diagnostic devices and reagents.

Technology for the manufacture of novel diagnostic imaging devices for both invasive and non-invasive techniques.

Technology for the manufacture and delivery of therapeutic drugs, including for example, synthetic process chemistry, separations methods, formulation, and dosage delivery.

Technology for the manufacture of implantable devices and materials, including drug delivery pumps, prosthetic organs, artificial tissues, electronic sensors and electrical stimulators.

Technology for the production of natural products derived from plant, animal, and microbial sources, such as antibiotics, anticancer drugs, and other therapeutic agents, and useful synthetic starting materials.

Technology for the production and isolation of biotechnology products, such as proteins, antibodies, nucleic acids, vaccines, and vectors for genetic engineering and gene therapy.

Technology for the production of new materials relevant to biomedical research and medical care delivery, including nanomaterials, carbon fibers, polymeric materials, self-assembled monolayers, controlled size, shape, and porosity particles, filters, membranes, silicon substrates for microarrays, superconducting materials for NMR and MRI magnets, and implantable magnetic materials for external magnetic manipulation.

Technology for manufacture of medical device power sources, such as high energy density, long life-time batteries, solar cells, and fuel cells.

Technology for the fabrication of medical care instruments and devices such as minimally invasive and magnetic field tolerant surgical instruments, orthopedic implants, prostheses, and enabling devices for the injured and disabled.

Rapid prototyping and manufacture technology suitable for remote site and on demand production processes.

Technology to promote the recovery, reuse, and remanufacture (recycling) of medical materials and equipment.

Technology for the manufacture of biomedically specialized computational and information technology equipment and software.

Development of innovative products that facilitate the safety and health training of hazardous materials workers, emergency responders, and skilled support personnel. (See also NIEHS Worker Education and Training Program at http://www.niehs.nih.gov/wetp/home.htm.)

**Development of Synthetic and Natural Biomaterial Reference Materials**

The NIH invites applications for the development of synthetic or natural biomaterial reference materials (RMs). RMs are used for standardization of studies of interactions between materials and blood and tissues, for calibration of physicochemical test methods, and/or for reference controls in physical, chemical, and materials structure characterization tests. All innovative developments of biomaterials and devices also need measurements to demonstrate their innovation and improvement. Because RMs lie at the heart of measurement technology, funding for their development could play a key role in future advances in biomaterials and biomedical material device technologies.

Industry uses biomaterial RMs for quality assurance and traceability. The Food and Drug Administration considers them useful for comparing new

biomaterials, or new uses of biomaterials, with existing standards and materials. In order to have maximum utilitarian value, it is intended that these biomaterial RMs be stored at, and distributed by, the National Institute of Standards and Technology (NIST). Hence, they must be produced to meet the stringent requirements of the NIST Standard Reference Material Program. *It is important for applicants to contact NIST (Dr. John A. Tesk, (301) 975-6799; Email: john.tesk@nist.gov) to obtain detailed information on requirements of that program prior to preparing and submitting their applications.*

Biomaterial RMs may be synthetic polymers, ceramics, metals, or mixtures of these, or may be derived from living tissues. The choice of RM to be developed is up to the applicant but must be fully justified based on the applicant's knowledge of the magnitude of the current or potential utilization of the biomaterial. RMs of known particular value include: (1) silica-filled poly(dimethylsiloxane), (2) aliphatic polyether urethane, (3) poly (vinylchloride), (4) poly(methylmethacrylate), (5) expanded poly (tetrafluoroethylene) of varying standardized internodal distances, (6) oxygen permeability standards, and (7) carbon materials used in mechanical heart valve designs.

RMs must be of appropriate size and shape. The form in which the reference material is produced and the tests necessary to characterize the material are the decision of the applicant based on the end use of the material. The applicant may consider NIST as a potential subcontractor for measurement and other professional services.

For additional information on this topic, please contact:

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Health Scientist Administrator
Bioengineering and Genomic Applications, SRG
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 9140, MSC 7940
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**National Center on Sleep Disorders Research**

The National Center on Sleep Disorders Research (NCSDR) was established within the National Heart, Lung, and Blood Institute (NHLBI) as a result of the National Institutes of Health (NIH) Revitalization Act of 1993. Its mandate is to conduct and support research, training, health information dissemination, and other activities with respect to sleep disorders, including biological and circadian rhythm research, basic understanding of sleep, chronobiological and other sleep related research and to coordinate the activities of the Center with similar activities of other Federal agencies, including the other agencies of the National Institutes of Health, and similar activities of other public entities and nonprofit entities.

Three specific types of research are emphasized: basic research using state-of-the-art approaches to elucidate the functions of sleep and the fundamental molecular and cellular processes underlying sleep; patient-oriented research to improve the diagnosis and treatment of sleep disorders; and applied research to evaluate the scope and health consequences of sleepiness and sleep disorders.

Research opportunities of potential interest to small businesses may include, but are not limited to the following examples:

A. Portable instrumentation for diagnostic in-home assessment of sleep disorders especially sleep disordered breathing.

B. Countermeasures for excessive daytime sleepiness, including methods that alter the output of the circadian clock to optimize sleep and wakefulness.

C. New technologies and instrumentation scaled for high-throughput phenotypic characterization of sleep in mice.

D. High volume, inexpensive assays to assess variations in gene expression related to circadian and behavioral state (sleep and wakefulness) related .

E. Improved methods for the diagnosis of sleep disordered breathing in infants, children, and adults.

F. Educational interventions to improve worksite productivity and school performance through the prevention and management of insufficient sleep and poor sleep environment conditions.

G. Portable inexpensive devices for ambulatory assessment of both sleep and physical activity in population-based biomedical research studies.

H. Methods to improve patient compliance with sleep disordered breathing treatments.

I. New pharmacological for the treatment of sleep disorders, especially sleep disordered breathing.

J. Noninvasive imaging technologies to assess neurophysiological and regional brain blood flow changes associated with sleep disorders and other causes of excessive daytime sleepiness.

For additional information on research topics, please see the National Sleep Disorders Research Plan (http://www.nhlbi.nih.gov/health/prof/sleep/res_plan/index.html) and contact:

Mr. Al Golden
Public Health Advisor
National Center on Sleep Disorders Research
NHLBI, 6701 Rockledge Drive
Bethesda, MD 20892
(301) 435-0199; Fax: (301) 480-3451
Email: goldena@nhlbi.nih.gov

**NATIONAL INSTITUTE ON AGING (NIA)**

The NIA supports biomedical, behavioral, and social research and research training on the aging process as well as on the diseases and other special problems and needs of older people. It supports grant research under four established programs: Biology of Aging, Behavioral and Social Research, Neuroscience and Neuropsychology of Aging, and Geriatrics and Clinical Gerontology.

Examples of research topics within the mission of the NIA that may be of interest to small businesses are shown below. These listings illustrate the range of areas that are of interest to the NIA and are not intended to be exhaustive.

For additional information about areas of interest to the NIA, please visit our home page at http://www.nia.nih.gov.

**Phase II Competing Renewal Awards**

NIA will accept Phase II 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). Such products include, but are not limited to: medical implants, drugs, vaccines, and new treatment or diagnostic tools that require FDA approval.

NIA will accept applications for up to two (2) years and up to $750,000 per year in total costs. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely.

Please contact Dr. Michael-David A.R.R. Kerns (see contact information below) before beginning any work on a Competing Renewal application. Potential applicants must obtain approval from NIA before submitting a Competing Renewal application. After obtaining approval from NIA, prospective applicants are requested to submit 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 Number (e.g., PA-06-XXX)

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 NIA SBIR/STTR Phase II awards will be eligible for a Competing Renewal grant.

The following examples would make appropriate topics for proposed SBIR or STTR Phase II Competing Renewal projects. These are meant for illustrative purposes only and are not exclusive of other appropriate activities. Research and development efforts can be focused on medications to treat, delay the progression of, or prevent age-related cognitive decline, Alzheimer's disease, and other dementias of aging.

1. Studies for preclinical discovery and development of drugs, natural products, or other types of compounds, including pharmacology and toxicology studies, beyond those conducted under the initial SBIR Phase I and Phase II grants. The studies conducted under the previous grants should be sufficient to provide a sound rationale for continued development of the drug or natural product.

2. Completion of studies as required by the FDA for an IND application.

3. Human clinical trials/studies to determine a drug's, natural product's, or other type of compound's safety profile, metabolism, and/or efficacy.

For questions relating to Phase II Competing Renewal applications, please contact:

Dr. Michael-David (MD) A.R.R. Kerns
(301) 402-7713, Fax: (301) 402-2945
Email: kernsmd@mail.nih.gov

**Behavioral and Social Research**

Research on basic and translational social and behavioral research on aging processes and the place of older people in society. The program focuses on how people change with age, on the interrelationships between older people and social institutions (e.g., the family, health-care systems), and on the societal impact of the changing age-composition of the population. Emphasis is placed upon the dynamic interplay between the aging of individuals and their changing social and physical environments. Special emphasis areas are Aging Minds (see *The Aging Mind: Opportunities in Cognitive Research*, http://books.nap.edu/catalog/9783.html); Genetics, Behavior and the Social Environment; Health Disparities; Health, Work and Retirement; Increasing Health Expectancy; and Interventions and Behavior Change. Areas that may be of interest to small businesses include, but are not limited to:

A. Cognitive and human factors interventions on the individual and environment to maintain independence, maintain functioning, increase well being, and prevent disease/disability. Such interventions can include behavioral technologies, environmental modifications and redesign, training and teaching efforts, or new programs, products and services. Interventions can be developed for home, community, health-care or work-place settings.

B. Research Innovation: Innovations and new products that improve data collection, data analysis, and data dissemination are encouraged. Examples of areas of interest in data collection include, but are not limited to: experience sampling methodologies; improved performance-oriented measures of cognitive and physical functioning suitable for use in field settings or in cross-national research; the development of miniaturization devices to improve real-time data collection, and the development of computer-assisted personal and telephone instrument modules to use with older respondents. New and innovative methods for improving the measurement of well-being in the older populations (both across subgroups and internationally), are particularly encouraged.

C. Social, behavioral, environmental and/or technical interventions on the individual for health maintenance and disease/disability prevention. Such interventions can include self management of chronic diseases including behavioral change technologies, enhancing compliance, especially for less educated patients with chronic diseases requiring strict adherence to complex regimens, or new programs, products and services to increase the health, functioning and well-being of older people. Interventions can be developed for home, community, health-care or work-place settings.

D. AIDS and aging. The development of intervention strategies which are designed to prevent the spread of AIDS in middle-aged and older populations. These strategies may include health education programs to inform the health care providers and public about risks of AIDS in older people.

E. Multi-Level Interventions are interventions that influence multiple levels. Levels include the social, community, family, institutional, and individual. More information about the use of multilevel methodology in the social sciences can be found in People and Pixels: Linking Remote Sensing and Social Science (http://books.nap.edu/openbook/0309064082/html/index.html). Other valuable information about social science interventions can be obtained from New Horizons in Health an Integrative Approach (http://books.nap.edu/openbook/0309072964/html/index.html). Interventions and technologies that address multiple levels are of particular interest to the Behavior and Social Research Program.

Dr. Elayne Heisler
(301) 496-3138, Fax: (301) 402-0051
Email: heislere@nia.nih.gov

F. Interventions for care provision. Development of strategies for care providers (both professionals and families) to deal with burdens

of care associated with chronic disabling illness or disease (including Alzheimer's disease). Interventions include new forms of adult day care, and family interventions. Development of work site programs to supply information on caregiving (including community respite and daycare facilities) and to enable advance planning by employees.

G. Death and dying. Programs that deal with decreasing the trauma and difficulty of elders, their families, and care providers faced with end-of-life decisions and those events that surround the end of life.

H. Long-term adherence. Development of strategies and technologies to enhance long-term adherence to medical regimes for chronic conditions and behavior-change interventions for health promotion in older adults. Adherence advances might target the healthcare provider, caregiver or patient, or a larger group, such as a social network.

Dr. Sidney M. Stahl
(301) 402-4156, Fax: (301) 402-0051
Email: StahlS@nia.nih.gov

I. Forecasting. Development of mathematical, economic, demographic and epidemiological models that will lead to improved forecasting of national, state and county level estimates of the demand for aging-related services and improved prediction of the effects of public health interventions, changes in health-care financing and insurance, social security, pension coverage or changes in the retirement age. For example, micro- and macro-simulation models of changes in health and economic status and methodological enhancements to existing models that takes into account health, intergenerational transfers, changes in family composition, and other characteristics of future cohorts. The program is interested in both domestic and international projections.

J. Measurement instruments and database support. The program supports collection of numerous large datasets and is therefore interested in technologies which lead to products that will facilitate distribution of data while ensuring the confidentiality of NIA supported longitudinal studies are of particular interest. Information on supported datasets can be found at: http://www.nia.nih.gov/research/extramural/behavior/datasets.pdf.

1. Development of new instruments using existing demographic and economic data and theory that yield defensible estimates of quality of health plans, hospitals, nursing homes, etc. The program is interested in both domestic and international estimates.
2. Development of improved performance-oriented measures of cognitive and physical functioning suitable for use in field settings or in cross-national research.
3. Development of new technologies which improve large scale longitudinal surveys in the US and abroad. Including the development of computer-assisted personal and telephone instrument modules, including expert systems, to use with older respondents, in order to determine information such as occupational status, migration, housing issues, disability status, and family structure.
4. Development of new databases (e.g., from administrative data) and database support to satisfy data and research needs on aging, and innovative data archives and methods for accessing archives to make current statistical and epidemiological data more accessible to researchers.
5. Development of innovative methods and software to provide improved high performance remote analytic access to complex longitudinal studies or surveys that cannot be placed in open data archives because of issues relating to confidentiality and the need to prevent re-identification of subjects or respondents. Such software would increase the ease with which data analysts could perform sophisticated analyses with a wide range of statistical software programs, while automatically preventing any analyses or remote requests that could compromise data security.
6. The development of high quality micro or macro simulations models that measure the impact of interventions on health expenditures, well-being and other outcomes.

K. Dissemination and teaching materials. Development of innovative teaching and dissemination tools (e.g., dataset-based computer programs, simulations/games, videotapes and other heuristic devices) to

teach dynamics of population aging and convey results of aging research. For example, teaching modules for secondary data analysis for high school and college students using, for example, data from the US Census Bureau, the National Center for Health Statistics, or an NIA sponsored study (see NIA website http://www.nia.nih.gov/research/extramural/behavior/datasets.pdf for available data sets) and projection data.

L. Interventions on the health-care system. Development and evaluation of strategies to improve health-care organization and delivery including attention to assisted living and new forms of in-home care.

Ms. Georgeanne Patmios, MA
(301) 496-3138, Fax: (301) 402-0051
Email: PatmiosG@nia.nih.gov

M. Development of indicators and measures of progress in the behavioral and social sciences, including bibliometric measures of citations and impact of research, measures of the rate of change and the formation of new research areas, and measures of the impact of behavioral and social research on public policy and well-being.

Dr. Richard Suzman
(301) 496-3131, Fax: (301) 402-0051
Email: SuzmanR@nia.nih.gov

N. Development of miniaturized devices to be used in behavioral and social research to improve real-time, remote monitoring, virtual data collection for instant, continuous, and/or interactive feedback system, and reliable data storage/retrieval.

Ms. Angie Chon-Lee, MPH
(301) 594-5943, Fax: (301) 402-0051
Email: Chon-LeA@nia.nih.gov

**Biology of Aging**

Research on the physiology, molecular, and cellular basis of aging processes. NIA also has responsibility for maintaining existing resources and developing new resources for aging research, such as populations of well-characterized animals and specific cell lines, for example, human fetal lung fibroblasts. Areas that may be of interest to small businesses include, but are not limited to:

A. Effects of metabolism on the aging process, e.g., how metabolic regulation influences longevity, and the development of anti-oxidant interventions to reduce oxidative stress in vivo.

Dr. David Finkelstein
(301) 496-6402, Fax: (301) 402-0010
Email: df18s@nih.gov

B. Development of minimally-perturbing techniques for collecting blood from mice, rats, and other animals several times a day in sufficient quantities for measurement of hormone levels and other circulating factors in young and old animals, or development of non-invasive research and test methods for use in animals.

Dr. Nancy Nadon
(301) 496-6402, Fax: (301) 402-0010
Email: nn37a@nih.gov

C. Development of molecular probes such as antibodies, DNA sequences and expression vectors useful in studying aging, senescence, and longevity both in vivo and in vitro.

Dr. Anna McCormick
(301) 496-6402, Fax: (301) 402-0010
Email: am38k@nih.gov

or

Dr. Rebecca Fuldner
(301) 496-6402, Fax: (301) 402-0010
Email: Fuldnerr@mail.nih.gov

D. Instruments and/or methodology to monitor dynamic progression of ovarian follicles from primordial through antral stages in humans and other mammals with sufficient sensitivity to obtain an accurate profile during the perimenopausal period when relatively small numbers of follicles are present.

Dr. Frank Bellino
(301) 496-6402, Fax: (301) 402-0010
Email: fb12a@nih.gov

E. Development of new animal models, including transgenic animals, for studying aging processes, as well as development of new biological model systems for research on aging to replace or reduce vertebrate animal use in research. These models may include better in vitro systems, improved cell culture methods, mathematical models, and computer simulations.

Dr. Nancy Nadon
(301) 496-6402, Fax: (301) 402-0010

Email: nn37a@nih.gov

F. Development of interventions to slow down the degenerative processes associated with aging. These would include techniques with commercial potential to: (1) manipulate the control of cell proliferation or programmed cell death, (2) reduce the level of damage to nucleic acids, proteins and lipids and the macromolecular complexes formed from these molecules, (3) improve the damage surveillance and repair potential of cells, (4) improve the immune response to foreign molecules or reduce the response to self, and (5) reverse age-related changes in hormone production and function.

Dr. Nancy Nadon
(301) 496-6402, Fax: (301) 402-0010
Email: nn37a@nih.gov

G. Development of treatments for wound healing in the aged.

Dr. Jill Carrington
(301) 496-6402, Fax: (301) 402-0010
Email: carringtonj@nia.nih.gov

H. Development of appropriate animal and human culture model systems to explore underlying molecular and cellular mechanisms of prostate growth in middle-aged and older subjects.

I. Development of appropriate animal model systems to explore underlying molecular and cellular model systems of female reproductive aging processes as well as the development of pathophysiologic processes associated with the human menopause, including bone loss, cardiovascular pathology, hot flashes, and excessive uterine bleeding.

Dr. Frank Bellino
(301) 496-6402, Fax: (301) 402-0010
Email: fb12a@nih.gov

**Neuroscience and Neuropsychology of Aging**

Research on age-related changes in the brain or nervous system in the context of other age-related physiological or homeostatic regulator changes (e.g., endocrine, dietary, immune, disease states); degenerative processes or pathological changes in the aging brain in the context of understanding normal age-related changes; and the sensory, perceptual and cognitive processes and changes that occur with aging as related to their underlying biological mechanisms. An important component of this program is the support of studies on Alzheimer's disease and related dementias of aging. Areas that may be of interest to small businesses include, but are not limited to:

A. Devices or intervention strategies that may prolong independence when there are dysfunctions of the central nervous system.

B. Development of sensitive, specific and standardized tests for diagnostic screening of cognitive decline and dementia, for example, the development of biochemical and neuroimaging criteria for the diagnosis of cognitive decline and Alzheimer's disease.

C. Discovery, development and/or evaluation of drugs, delivery systems, or treatments to enhance cognitive functioning in normal aging and to treat the cognitive deterioration and/or behavioral symptoms associated with Alzheimer's disease as well as to slow and/or reverse the course of the disease, or prevent it entirely.

Dr. Neil Buckholtz
(301) 496-9350, Fax: (301) 496-1494
Email: nb12s@nih.gov

D. Nutritional interventions to restore brain biochemical changes in aging and neurodegenerative diseases.

E. Biosensors and prosthetic devices to aid sensory and memory dysfunctions.

Dr. Judith Finkelstein
(301) 496-9350, Fax: (301) 496-1494
Email: jf119k@nih.gov

F. New technologies to screen for the presence of sleep disorders in older persons, to aid in the diagnosis of these disorders, and to enable their remediation.

Dr. Andrew Monjan
(301) 496-9350, Fax: (301) 496-1494
Email: am39m@nih.gov

G. Improved instrumentation, imaging technology, related devices, and software packages for use in visualizing neural activity during cognitive or sensory behavior in older adults. Also of interest would be new technologies to combine neural imaging and behavioral assessment in awake unanesthetized animals.

Dr. Molly Wagster
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H. Development of technology and analysis tools to examine cellular patterns of gene and protein expression in the normal and diseased aging nervous system, including the identification of aberrant gene products expressed in the aging brain. Development of molecular imaging technology for the in vitro and in vivo analysis of gene and protein function in the normal aging brain and in the diseased aging nervous system.

I. Development of technology such as non-invasive methods, to identify neural stem cells and to monitor their function in the adult and aged nervous system Development of novel markers of stem cell proliferation, migration, and differentiation, as well as methods to assess the integration and function of stem cells in the nervous system.

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Dr. D. Stephen Snyder (Alzheimer's disease and other dementias of aging)
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**Geriatrics and Clinical Gerontology**

The Geriatrics and Clinical Gerontology (GCG) Program supports research on health and disease in the aged and research on aging over the human life span and its relationships to health outcomes. Research on Geriatrics focuses primarily on health issues regarding the aged, and deals with research on disease and disability in older persons, including both specific conditions and issues related to multiple morbidity. Clinical Gerontology Research focuses primarily on clinically related issues regarding aging, and deals with research on aging changes over the life span. A major focus is on the determinants of rates of progression of age-related changes that affect disease risk, particularly those affecting risk for multiple age-related conditions.

Areas of interest include but are not limited to:

A. Research on better ways to prevent injuries and deaths associated with the use of currently available bed rails in older patients; this will include improved designs of bed systems for use in the home, nursing home and hospital.

B. 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.

C. Techniques for preventing or treating urinary incontinence.

Dr. Susan Nayfield
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D. Refinements in techniques for the measurement of age-related changes in hormone levels, status or pharmacokinetics (e.g., those of growth hormone, IGF-1 and its binding proteins; estrogen, progesterone, testosterone; other markers of ovarian, testicular, hypothalamic and pituitary function). The objective is to enhance sensitivity and achieve greater economy in the assay cost.

E. Effects of menopause on woman's aging and subsequent health. Effects of age-related changes in endocrine status in men on subsequent aging, morbidity and mortality.

1. Refinements in techniques for the measurement of age-related changes in hormone levels or pharmacokinetics (e.g., those of growth hormone, IGF-1 and its binding proteins; estrogen, progesterone, testosterone; other markers of ovarian, testicular, hypothalamic and pituitary function).

2 Development and testing of alternative strategies (to conventional estrogen/ progestin therapy) for the management of short-term menopausal symptoms and for the reduction in risks of cardiovascular disease, osteoporosis, and other menopause-related conditions, disorders and diseases. Development and testing of new tissue-specific modulators of estrogen/ androgen receptor activity in men and in women for the prevention or treatment of age-related diseases.

3. Development, testing and validation of new surrogate measures of clinically relevant outcomes and endpoints (e.g., fractures) for (1) more immediate and accurate assessment of the risk or progression of age-related diseases (e.g., osteoporosis) or (2) to predict or monitor efficacy of

treatment or enhanced risk or progression of adverse effects/events.

4. Determine drug interactions, i.e., potential alterations in pharmacokinetics and pharmacodynamic properties of drugs taken concomitantly with postmenopausal hormones.

F. Osteoporosis. Development, testing and validation of new surrogate measures of clinically relevant outcomes and endpoints (e.g., fractures) for (1) more immediate and accurate assessment of the risk or progression of age-related diseases (e.g., osteoporosis) or (2) to predict or monitor efficacy, response to treatment or enhanced risk or progression of adverse effects/events.

Dr. Sherry Sherman
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Email: ss80t@nih.gov

G. Improved instrumentation (e.g., accelerometers) for assessment of physical activity, and improved monitors for visually and/or biomechanically characterizing falls in older patients.

H. Improved instrumentation and imaging techniques for measuring body composition and properties such as muscle function in older persons.

I. Development and validation of non-invasive methods of examining bone quality (density, architecture, and strength of bone).

J. Development of techniques/devices (e.g., non-invasive, portable) for improved monitoring of caloric intake and/or energy expenditure in epidemiological studies.

K. Measurement of deficits in muscle strength and balance among older persons.

1. Instrumentation for biomechanical assessment of ambulation and falls.

2. Quantitative methods of assessing postural perturbations relevant to activities of daily living.

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L. Techniques and methods for screening, diagnosis, and treatment of cancer in older persons.

1. Development of geriatric assessment instruments and/or methodology to assist oncologists in patient evaluation and diagnostic work-up to determine the older patient's overall physical and physiologic health status.

2. Techniques to promote effective pain management in older-aged cancer patients. This includes documentation and assessment of pain intensity and its characteristics prior to and after pharmacologic and non-pharmacologic interventions.

3. Development of innovative teaching tools for physicians, nurses, and other health professionals in the following areas: (1) to convey benefits of screening and early detection of cancer for use with older-aged persons; (2) to assist in teaching older-aged patients in self-examination for early warning signs of cancer; and (3) to teach older aged patients how to care for themselves after cancer surgery (e.g., ostomy patients).

4. Development of methods to be used as guidance for physicians to estimate proper medication dosage in elderly cancer patients given body composition, size, age, other health problems, kidney functioning, and other physiologic parameters. This includes estimates of an initial or loading dose of therapeutic drugs and daily maintenance for continuance of therapeutic concentration of drugs in the patient's bloodstream.

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M. Development of devices and techniques for screening substantial numbers of individuals for particular alleles at loci of relevance to human genetic studies of aging.

N. Development and validation of imaging and sensor technologies to improve measures of physiologic changes with age.

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**Other Research Topic(s) Within the Mission of the Institute**

For additional information on research topics, contact:

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For administrative and budget management questions, contact:

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**NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)**

The NIAAA supports research on the causes, prevention, control, and treatment of the major health problems of alcohol abuse, alcoholism, and alcohol-related problems. Through its extramural research programs, the 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. The NIAAA also is concerned with strengthening research dissemination, scientific communications, public education, and data collection activities in the areas of its research programs.

For additional information about areas of interest to the NIAAA, you are invited to visit our home page at http://www.niaaa.nih.gov.

**Phase II Competing Renewal Awards**

NIAAA will accept Phase II SBIR/STTR Competing Renewal grant applications 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, 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.

You are strongly encouraged to contact Dr. Karen Peterson (contact information provided below) before beginning the process of putting a Phase II Competing Renewal application together. Prospective applicants are also strongly encouraged to submit to Dr. Peterson 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 Number (e.g., PA-06-XXX)

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 NIAAA SBIR/STTR Phase II awards will be eligible for a competing renewal grant.

The following examples would make appropriate topics for proposed SBIR or STTR Phase II competing renewal projects.

These examples are meant for illustrative purposes and are not exclusive of other appropriate activities:

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the Phase I (R43) and initial Phase II (R44) 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.
- Development and clinical evaluation of new alcohol-sensitive biomarkers.

- Assessment of devices with regard to performance standards related to the FDA approval process.
- Safety and effectiveness studies of novel medical devices.
- Biocompatibility studies of surface materials of putative medical implants.
- Evaluation of novel imaging approaches for diagnostic purposes.
- Clinical studies in support of New Drug Application approval by the FDA.
- Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.

Direct your questions about scientific/research issues to:

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Peter B. Silverman, Ph.D.
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Forward Letter of Intent to:

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**Pharmaceutical Development for Alcoholism Treatment**

Applied and, where appropriate, clinical research on pharmacologic agents for use in the treatment or medical management of alcoholism, disorders resulting from alcoholism, the improvement and refinement of drugs currently available for therapeutic purposes, or drugs suitable for use in basic research studies on alcohol addiction. Areas that may be of interest to small businesses include, but are not limited to:

A. Development of agents to attenuate drinking behavior, e.g., drugs to curb craving.

B. Development of aversive agents such as disulfiram that attenuates drinking behavior.

C. Development of agents to treat acute alcohol withdrawal.

D. Development of agents to treat the protracted withdrawal syndrome.

E. Development of neurotransmitter agonists and antagonists, or drugs that enhance the efficacy of neurotransmission, which are capable of improving or reversing alcohol-induced cognitive impairments.

F. Development of agents to induce sobriety in intoxicated individuals (amethystic agents).

G. Development of agents to diminish drinking by treating associated psychiatric disorders and/or drug abuse.

H. Development of improved methods of drug delivery for the treatment of alcoholism. The systems developed must be capable of maintaining therapeutic drug levels for extended periods of time to alleviate compliance problems.

I. Development of drugs for the treatment of alcoholic hepatitis, cirrhosis, pancreatitis, and cardiomyopathy.

J. Research on the pharmacokinetics of concurrent ethanol and other drug use.

For clinical questions, contact:

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For pre-clinical questions, contact:

Mark Egli, Ph.D.
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**Diagnostic Assessment of Alcohol Use Disorders and Comorbidity**

Innovative self-report and biochemical approaches to the early identification of alcohol use problems and diagnosis of alcohol use disorders and comorbidity are needed. The research design should include measurements of reliability and validity in appropriate population samples. Areas that may be

of interest to small businesses include, but are not limited to:

A. Development or adaptation of diagnostic instruments measuring alcohol use disorders and related comorbid conditions in general population and treated samples, including youth, the elderly, pregnant women, ethnic minorities, the handicapped, and persons with low-level reading skills).

B. Development and testing of methodology to translate diagnostic instruments for alcohol use disorders and associated disabilities into relevant different languages (e.g., various Hispanic languages).

C. Development and testing of computer algorithms necessary to derive diagnoses of alcohol use disorders and associated comorbidity.

D. Development of computer software for utilization of assessment instruments in a clinical setting. Development and testing of detailed audio, visual, or printed training modules to accompany diagnostic instruments.

E. Application of statistical and mathematical analyses to develop models designed to increase our understanding of (1) etiologic relationship between alcohol use disorders and their associated disabilities, and (2) the factors that influence the initiation and maintenance of alcohol use disorders.

F. Identification, validation, and assay of physiological and/or biochemical measures capable of identifying individuals at risk for becoming alcoholics or individuals who already exhibit alcohol problems. The accurate measurement of acetaldehyde conjugates or abnormal glycoconjugates in blood is one promising approach.

G. Development of biochemical/physiological methods for early detection of alcohol-derived pathology, e.g., alcoholic hepatitis or cirrhosis. Development and characterization of markers to accurately predict vulnerability to alcohol-derived pathology.

Cherry Lowman, Ph.D.
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**Treatment of Alcoholism**

A. Development and evaluation of innovative treatment approaches. These approaches can include outreach, shelter, detoxification, treatment and recovery, and alcohol-free housing, as appropriate.

B. Development and validation of tools to aid in the clinical management of patients, including selection of appropriate interventions, process evaluation, assessment of outcome, aftercare, and patient tracking, in various treatment settings.

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**Measurement of Alcohol Consumption/Impairment**

Development of new methods for quantitative measurement of alcohol consumption, development of new and more accurate cost-effective technological approaches for non-invasive measurement of blood alcohol concentration, and development of novel approaches to measure and quantify alcohol-induced impairment of human performance. Areas that may be of interest to small businesses include, but are not limited to:

A. Development of new methods for quantitatively estimating alcohol use over a period of days or weeks. The approaches should have high sensitivity and specificity and have utility in a variety of settings, including treatment compliance monitoring. Integration of measurement devices with electronic devices to transmit and/or record data in real time is desirable.

B. Development of new and more accurate cost-effective technological approaches (such as breathalyzers) for non-invasive measurement of blood alcohol concentration in law enforcement, workplace, research, and clinical settings.

C. Development of instruments involving tests of behavioral, cognitive, and/or motor function to measure and quantify alcohol-induced impairment of human performance. Such instruments may be computer-based and may be designed to simulate specific work situations such as driving performance, use of complex machinery, learning and retention of new information.

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**Promoting Adherence to Medical, Pharmacologic, and Behavioral Treatments**

Several recent reports and literature reviews point to the continuing need for improving adherence to therapeutic regimens. Adherence rates vary considerably across diseases and treatments, measuring instruments, and populations, with rates ranging from 30% to 60% in many instances. The reasons for non-adherence are multifaceted. Health-care providers, organizational systems, and patient factors all play a role in adherence to therapeutic regimens. Thus, to understand and eventually improve adherence, conceptual frameworks and interventions need to take into account institutional, system, situational, interpersonal, and personal factors as well as the characteristics of the illness or condition and of the treatment regimen. While extensive research exists and successful techniques have been identified, greater efforts are needed to develop and implement programs based upon these findings. Applications are sought to develop:

A. Programs to implement effective interventions and to evaluate their implementation.

B. Professional education courses or web-based training modules on interventions and to monitor their effectiveness.

In both cases, the emphasis is on how to encourage health practitioners to utilize interventions that will improve their patients' adherence to medical, pharmacologic, and behavioral regimens for alcohol abuse and dependence.

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**Prevention**

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. 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:

A. 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 alcoholics, women, the handicapped, 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.

B. Development and evaluation of educational materials designed to inform the elderly about 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.

C. Development and evaluation of educational materials designed to provide information on date rape, spouse abuse, child abuse, and other types of violence that have been found to be associated with alcohol use and/or abuse. The development of strategies for preventing victimization would also be appropriate.

D. Development of instruments and educational materials designed to improve the effectiveness of employee assistance programs, especially with respect to assessment, referral, and health promotion as it relates to alcohol use and abuse.

E. 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; 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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**Health Services Research on Alcohol-Related Problems**

Research projects are sought that will expand knowledge and improve delivery of alcohol treatment and prevention services. The research objectives include, but are not limited to: the effects of organizational structures and financing mechanisms on the availability, accessibility, utilization, delivery, content, quality, outcomes, and costs of alcohol treatment services. Objectives also include studying the effectiveness and cost-effectiveness of alcohol prevention services in reducing the demand for health care services and improving the methodological tools useful for conducting health services research. Areas that may be of interest to small businesses include, but are not limited to:

A. Development of computer software or other protocols to assist in the management of treatment delivery. Software should be useful for assessment, diagnosis, patient placement criteria, monitoring of services received, tracking patient progress, and billing.

B. Development of software or other protocols to assist clinicians in scoring and norming results of commonly used assessment instruments. Output should be in a form useful for guiding client feedback.

C. Development of software or other protocols to assist treatment programs and service agencies in measuring, assessing, or otherwise documenting indicators of clinical performance or improvements in quality of service provision.

D. Development of products to facilitate the adoption of evidence-based research findings into everyday clinical practice. For example, training videos or other materials illustrating research-based improvements in treatment practice could provide clinicians with practical examples of orienting patients to pharmacotherapy, assessing motivational readiness, giving motivational feedback, establishing contracts for behavioral couple therapy, and conducting brief interventions in primary care settings.

E. Development of software or other protocols to facilitate the incorporation of screening and identification tools into routine usage in primary care, emergency, obstetric, mental health, and other health care settings. Research projects should facilitate both the provisions of brief interventions and effective referral to specialized alcohol treatment.

F. Development of software or other protocols for monitoring clinical costs of alcohol treatment services. These tools should provide a user-friendly system of monitoring costs that could be implemented without additional accounting expertise by the staff at a typical treatment setting. At the same time, such tools should be defensible as measures of the true opportunity costs of providing alcohol treatment services. Such software might be bundled with billing software.

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**Training in Alcoholism Assessment and Treatment Techniques**

Development of educational materials, including computer-based approaches, for training of health professionals in the use of various assessment techniques and treatment strategies. Areas that may be of interest to small businesses include, but are not limited to:

A. Development of educational materials, including computer-based approaches, for training of health professionals and paraprofessionals in the use of various assessment techniques and instruments.

B. Development and evaluation of clinical protocols which enable health professionals to relate assessment to appropriate intervention and treatment strategies.

C. Development and evaluation of effective health professions training programs which utilize state-of-the-art educational technology and are based upon currently accepted clinical and behavioral strategies. Examples include experiential teaching technologies such as standardized patient, interactive video, and computer simulation.

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**Fetal Alcohol Syndrome (FAS) and Alcohol-Related Birth Defects**

FAS is a severe developmental disorder that includes mental retardation, cognitive and behavioral disabilities, and motor impairment. The NIAAA supports research leading to improved diagnosis and assessment of impairment and disability, as well as the development of tools to enhance academic and daily living skills. Areas that may be of interest to small businesses include, but are not limited to:

A. Development of diagnostic and/or screening methods that can be used prenatally to identify fetuses affected by ethanol.

B. Development and validation of assessment methods to provide more accurate clinical diagnosis of FAS at all life stages.

C. Development and testing of skill-building, therapeutic, and education program products that enhance the social, cognitive, adaptive and motor abilities of individuals with FAS or fetal alcohol effects.

D. 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.

E. 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.

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For basic research questions, contact:

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**Science Education**

The NIAAA Science Education program is intended to: (1) supplement in-service education of health professionals and paraprofessionals with respect to their recognition and treatment of alcohol-related medical problems; (2) stimulate the interest of both precollege and college students, especially among underserved populations, in career opportunities in the biomedical and behavioral sciences generally and the alcohol field specifically; (3) enhance precollege education in the classroom, both directly and via support to teachers, in the life sciences and in education regarding science-related personal and societal challenges; and (4) improve public understanding of science generally and with particular regard to the role of and need for alcohol research. The NIAAA Science Education program complements, but does not duplicate, the education and training components described under other NIAAA topics.

Efforts in science education might include, but are not limited to:

A. Development of methodology to transfer new alcohol research knowledge and directions of scientific knowledge growth to curriculum developers and science teachers, consistent with the National Research Council's National Science Education Standards (1996).

B. Development and testing of specific science education materials, activities or programs to implement one (or more) of the four stated objectives of the NIAAA science education program. The creative use of emerging educational and telecommunications technologies in this regard is of special interest.

C. Development and testing of methodology to present science and alcohol abuse-related curricula and educational materials to particular underserved group(s) in culturally relevant ways, and/or to obtain community support for education in science-related and alcohol-related topics that may be culturally sensitive.

D. Development of resource materials on scientific career opportunities in fields of interest to NIAAA, reflecting activities (e.g., focus groups) and research on motivational factors influencing high school students' career choices, and reflecting economic and social projections of career outlooks for the 21st century.

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**Longitudinal Analysis of Complex Survey Data**

Despite recent advances made in developing software programs for longitudinal latent and observed variable structural modeling, very little has been accomplished in this research arena regarding modeling with complex sample data. Currently there is no comprehensive statistical software package that allows such modeling that takes into account sampling weights, stratification and clustering while at the same time allowing for these observed variables to be either categorical, continuous, or a combination of both. Moreover, there is no currently available comprehensive statistical package that allows for the longitudinal analysis of complex survey data for the variety of models necessary for the analysis of alcohol-related longitudinal data (e.g., linear, probit and logistic regression, survival analysis [continuous and discrete-time allowing for time-varying covariates], path analysis, exploratory and confirmatory factor analysis, growth modeling, growth mixture modeling, multilevel modeling, linear and nonlinear growth modeling, and combinations and variants of these models).

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**Research Tools**

The NIAAA supports basic and applied research to develop new or improved tools to enhance laboratory studies on humans and animals. Examples include transgenic animal models, cell lines, new ligands for neuroimaging, and simulators of alcohol impairment. Areas that may be of interest to small businesses include, but are not limited to:

A. Development of animal models, including transgenic animals, possessing specific traits of significance for the study of alcoholism, 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 new methods of ethanol administration to animals that produce precise dose control.

D. Development of specialized cell culture chambers to provide controlled administration of ethanol to in vitro cell systems.

E. Development of ligands for alcohol-relevant neurotransmitter systems which will enhance the potential usefulness of PET and SPECT imaging technologies for the study of the etiology of alcoholism and related brain pathology.

F. Development of instruments that simulate driving, piloting aircraft, or using other complex machinery under hypothetical or actual drinking handicaps and are designed to predict fatal and nonfatal accident involvement.

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**Development and Clinical Testing of Biochemical Markers**

The development of effective biochemical markers represents a powerful means for early diagnosis and treatment of alcohol dependent/abuse patients and for the identification of individuals who have a predisposition for alcoholism. There are two different types of biochemical markers: trait markers and state markers.

Trait biomarkers have the ability to detect inborn characteristics of individuals who are vulnerable for alcoholism. This type of marker would be invaluable for screening of high-risk individuals (e.g., children of alcoholics) and targeting them with preventive or early treatment interventions. In addition, trait markers might assist practitioners in identifying subpopulations of alcoholics who may need different treatment strategies. An ideal trait marker should have several features. First, it should display validity in detecting people susceptible to alcoholism, particularly before the onset of alcoholism or during periods of stable abstinence. Second, it should be easily and reliably measured. Third, it should be specific for alcoholism only and not affected by other medical or psychiatric disorders or drugs. Since alcoholism is a complex disease, it is likely that more than one type of gene and protein exist as trait marker.

State markers or markers of alcohol consumption serve several important purposes. First, they can assist physicians in diagnosing individuals with chronic drinking problems, particularly patients who deny excessive drinking. Moreover, they may also

identify individuals in early stages of heavy drinking, thus avoiding the long-term medical, psychological, and social consequences of chronic alcoholism. Second, state biomarkers can aid in the diagnosis and treatment of other diseases (liver diseases, pancreatitis, and cardiovascular diseases) that were, at least, caused by excessive drinking. Third, they are useful in alcohol treatment and prevention programs. Since the goal of many of programs is abstinence, monitoring relapse is important in gauging success. Last, state biomarkers are important in clinical alcohol trials. Although self-reports have become more sophisticated and valid (e.g., Timeline Followback), they still rely on accurate reporting. These new and reliable biomarkers could then be used to confirm the self-report. Several biomarkers with certain limitations are currently in use including carbohydrate-deficient transferrin (CDT), gamma glutamy transferase (GGT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), and mean corpuscular volume (MCV). New state markers need to be developed that incorporate the following attributes: validity, reliability, stability, cost, practicability, acceptability, and transportability.

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

A. Develop and evaluate clinically alcohol-sensitive biomarkers to identify individuals who are predisposed to alcoholism; determine relapse; measure levels of drinking; and determine alcohol-induced tissue damage.

B. Identify genes, and proteins that are expressed during the development of alcohol dependence for biomarker development.

C. Develop methodologies for high throughput identification of alcohol metabolites and other signaling molecules that are expressed during alcohol intake.

D. Use knowledge of genetic and molecular mechanisms underlying alcohol-induced organ damage (including alcohol-related liver, pancreas, heart disease and FAS) to develop new biomarkers of tissue and cell damage.

E. Evaluate clinically innovative alcohol-sensitive biomarkers (trait, relapse, organ damage) for sensitivity and specificity.

For clinical questions contact:

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For pre-clinical questions, contact:

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**Other Research Topic(s) Within the Mission of the Institute**

For additional information on research topics, contact:

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For administrative and business management questions, contact:

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## NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

The NIAID's Division of AIDS, Division of Allergy, Immunology, and Transplantation, and Division of Microbiology and Infectious Diseases fund SBIR/STTR grants on topics related to their mission and activities as described below. Questions on specific research areas may be addressed to the NIAID Program Officials listed below. General questions on the NIAID SBIR and STTR programs and on administrative and business management may be addressed to contacts listed for the NIAID section. When possible, *applicants are encouraged to use email* for communication.

For information about NIAID's Small Business High-Priority Areas of Interest, please visit http://www.niaid.nih.gov/ncn/sbir/sbirareas.htm.

**Phase II Competing Renewal Awards**

The NIAID will accept Phase II SBIR/STTR Competing Renewal SBIR/STTR grant applications to continue the process of developing products that require approval of a Federal regulatory agency (e.g., FDA). Projects that are particularly encouraged include those in the NIAID Small Business High Priority Areas of Interest (http://www.niaid.nih.gov/ncn/sbir/sbirareas.htm) and also:

- therapeutics (drugs or antibodies) to treat HIV infections
- therapeutics (drugs or antibodies) for HIV-related opportunistic infections
- anti-inflammatory therapeutics
- transgenic transplantation strategies
- new or improved vaccines, antiviral or antimicrobial agents for infectious diseases

NIAID will accept Phase II Competing Renewal applications for a project period of up to three years and a budget not to exceed a total cost of $1 million per year (including direct cost, F&A, and fee/profit) provided the time period and amount are well justified.

The total amount of all consultant costs and contractual costs normally may not exceed 50% of the total costs requested for initial SBIR Phase II applications. SBIR Phase II Competing Renewal grant applications may exceed this guideline, however, when well justified and when those costs are necessary to support clinical studies or trials and related expenses. Examples of well founded reasons for exceeding this guideline include, but are not limited to, subcontracts for safety, toxicity, or efficacy testing in animals, subcontracts to clinical research organizations to carry out aspects of clinical evaluation or subcontracts to assure compliance with Good Manufacturing Practices expectations of the FDA.

Human clinical trials may not be a component of the proposed research. As announced in Notice NOT-AI-05-021 (http://grants.nih.gov/grants/guide/notice-files/NOT-AI-05-021.html) NIAID will only support investigator-initiated clinical trials through a two part grant process: (1) a clinical trial planning grant followed by (2) a clinical trial implementation cooperative agreement.

NIAID does NOT request a letter of intent. However, prior to submission of a Competing Renewal application, applicants are strongly encouraged to contact:

Gregory Milman, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Room 2153, MSC-7610
6700-B Rockledge Drive
Bethesda, MD 20892-7610 (US Mail)
Rockville, MD 20817-7610 (Delivery Services)
Telephone (301) 496-8666
Fax: (301) 402-0369
Email: gm16s@nih.gov

**Division of AIDS**

The Division of AIDS (DAIDS) supports research on the pathogenesis, natural history, and transmission of HIV and HIV disease, and promotes progress in its detection, treatment, and prevention.

Director: Dr. Ed Tramont
(301) 496-0545
Email: et89f@nih.gov

**BIOSTATISTICS RESEARCH BRANCH**

Statistical methods in HIV studies.

Dr: Misrak Gezmu
(301) 435-3722
Email: mgezmu@niaid.nih.gov

**BASIC SCIENCES PROGRAM**

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

Director: Dr. Carl Dieffenbach
(301) 496-9112
Email: cdd@nih.gov

A. ***Epidemiology Branch.*** Population-based research of HIV transmission and associated biological, behavioral, and environmental factors including correlation between immunologic and virologic events and clinical outcome trends in natural history; correlation between immunologic and virologic events and clinical outcome; and trends in natural history.

Contact: Joana Roe
(301) 435-3759
Email: jr108r@nih.gov

B. ***Pathogenesis Branch.*** Molecular and cellular biology, virology, and immunology of virus-host interactions and mechanisms of immunopathogenesis and HIV transmission.

Contact: Ann Namkung, M.P.H.
(301) 496-9176
Email: an107z@nih.gov

C. ***Targeted Interventions Branch.*** Research areas: (1) targeted therapeutics emphasizing under-explored viral and cellular targets; (2) innovative therapeutic strategies including immune-based and gene-based therapies and therapeutic vaccines; (3) translational research for effective therapeutics spanning preclinical discovery to pilot clinical studies in humans; (4) preclinical discovery and development of topical microbicides and other entities for non-vaccine prevention strategies; and (5) animal models for evaluating new therapeutic entities, regimens, and strategies.

Contact: Dr. Roger Miller
(301) 496-6430
Email: rm42i@nih.gov

**VACCINE AND PREVENTION RESEARCH PROGRAM**

Supports the development of vaccines and other biomedical and behavioral interventions to prevent AIDS.

Director: Dr. Margaret (Peggy) Johnston
(301) 402-0846
Email: pj7p@nih.gov

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

Acting Chief: Dr. Joseph Chiu
(301) 402-2311
Email: jchiu@niaid.nih.gov

B. ***Prevention Science Branch.*** Conduct of 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. Basic research on mechanisms of sexual and mother-to-child HIV transmission supportive of new biomedical strategies for interrupting transmission. Translational research on microbicides, spanning preclinical through pilot human clinical research. Pilot clinical studies of the performance of microbicide vehicles and applicators with regard to coverage of and persistence on mucosal surfaces as well as behavioral acceptability.

Acting Chief: Dr. Monica Ruiz
(301) 435-8896
Email: mruiz@niaid.nih.gov

C. ***Preclinical Research and Development Branch.*** Support of applied preclinical development of candidate AIDS vaccines, delivery methods, 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 trials in non-human primates; genetic and immunologic variation; and mucosal immunity in SIV, HIV, and SHIV models.

Contact: Dr. Yen Li
(301) 496-3816
Email: yl81g@nih.gov

**THERAPEUTICS RESEARCH PROGRAM**

Develops and oversees research and development of therapies for HIV disease, including complications and co infections, and cancers, in adults, infants, children, and adolescents.

Director: Dr. Sandra Lehrman
(301) 496-8210
Email: slehrman@niaid.nih.gov

A. ***Clinical Research Management Branch.*** Management of grants and contracts supporting therapeutic clinical trials.

Chief: Ms. Margaret Matula
(301) 496-8214
Email: mmatula@niaid.nih.gov

B. ***Drug Development and Clinical Sciences Branch.*** Discovery and preclinical development of experimental therapies for HIV, TB and other infectious diseases; maintenance of a database of potential anti-HIV and -OI compounds; immunologic, virologic, and