National Institutes of Health
Office of Extramural Research

HHS SBIR Contract RFP Informational Webinar PHS 2016-1

August 13, 2015

NIH and CDC SBIR and Contracts Staff

Hosted by Matthew Portnoy, Ph.D.

NIH SBIR/STTR Program Coordinator

Agenda

1. Overview of SBIR and contract RFP
2. Differences from HHS SBIR grant program
3. Deadlines for Q&A and proposals
4. Electronic proposal submission with eCPS
5. Overview of topics
   - a. NCI
   - b. NCATS
   - c. NHLBI
   - d. NIAAA (no slides)
   - e. NIAID
   - f. NIDA (no slides)
   - g. CDC

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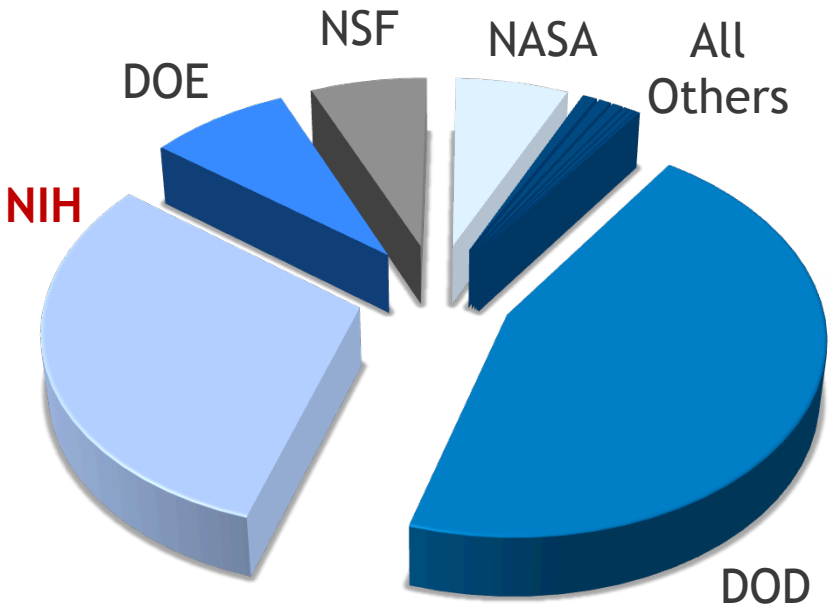
SBIR/STTR Budgets by Agency FY2013



~ $2.3B in FY13 across all agencies

Agencies with SBIR and STTR Programs	
Department of Defense (DOD)	$ 1.0 B
Department of Health and Human Services: National Institutes of Health (NIH)	**$697.0 M**
Department of Energy (DOE), including ARPA-E	$183.9M
National Science Foundation (NSF)	$153.0 M
National Aeronautics and Space Administration (NASA)	$ 148.8 M
Agencies with SBIR Programs	
U.S. Department of Agriculture (USDA)	$18.4M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) and Domestic Nuclear Detection Office (DNDO)	$15.7 M
Department of Education (ED)	$13.4 M
Department of Transportation (DOT)	$7.6 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)	$7.4 M
Environmental Protection Agency (EPA)	$3.8 M

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HHS Program Funding

2015 Budget	SBIR	STTR
NIH	$691M	$95M
CDC	$7.0M	N/A
ACL (NIDILRR)	$2.7M	N/A
FDA	$1.5M	N/A
ACF	$88K	N/A

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NIH SBIR/STTR 3-Phase Program

Discovery

Phase I

Phase I Feasibility Study

Budget Guide: $150K for SBIR and STTR
Project Period: 6 months (SBIR); 1 year (STTR)

Development

Phase II

Phase II Full Research/R&D

$1M for SBIR and STTR, over two years

Phase IIB

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/Tools to FDA
Many, but not all, IC's participate
Varies~$1M per year; up to 3 years

Commercialization

Phase III

Phase III Commercialization Stage

NIH, generally, not the "customer"
Consider partnering and exit strategy early

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NIH SBIR/STTR Website

http://sbir.nih.gov

Solicitations and Due Dates

- **NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation "Parent" FOAs; SBIR: PA-15-269 STTR: PA-15-270**

  Released: **June**

  Standard Due Dates: September 5, January 5, April 5

- **SBIR Contract Solicitation (NIH, CDC)**

  Release: **July 24, 2015** Close Date: **October 16**

- **NIH Guide for Grants and Contracts**

  Release: Weekly Receipt dates specified in each FOA

  (http://grants.nih.gov/grants/guide/index.html)

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HHS SBIR Contract RFP Sources

https://sbir.nih.gov/funding#phased1 NIH SBIR site

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HHS SBIR Contract RFP Sources

http://grants.nih.gov/grants/forms.htm#contracts

NIH SBIR contract site

SBIR Contracts		
PHS 2016-1 (PDF – 2 MB) **PHS 2016-1** (MS Word - 2 MB)	07/2015	**Competing - SBIR Phase I and II Contract Solicitation** Receipt date: October 16, 2015, 5PM EDT **Forms for Phase I** Proposals: Appendices: **A** (PDF - 88 KB or MS Word - 31 KB **B** (PDF - 86 KB or MS Word - 30 KB), **C** (PDF - 124 KB or MS Word - 47 KB) **Forms for Phase II and Fast-Track** Proposals: Appendices: **B** (PDF - 86 KB or MS Word - 29 KB), **C** (PDF - 124 KB or MS Word - 30 KB), **D** (PDF - 90 KB or MS Word - 31 KB), **E** (PDF - 14 KB or MS Word - 31 KB), **F** (PDF - 94 KB or MS Word - 26 KB), **G** (PDF - 265 KB or MS Word - 35 KB) **Forms for Fast-Track** Proposals: ALL Forms (Appendices A-G) are REQUIRED

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HHS SBIR Contract RFP Sources

https://www.fbo.gov/index?s=opportunity&mode=form&id=7f61705626fff25456ed99edeec703da&tab=core&_cview=1

A SOLICITATION OF THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) CONTRACT PROPOSALS

Solicitation Number: PHS-2016-1
Agency: Department of Health and Human Services
Office: National Institutes of Health
Location: National Institute of Allergy and Infectious Diseases

Notice Details | Packages | Print | Link

Complete View
- Original Synopsis
  Presolicitation
  Jul 02, 2015
  3:21 pm
- Changed
  Jul 24, 2015
  2:32 pm
  Solicitation

Return To Opportunities List | Watch This Opportunity | Add Me To Interested Vendors

Solicitation Number: PHS-2016-1

Notice Type: Solicitation

Synopsis:
Added: Jul 02, 2015 3:21 pm Modified: Jul 24, 2015 2:29 pm Track Changes

National Institutes of Health, Bethesda, MD 20892 and Centers for Disease Control and Prevention, Atlanta, GA 30305 are soliciting proposals from small business concerns that possess the research and development (R&D) expertise to conduct innovative research that will contribute toward meeting the program objectives of the agencies.

ALL FILES
Solicitation 1
Jul 24, 2015
PHS2016-1.pdf

GENERAL INFORMATION
Notice Type:
Solicitation
Original Posted Date:
July 2, 2015
Posted Date:
July 24, 2015
Response Date:
Oct 16, 2015 5:00 pm Eastern
Original Response Date:
Oct 16, 2015 5:00 pm

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

PROGRAM SOLICITATION PHS 2016-1

Closing Date: October 16, 2015, 5:00 PM Eastern Daylight Time

Participating HHS Components:

- The National Institutes of Health (NIH)
- The Centers for Disease Control and Prevention (CDC)

IMPORTANT

Deadline for Receipt: Proposals must be received by October 16, 2015, 5:00 PM Eastern Daylight Time.

Please read the entire solicitation carefully prior to submitting your proposal.

IMPORTANT: All proposals must be submitted using the new electronic contract proposal submission (eCPS) website. **Paper proposals will not be accepted.**

Please go to https://www.sbir.gov/sites/default/files/sbir_pd_with_1-8-14_amendments_2-24-14.pdf to read the SBIR/STTR Policy Directive issued by the Small Business Administration for further information.

Overview of RFP

1 INTRODUCTION
2 PROGRAM DESCRIPTION
3 DEFINITIONS
4 PROPOSAL FUNDAMENTALS
5 CONTRACT REQUIREMENTS
6 METHOD OF EVALUATION
7 PROPOSAL SUBMISSION
8 PROPOSAL PREPARATION AND INSTRUCTIONS
9 HHS COMPONENTS ANTICIPATED NUMBER OF AWARDS
10 CONTRACTING OFFICER POINTS OF CONTACT
11 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES
12 COMPONENT INSTRUCTIONS AND TECHNICAL TOPIC DESCRIPTIONS

#1 Piece of Advice

Read the entire RFP several times

Section 2.6 Awarding Components

- National Institutes of Health (NIH):
  - NCI
  - NCATS
  - NHLBI
  - NIAAA
  - NIAID
  - NIDA
- Centers for Disease Control and Prevention (CDC):
  - Center for Global Health (CGH)
  - National Center for Emerging Zoonotic and Infectious Diseases (NCEZID)
  - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)
  - National Center for Immunization and Respiratory Diseases (NCIRD)

Types of SBIR Proposals Allowed Section 1 and 12

TOPIC NUMBER	PHASE I PROPOSAL ALLOWED? (INCLUDES ONLY A PHASE I PROPOSAL)	FAST TRACK PROPOSAL ALLOWED? (INCLUDES A PHASE I PROPOSAL AND A PHASE II PROPOSAL)	DIRECT TO PHASE II ALLOWED? (INCLUDES ONLY A PHASE II PROPOSAL)	TOPIC TITLE
NIH/ NCI 341	Yes	Yes	No	Development of Metabolomics Data Integration Methods and Software
NIH/ NCI 342	No	No	Yes	Validation of Mobile Technologies for Clinical Assessment, Monitoring and Intervention
NIH/ NCI 343	Yes	Yes	No	An Electronic Platform for Cognitive Assessment in Cancer Patients
NIH/ NCI 344	Yes	No	No	Technologies for Differential Isolation of Exosomes and Oncosomes

What is a complete Phase I submission? Section 8.3

TECHNICAL PROPOSAL (1 PDF)

- Item 1: Technical Element
- Proposal Cover Sheet Appendix A
- Table of Contents
- Abstract of the Research Plan, (Appendix B)
- Content of the Technical Element

BUSINESS PROPOSAL (1 PDF)

- Item 2: Pricing Proposal (Appendix C)
- Item 3: SBIR Application VCOC Certification, if applicable
- Item 4: Proof of Registration in the SBA Company Registry

What is a complete Phase II submission? Section 8.4

TECHNICAL PROPOSAL (1 PDF)

- Item 1: Technical Element
- Technical Proposal Cover Sheet Appendix D
- Table of Contents
- Abstract of the Research Plan, (Appendix B)
- Content of the Technical Element
- Draft Statement of Work (Appendix E)
- Summary of Related Activities (Appendix F)
- **BUSINESS PROPOSAL (1PDF)**
- Item 2: Pricing Proposal (Appendix C)
- Item 3: SBIR Application VCOC Certification, if applicable
- Item 4: Proof of Reg. in the SBA Company Registry

Human Subjects or Vertebrate Animal Work?

- Section 3 for Definitions
- Section 4.9 Research Involving Human Subject
- Section 4.10 Inclusion of Women, Minorities, and Children in Clinical Research
- Section 4.11 Care of Vertebrate Animals
- Section 8.9 Human Subjects Research and Protection from Risk Instructions
- Section 8.10 Inclusion of Women, Minorities, and Children in Clinical Research Instructions
- Section 8.11Research Involving Human Fetal Tissue Instructions
- Section 8.12 Research Involving Vertebrate Animals Instructions

Page Limits Section 7.3

- SBIR Phase I technical proposals (Item 1) shall not exceed 50 pages.
- SBIR Phase II technical proposals (Item 1) shall not exceed 150 pages.
- Fast Track = a complete Phase I + a complete Phase II
- Single-sided, single-spaced pages for entire proposal
- All inclusive [including all pages, cover sheet(s), tables, CVs, resumes, references, pictures/graphics, and all enclosures, appendices or attachments, etc.]
- No exclusions to page limits. Pages in excess of the page limitation will be removed from the proposal and will not be considered or evaluated

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    f. NIDA (no slides)
    g. CDC

Differences between contracts and grants

Contracts	Grants
Acquisition mechanism	Assistance mechanism
Follows FAR and SBIR Policy Directive	Follows Grants Policy and SBIR PD
NOT Investigator Initiated	Investigator Initiated
Narrow, well defined topics	Broad or narrow topics
RFP: Offeror: Contractor: Proposal	PA, PAR, RFA: Applicant: Grantee: Application
Only contact is Contracting Officer	Call PO anytime for anything
eCPS – New (used to be on paper)	SF424, grants.gov, eRA Commons

Differences between contracts and grants

	Need to use for Contract?
SBIR Company Registry	Yes – for all offerors
VCOC Certification	Yes, if applicable
DUNS	Yes
SAM	Yes (at time of award)
Grants.gov	No
eRA Commons	No (can use to reg in eCPS)
Electronic Contact Proposal Submission (eCPS)	Yes – required to submit all proposals to PHS 2016-1

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Question Deadline Section 7.1

- Reminder only contact is with Contracting Officer listed in Section 10.
- Questions must be submitted in writing (email) to the Contracting Officer.
- **Deadline for Questions is August 21, 2015 close of business.**
- An Q&A Amendment will be issued in early-mid September in FBO and on NIH SBIR websites.
  - **Yes your questions and the answers will be posted to the public.**
- Additional questions will be answered at the discretion of the CO.

Deadline for receipt of ALL Proposals

FRIDAY October 16, 2015

5:00 PM Eastern Daylight Time

Electronic submission must be complete.

No paper submissions.

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Electronic Submission of Proposals

- REQUIRED for ALL PROPOSALS
- Paper proposals no longer accepted
- Section 7.4 Submission, Modifications, Revision, and Withdrawal of Proposal

electronic Contract Proposal Submission (eCPS)

https://ecps.nih.gov/sbirsttr

Live demo of eCPS

https://ecps.nih.gov/sbirsttr

Proposal Name

- The Proposal Name you enter in eCPS shall include:

- Proposal Name Format
  1) The phase the proposal is for
  2) The name of the offeror
  3) The NIH or CDC awarding component
  4) The topic being proposed under

- Name Format Sample: Phase I_XYZ Company_NIAID_Topic 033

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Technical and Business File Names

- Shall include
  - Offeror name
  - NIH or CDC awarding component
  - Topic being proposed under
  - Type of proposal (i.e., Technical, Business or Excel Workbook)
- Technical Proposal sample name
  - XYZ Company_NIAID_TOPIC_033_Technical.pdf
- Business Proposal sample name
  - XYZ Company_NIAID_TOPIC_033_Business.pdf
- Excel Workbook (optional)
  - XYZ Company_NIAID_TOPIC_033_Business.xlsx

Submitting a Fast Track Proposal

How do I submit a FAST TRACK Proposal?

For Phase I – include "FAST TRACK" after the Phase. Example:

- Phase I FAST TRACK_XYZ Company_NIAID_Topic_033

Upload the Phase I technical and business proposals and click Submit

After Phase I submission, click "Submit new/alternate proposal" button

For Phase II – include "FAST TRACK" after the Phase. Example:

- Phase II FAST TRACK_XYZ Company_NIAID_Topic_033

Upload the Phase II technical and business proposals and click Submit

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    f. NIDA (no slides)
    g. CDC

SBIR & STTR

NATIONAL CANCER INSTITUTE

NCI SBIR
Contract Funding Opportunities

http://sbir.cancer.gov/funding/contracts

SBIR Contracts vs. Grants

	SBIR Grants	SBIR Contracts
Scope of the proposal	Investigator-defined within the mission of NIH	**Defined (narrowly) by the NIH**
Questions during solicitation period?	May speak with any Program Officer	**MUST** contact the contracting officer [eshanahan@mail.nih.gov]
Receipt Dates	3 times/year for Omnibus	Only ONCE per year
Peer Review Locus	NIH Center for Scientific Review (CSR)	**NCI DEA (target 50% business reviewers)**
Basis for Award	Peer review score/ Program assessment	Peer review score/negotiation of technical deliverables, budget
Reporting	One final report (Phase I); Annual reports (Phase II)	Kickoff presentation, quarterly progress reports, final report, commercialization plan
Set-aside funds for particular areas?	No	Yes
Program Staff Involvement	Low	**High**

Funding Opportunity Summary

- **PHS-2016-1 "HHS Small Business Innovation Research (SBIR) Program Contract Solicitation"**

- **ONE application receipt date per year:**
  - Published July 24, 2015

Receipt Date: October 16, 2015, 5:00 PM ET

- **RFP can be found at:**
  - http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-130.html

- **More info about NCI's topic areas:**
  - http://sbir.cancer.gov/funding/contracts/

NCI Contract Topics for FY16

SBIR & STTR

http://sbir.cancer.gov/funding/contracts

- **NIH/NCI 341:** Development of Metabolomics Data Integration Methods and Software
- **NIH/NCI 342:** Validation of Mobile Technologies for Clinical Assessment, Monitoring, and Intervention
- **NIH/NCI 343:** An Electronic Platform for Cognitive Assessment in Cancer Patients
- **NIH/NCI 344:** Technologies for Differential Isolation of Exosomes and Oncosomes
- **NIH/NCI 345:** Predictive Biomarkers of Adverse Reactions to Radiation Treatment
- **NIH/NCI 346:** Molecularly Targeted Radiation Therapy For Cancer Treatment
- **NIH/NCI 347:** Signal Amplification to Enable Attomolar Quantitation in Slide-Based or ELISA Biomarker Immunoassays
- **NIH/NCI 348:** Identification and Capture of Enriched Tumor Zones with Preservation of Labile Bi omarkers from Ultra-Cold Biopsies
- **NIH/NCI 349:** Proximity Slide Based Sandwich Immunoassay to Visualize Intramolecular Epitopes of Analytes in Tissue Sections
- **NIH/NCI 350:** Highly Innovative Tools for Quantifying Redox Effector Dynamics in Cancer
- **NIH/NCI 351:** Modulating the Microbiome to Improve Efficacy of Cancer Therapeutics
- **NIH/NCI 352:** Cell and Animal-Based Models to Advance Cancer Health Disparity Research
- **NIH/NCI 353:** Cell-Free Nucleic Acid-Based Assay Development for Cancer Diagnosis
- **NIH/NCI 354:** Companion Diagnostics for Cancer Immunotherapies

NIH/NCI 341: Development of Metabolomics Data Integration Methods and Software

SBIR & STTR

Budget: Phase I $225,000 for 9 months; Phase II $1.5M for 2 years
Number of Anticipated Awards: 22 3
Fast-Track proposals will be accepted.
*Direct-to-Phase II will **not** be accepted.*

Goal: support the development of new and innovative methods to integrate metabolite data across analytical technologies and laboratory platforms, and in turn, design software tool(s) applying these methods for data integration.

Phase I Activities & Deliverables Include:

- Develop database formats that support the import and export of individual datasets and "combined" datasets, store structured data from different sources of metabolite data, and are readily used for data integration and QC protocols.
- Provide wireframes and user workflows for the proposed Graphical User Interface (GUI) and software functions
- Develop functional prototype software that integrates data from planned Phase I technology compatibility matrix data sources using automated algorithms and methods.

NIH/NCI 342: Validation of Mobile Technologies for Clinical Assessment, Monitoring, and Intervention

SBIR & STTR

Budget: Phase II $1.5M for 2 years
Number of Anticipated Awards: 2-3
Phase I proposals **not** accepted. *Fast-Track proposals **not** accepted.*
Direct-to-Phase-II proposals accepted.

Goal: support validation of mobile technologies for clinical assessment, screening, di agnostics, monitoring or intervention delivery focused on cancer prevention, and control objectives. *This topic in not intended to support the development of new technologies.*

Responses to this topic are expected to address one or more of the following areas of mobile/wireless health research:

- Evaluation of the reliability of mobile screening, diagnostic, assessment or monitoring technologies & methods
- Evaluation of the validity of mobile screening, diagnostic, assessment or mon itoring technologies & methods
- Evaluation of the efficacy and effectiveness of mobile technology and systems for behavioral analytics, clinical decision support, or intervention delivery.

NIH/NCI 343: An Electronic Platform for Cognitive Assessment in Cancer Patients

SBIR & STTR

Budget: Phase I $225,000 for 9 months; Phase II $1.5M for 2 years
Number of Anticipated Awards: 1 – 3
Fast-Track proposals accepted.
*Direct-to-Phase II proposals **not** accepted.*

Goal: Develop a scalable, secure, and privacy-compliant software system, and tools to support computerized administration of brief cognitive assessments specifically focused on measuring the subtle cognitive changes associated with cancer and cancer treatment.

Short Term Goals:

-Develop innovative software systems which support brief, remotely administered patient assessments & scoring of cognitive processes affected by cancer & cancer treatment
-Develop paired provider portal tools for remote administration & management of patient assessments and results
-Conduct user testing of the client side assessment tools and modes of administration
-Conduct clinical validation of the cancer cognitive assessment instruments delivered via the software system

Phase I Activities & Deliverables Include:

- Develop a functional prototype system
- Conduct user testing of client side software visual designs (or functional software) and proposed user experience
- Provide a report detailing output reporting systems feasibility, proposed timelines, data standards, & communcation architecture for reporting summary outputs to patients/subjects, clinicians/researchers, electronic medical records, and health surveillance systems.

NIH/NCI 344: Technologies for Differential Isolation of Exosomes and Oncosomes

SBIR & STTR

Budget: Phase I $300,000 for 9 months; Phase II $2M for 2 years
Number of Anticipated Awards: 2-3
*Fast-Track proposals **not** accepted. Direct-to-Phase II proposals **not** accepted.*

Goal: Support the development of large scale or high-throughput technologies for di fferential isolation of tissue-specific exosomes and tumor-derived oncosomes from any body fluid(s). Obtain enrched,distinct preparations useful for downstream comparative molecular profiling or therapeutic use.

Phase I Activities & Deliverables Include:

- Develop a technology for differential isolation of exosomes with highly selective isolation of oncosomes from the exosome population.
- Demonstrate that the technology can obtain distinct preparations of exosomes and oncosomes from the routinely collected fresh/archived body fluids, and yields sufficient quantity for downstream analysis.
- Demonstrate that the reproducibility is >90% and yield is >70%
- Demonstrate the integrity of exosomes/oncosomes is >80% using physicochemical methods
- Benchmark the developed technology against at least 2 current techniques & demonstrate comparable purity and yield from clinically appropriate sample sizes for the specific bodily fluid.

NIH/NCI 345: Predictive Biomarkers of Adverse Reactions to Radiation Treatment

SBIR & STTR

Budget: Phase I $300,000 for 6-12 months; Phase II $2M for 2 years
Number of Anticipated Awards: 2 – 3
Fast-Track proposals accepted.
*Direct-to-Phase II proposals **not** accepted.*

Goal: Identify, develop, and validate a simple, cost-effective biomarker(s) to rapidly assess inter-individual differences in radiation sensitivity and predict early and late complications among patients with cancer prior to radiation therapy.

Phase I Activities & Deliverables Include:

- Develop a working qualitative test correlating the presence or absence of the biomarker(s) with potential outcome or a quantitative assay to assess radiation sensitivity
- Provide assay characteristics, including but not limited to performance, reproducibility, specificity, and sensitivity data using frozen (or other) samples from past clinical trials, or retrospective clinical studies providing adequate power calculations
- Demonstrate suitability of the test for use in the clinic, including kinetics of biomarker, if transient.
- Determine the effect of confounders, such as any induction or concurrent chemotherapy regimens.

NIH/NCI 346: Molecularly Targeted Radiation Therapy For Cancer Treatment

Budget: Phase I $300,000 for 9 months; Phase II $2M for 2 years **Number of Anticipated Awards:** 2 – 3
Fast-Track proposals accepted.
*Direct-to-Phase II proposals **not** accepted.*

- **Goal:** stimulate research, development, and commercialization of innovative TRT techniques that could potentially shorten treatment cycles and reduce toxi city to normal tissues.

Phase I Activities & Deliverables Include:

- Proof-of-concept of the conjugation or attachment of the radioisotope to the antibody or other targeting moiety.
- Radiation dosimetry studies in an appropriate small animal model
- Proof-of-concept small animal studies demonstrating an improved therapeutic efficacy and improved therapeutic index, assessment of toxicity to normal tissues, and pharmacokinetic/pharmacodynamic studies utilizing an appropriate animal model.

NIH/NCI 347: Signal Amplification to Enable Attomolar Quantitation in Slide-Based or ELISA Biomarker Immunoassays

SBIR & STTR

Budget: Phase I $225,000 for 6 months; Phase II $1.5M for 2 years **Number of Anticipated Awards:** 2 – 3
Fast Track proposals accepted.
Directl tol Phase II proposals ***not*** *accepted.*

Goal: Incorporate recent advances in signal amplification methods into the development of quantitative ELISA and/or slide-based antibody assays (IFA/IHC) to low abundance but high value cancer biomarkers.

Phase I Activities & Deliverables Include:

- The amplification technology must provide a significant improvement in assay sensitivity (10^2-10^6 fold) to high value low abundant cancer biomarkers using tumor tissue. Two assays are to be developed with the new amplification system.
- The amplification technology must be consistently manufacturable, and if new instrumentation is required, size and cost of prototype instrumentation should be within reach of a clinical lab.
- Any alteration in the assay design or assay protocol as an attempt to increase the sensitivity of the assay constitutes a critical issue and introduces bias resulting from the changes made.

NIH/NCI 348: Identification and Capture of Enriched Tumor Zones with Preservation of Labile Biomarkers from Ultra-Cold Biopsies

Budget: Phase I $300,000 for 9 months; Phase II $2M for 2 years **Number of Anticipated Awards:** 2 – 3
Fast Track proposals accepted.
Direct-to-Phase II proposals **not** accepted.

Goal: Develop a reliable visualization approach to identify and capture zones of 'viab le' tumor cells from frozen solid tumor biopsies that lead to at least 50% enri chment of tumor zones.

Phase I Activities & Deliverables Include:

- Develop a microscopic visualization/microdissection method to identify and capture 'viable/cellular' tumor zones from frozen tumor biopsies/thick sections from at least two solid tumor types while maintaining the frozen state of the specimen.
- The purity and cellularity of the captured zones can be assessed by H&E staining and imaging.
- Demonstrate that the visualization/capture technology preserves in the enriched tumor cells at least one of labile protein biomarkers of interest to NCI.
- The device and methodology need to be independently tested at a different laboratory.

NIH/NCI 349: Proximity Slide Based Sandwich Immunoassay to Visualize Intramolecular Epitopes of Analytes in Tissue Sections

SBIR & STTR

Budget: Phase I $300,000 for 6 months; Phase II $2M for 2 years **Number of Anticipated Awards:** 2 – 3
Fast Track proposals accepted.
Direct-to-Phase II proposals **not** accepted.

Goal: develop reagents/methods for use of dual primary antibodies to different epitopes of the same analyte or to different subunits of a target that, upon binding of the molecule(s) in cells within a tissue section, will generate a proximity signal due to close spatial association of the antibody reagents containing donor/acceptor tags, respectively (e.g., flurochromes).

Phase I Activities & Deliverables Include:

- Develop Reagent parameters [proximity tags], assay parameters, imaging platform paramet ers, and image capture and analysis strategy for the proximity measurements.
- Select appropriate donor and acceptor probes for the 2 analyte specific antibodies chosen for each target and determine the manner in which they are employed as molecular labels to obtain optimal energy transfer/signal
- Optimize reaction and stabilization conditions. Develop measurement strat egy for capturing the intensity of signal.
- Prove that proximity signals are emanating from the same protein molecules, rather than adjacent or nearby protein molecules.

NIH/NCI 350: Highly Innovative Tools for Quantifying Redox Effector Dynamics in Cancer

SBIR & STTR

Budget: Phase I $225,000 for 9 months; Phase II $1.5M for 2 years **Number of Anticipated Awards:** 3 – 4
Fast Track proposals accepted.
Direct-to-Phase II proposals **not** accepted.

Goal: Develop quantitative tools to measure redox dynamics in biological systems.

Phase I Activities & Deliverables Include:

- Describe the current state of the art technologies for sensing and measuring the redox effector being addressed by their proposal, and outline the advantages that their approach wi ll offer.
- Develop and characterize a redox probe or biosensor.
- Develop an assay or system that demonstrates proof2 of2 concept testing and benchmark ing of specificity and sensitivity parameters of the agent or syst em for a range of redox effector species
- Demonstrate feasibility to sense, interrogate, detect or resolve the spatiotemporal dynamics of redox effector species in live cells or animal model, ideally with a minimally invasive perturbation of the system.

NIH/NCI 351: Modulating the Microbiome to Improve Efficacy of Cancer Therapeutics

SBIR & STTR

Budget: Phase I $300,000 for 9 months; Phase II $2M for 2 y
ears **Number of Anticipated Awards:** 3 – 4
*Fast Track proposals **not** accepted.*
Direct-to-Phase II proposals **not** accepted.

Goal: Develop innovative technologies and methods designed to modulate the GI microbiota in order to enhance the therapeutic efficacy of existing or novel cancer therapies, or ameliorate sid e effects of these therapies.

Phase I Activities & Deliverables Include:

- Define and characterize a microbial activity/interaction that affects therapeutic efficacy, d emonstrated through appropriate *in vitro* and *in vivo* experiments.
- Develop targeted microbiota regulated/directed intervention strategies designed to improve, either alone or in combination, patient outcomes for new or current therapeutic agents.
- Test and refine therapeutic approaches.
- Lead candidate or agent should be able to successfully accomplish the desired perturbation or modulation of the microbiome to a level that can reasonably be expected to be have an i mpact on the efficacy of the therapeutic interventions.
- Determine and justify the assays and endpoints that will be used to evaluat e the success of their approach .

NIH/NCI 352: Cell and Animal-Based Models to Advance Cancer Health Disparity Research

Budget: Phase I $225,000 for 9 months; Phase II $1.5M for 2 y
ears **Number of Anticipated Awards:** 3 – 4
*Fast Track proposals **not** accepted.*
Direct-to-Phase II proposals **not** accepted.

Goal: Develop new, commercially available models relevant to diverse racial/ethnic populations. These models may be used to enhance research capabilities of basic scientists and/or provid
e novel tools to pharmaceutical companies for preclinical oncology studies.

Phase I Activities & Deliverables Include:

- Establish an experimental model relevant to CHD research that may include
  - Cancer cell line or primary cells established from racial/ethnic minorities
  - PDX animal model established from racial/ethnic minorities
  - GEM modelanimal model established from racial/ethnic minorities GEM model
- Validate the genetic ancestry of patients (if applicable) from which a model was established using a panel of ancestry informative makers (AIMs).

NIH/NCI 353: Cell-Free Nucleic Acid-Based Assay Development for Cancer Diagnosis

SBIR & STTR

Budget: Phase I $300,000 for 6 months; Phase II $2M for 2 y
ears **Number of Anticipated Awards:** 3 – 4
Fast Track proposals accepted.
Direct-to-Phase II proposals **not** accepted.

Goal: Develop a cfNA-based assay for clinical use in the evaluation of cancer diagnostics, prognostics, and response to therapy.

Phase I Activities & Deliverables Include:

- Select one or a set of validated cfNA markers with samples of a choice (e.g., plasma, serum or/and urine) for detection of a cancer or subtype (e.g., breast cancer or triple negative breast cancer).
- Develop an assay to identify these markers effectively to distinguish the cancer samples from healthy samples.
- Demonstrate high reproducibility and accuracy with the assay.
- Demonstrate high specificity and sensitivity of the assay.

NIH/NCI 354: Companion Diagnostics for Cancer Immunotherapies

Budget: Phase I $225,000 for 6-9 months; Phase II $1.5M for 2 years
Number of Anticipated Awards: 3 – 4
Fast Track proposals accepted.
Direct-to-Phase II proposals **not** accepted.

Goal: Develop companion diagnostic assays and technologies capable of identifying individual patients for whom a particular cancer immunotherapy regimen will be safe and effective.

Phase I Activities & Deliverables Include:

- Develop a working companion diagnostic test for a specific cancer immunotherapy regimen
- Characterize the variation, reproducibility, and accuracy of the test, and implement a QA/QC plan
- Demonstrate suitability of the test for use in the clinic, and conduct benchmarking studies against current tests (if available)
- Establish a collaboration or partnership with a diagnostic and/or pharmaceutical company and/or clinical/research institution that can provide relevant clinical trial specimens;

Questions About Contracts?

Ms. Rosemary M. Hamill

ncioasbir@mail.nih.gov

Please reference solicitation PHS 2016-1 and the Topic number with any questions.

http://sbir.cancer.gov/funding/contracts/

NCATS SBIR Contract Topics For NIH Pre-Proposal Webinar

PRESENTED BY: LILI M. PORTILLA, MPA
DIRECTOR, OFFICE OF STRATEGIC ALLIANCES, NCATS
AUGUST 13, 2015

NCATS

NCATS Topic 013 - Development of Stem Cell-Based Assays for High-Throughput Screening of Chemicals of Toxicological Concern

- Number of Anticipated Awards 2 to 3
  - Budget: Phase 1: up to $225K for up to 12 months
  - Budget: Phase 2: up to $1.5 million for up to 2 years

- For the Phase I contract, the goal is to develop toxicological related assays in homogenous format. These assays can be used for testing targets, pathways, and cellular phenotypes related to any xenobiotic toxicity in human stem cell or iPS-derived cells.
- For Phase II contracts, the goal is to miniaturize the assays into 384-well and preferably 1536-well plate format.

Questions? Please contact Jeffrey Schmidt via email at jeffrey.schmidt@nih.gov

NCATS Topic 014 – Development of Smart Plate Technology

- Number of Anticipated Awards 2 to 3
  - Budget: Phase 1: up to $225K for up to 9 months
  - Budget: Phase 2: up to $1.5 million for up to 2 years

- Phase 1: The key goal is to develop prototype specifications to transform a microtiter plate from being a single use vessel for experiments, to becoming one which could provide more data about the samples under test and real-time measurements.

- Phase 2: Build the prototype using Phase 1 specifications and evaluate its features.

Questions? Please contact Jeffrey Schmidt via email at jeffrey.schmidt@nih.gov

Contract Topics for the National Heart, Lung, and Blood Institute (NHLBI)

Questions? Contact:

John Taylor
taylorjc@nhlbi.nih.gov

Find resources and additional funding opportunities
http://www.nhlbi.nih.gov/sbir

National Heart, Lung, and Blood Institute

NHLBI 094 Transcatheter Cavopulmonary Bypass Endograft

- **Project Goals**
  - Development and testing of a transcatheter cavopulmonary bypass endograft clinical device, with FDA Investigational Device Exemption (IDE) for first-in-human testing in the US.
- **Phase I Activities and Expected Deliverables**
  - Activities will focus on the mechanical and biological performance of the proposed endograft.
  - Candidate design of a transcatheter endograft to be delivered using conventional interventional cardiovascular techniques to be selected for clinical development based on in vivo performance of a mature prototype resembling a final design.
- **Phase II Activities and Expected Deliverables**
  - Activities should align with required testing and development milestones agreed upon with the FDA .
  - IDE submission for a US-based first-in-human research protocol involving at least 10 subjects

Budget (total costs)
Phase I: up to **$250,000** for up to 12 months
Phase II: up to **$3,000,000** for up to 36 months

Fast-Track and Direct-to-Phase II proposals **will** be accepted.

Anticipated awards: 2

- NHLBI is willing to perform a limited number in vivo proof-of-principal experiments in swine to confirm mechanical performance.
- NHLBI offers, but does not require, to perform the clinical trial at no expense to the offeror, to participate in the development of the clinical protocol, and to provide clinical research services.
- The offeror is expected to perform or obtain safety-related in vivo experiments and data to support the IDE application.

NHLBI 095 Active MRI Transseptal Needle

- **Project Goals**
  - Development and testing of an active MRI transseptal needle catheter clinical device, with FDA Investigational Device Exemption (IDE) for first-in-human testing in the US.
- **Phase I Activities and Expected Deliverables**
  - A Phase I award would support the development and testing of actively visualized atrial transseptal needle system prototypes.
  - Deliverable is a complete clinically-relevant system
- **Phase II Activities and Expected Deliverables**
  - Regulatory development and testing for the device to be used in first-in-human investigation in the US
  - Deliverable is IDE or 510(k) clearance

Budget (total costs)
Phase I: up to **$200,000** for up to 12 months
Phase II: up to **$2,000,000** for up to 36 months

Fast-Track and Direct-to-Phase II proposals **will** be accepted.

Anticipated awards: 2

- NHLBI is willing to provide feedback about design at all stages of development, and will test the final deliverable device for success in vivo in swine. This requires specific hardware compatibility with the NIH Siemens Aera 1.5T MRI system.

NHLBI 096 Bioabsorbable Stents for Neonatal Aortic Coarctation

- **Project Goals**
  - Development of an absorbable scaffold stent for neonatal aortic coarctation.
- **Phase I Activities and Expected Deliverables**
  - The Phase I award is intended to support the development of a mature prototype with the requisite geometry, strength, deliverability, and absorption characteristics required for the clinical product.
- **Phase II Activities and Expected Deliverables**
  - The Phase II award is intended to result in an Investigational Device Exemption (IDE) for a first human clinical test in the United States.

Budget (total costs)
Phase I: up to **$400,000** for up to 12 months
Phase II: up to **$3,000,000** for up to 36 months

Fast-Track and Direct-to-Phase II proposals **will** be accepted.

Anticipated awards: 2

- NHLBI is willing to perform a limited number in vivo proof-of-principal experiments in swine to confirm mechanical performance.
- NHLBI offers, but does not require, to perform the clinical trial at no expense to the offeror, to participate in the development of the clinical protocol, and to provide clinical research services.
- The offeror is expected to perform or obtain safety-related in vivo experiments and data to support the IDE application.

NHLBI 097 Early Detection and Monitoring of Cardiac Injury Due to Cardiotoxicity

- **Project Goals**
  - Development of innovative methods to detect and monitor cancer therapy-induced cardiac injury as early as possible through minimally invasive means.
- **Phase I Activities and Expected Deliverables**
  - Proof-of-concept studies demonstrating feasibility. Examples may include: development of imaging methods to assess subclinical myocardial injury using clinical imaging modalities or biomarker-based monitoring methods.
- **Phase II Activities and Expected Deliverables**
  - Demonstration of strong proof of principle studies for which feasibility was successfully demonstrated in Phase I. It is expected that the Phase II awardees collect all the required preclinical data for regulatory filing.

Budget (total costs)
Phase I: up to **$250,000** for up to 12 months
Phase II: up to **$750,000** for up to 36 months

Fast-Track and Direct-to-Phase II proposals **will** be accepted.

Anticipated awards:
Phase I: 2 – 4
Fast-Track/D2P2: 1 - 3

PHS2016-1
SBIR Contract Topics for NIAID

National Institute of Allergy and Infectious Diseases

Topic 033

Precision Genome Engineering for HIV Eradication

- **Objective:** To design improved nucleases for disruption of integrated HIV provirus and/or essential cellular proteins, so HIV replication is no longer supported.

NIH National Institute of Allergy and Infectious Diseases

Topic 034

High-Throughput Assay Platform for Quantifying Latent HIV Reservoirs

- **Objective:** To develop innovative approaches to quantify latent, replication-competent HIV that are more efficient than a viral outgrowth assay (Q-VOA).

NIH National Institute of Allergy and Infectious Diseases

Topic 035

Method for the Detection of Minority Populations of Drug Resistant HIV

- **Objective:** To develop inexpensive methods to detect important minor variant mutations causing resistance to each of the antiretroviral drugs. These must be detected in all HIV subtypes. Methods that detect a set of relevant point mutations and methods that collect full sequences are both acceptable.

Topic 036

Simple, Inexpensive Device to Purify DNA from Sputum for Tuberculosis Testing

- **Objective:** To develop a simple, inexpensive device to purify DNA from sputum for use in molecular TB diagnostic and drug resistance testing. The purified DNA sample should be compatible with different technologies, thus removing the sample processing step from development of the tests. This would also allow the sputum processing to be done at the point of care.

NIH National Institute of Allergy and Infectious Diseases

Topic 037

Telemonitoring for Infectious Diseases: A Remote System for Assessing Patient Parameters and Specimen Analysis

- **Objective:** To develop a device that can, in a non-clinical setting, monitor and report data on the emergence & progression of an infectious disease. Systems that remotely monitor/report physiological status with minimally-invasive specimen collection would be critical in informing and supporting the clinical management of disease, e.g., premature infants at risk for RSV.

NIH National Institute of Allergy and Infectious Diseases

Topic 038

Innovative Oral Formulations for Anti-Infective Drugs

- **Objective:** To develop alternative formulations of FDA approved anti-infective agents for use in children and adults who have difficulty taking traditional tableted drugs.

NIH National Institute of Allergy and Infectious Diseases

Topic 039

Vaccines against Pathogens with Small Market Potential

- **Objective:** To promote the development of vaccines against pathogens with limited market potential. Examples of unmet vaccine needs include Valley Fever, Lyme disease, and vaccines for selected high risk populations.

NIH National Institute of Allergy and Infectious Diseases

Questions?

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NIH National Institute of Allergy and Infectious Diseases

Centers for Disease Control and Prevention

SBIR PHS 2016-1 Contract Topics
For HHS Pre-Proposal Webinar

Presented by

Sean David Griffiths, M.P.H.

Small Business Innovation Research (SBIR) Program

Office of Technology and Innovation

Office of the Associate Director for Science

August 13, 2015

CDC SBIR Program

- CDC's Office of the Associate Director for Science (OADS) manages the SBIR Program and works with CDC's Centers, Institutes and Offices to make determinations as to where SBIR funds would best be used to support high quality, high impact SBIR projects that will be of overall benefit to public health

- CDC participates in the HHS/NIH omnibus grant and contract solicitations
  - CDC does not participate in the STTR Program (at this time)
  - CDC has opted to participate in the Majority VC ownership authority (FY15)

- Budget - CDC SBIR set-aside approx $7.0 million (FY15)

CDC SBIR Program

- Uniqueness of CDC's SBIR Program – life sciences; public health; emergency response – domestic & international

- Awards - ≈ 25 Phase I's up to $150,000 each and ≈ 5-6 Phase II's per year up to $1.0 M each

- Grants vs. Contracts –
  - FY13 – 58% grants & 42% contracts
  - FY14 – 25% grants & 75% contracts

CDC Strategic Priorities

- Strengthen surveillance, epidemiology, and laboratory services;
- Improve the ability to support state, tribal, local and territorial public health;
- Improve global health impact;
- Increase policy impact; and,
- Better prevent illness, injury, disability and death.

Key Winnable Public Health Battles for the United States

Tobacco

Nutrition, Physical Activity, Obesity and Food Safety

Healthcare-Associated Infections

Motor Vehicle Injuries

Teen Pregnancy

HIV

CDC

Where CDC's SBIR Program Intersects with Small Business Concerns/VCs/Entrepreneurs

- Help CDC as we confront the many public health challenges before us:
  - CDC supports groundbreaking health and medical research and real-time emergency response activities to keep the U.S. safe, healthy, and secure;
  - CDC will promote and fund research and development that supports the mission and/or strategic priorities;
  - CDC has roles at the local, state, federal and global levels; and,
  - The SBIR program is a way for innovators and entrepreneurs to contribute to making not only the U.S., but the world a healthier and safer place.

CDC / Center for Global Health (CGH) – (008) Diagnostic Tools to Support the Elimination and Control of Neglected Tropical Diseases (NTD)

- Number of anticipated awards 1-2
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal: The specific project goal is to have prototype field-compatible tests that can address the following issues currently faced by national NTD programs –
  - the need for rapid determination of infection prevalence in support of micro mapping;
  - the detection of co-infections that hamper MDA activities;
  - epidemiological surveillance, evaluation of program impact through serological monitoring, and surveillance for infection or exposure following apparent interruption of transmission.

CDC / National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) – (012) De novo assembly of arthropod genomes of public health importance

- Number of anticipated awards 1
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - The goals of the proposed research are to rapidly and cost-effectively assemble high-quality arthropod genomes de novo. The innovation should ultimately enable large numbers of genomes to be assembled in multi-megabase scaffolds rapidly and affordably.
  - A scalable, parallelizable approach will enable much broader surveys and targeted studies of arthropod genomes to better understand their role in disease transmission and myriad costs to society.

CDC / National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) – (013) Detecting Lower Intestinal Microbiome Disruption and Multidrug Resistant Organisms

- Number of anticipated awards 1
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - Develop a proof of concept assay that could be used as the basis of a diagnostic method for stool that quantitatively detects not only the presence and relative amount of one or more of the previously described MDROs (i.e., CRE, VRE, ESBL, and/or C. difficile), but also the taxonomic components and diversity of the gut microbiome.
  - The approach to both MDRO detection and microbiome description may utilize a number of different existing technologic platforms and combinations thereof including, but not limited to, single or multiplex PCR platforms, 16S ribosomal RNA-encoding DNA amplification and sequencing, deep DNA sequencing, or other advanced metagenomic or metabolomic methods.

CDC / National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) – (046) Serologic measurement of hepatitis B virus cccDNA

- Number of anticipated awards 1
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - The purpose of this project is to identify a panel of sera from treated and untreated HBV-infected patients, validate and develop an assay for quantitative detection of cccDNA in serum or plasma, establish the performance characteristics of assay, and establish and validate the cccDNA detection kit.
    - Phase I Activities and Deliverables
      1. Design assay for quantitative detection of HBV cccDNA in serum or plasma from HBV-infected patients.
      2. Validate assay and determine sensitivity and specificity using seroconversion panels.

CDC / National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) – (047) Serologic detection and quantification of hepatitis B core antigen

- Number of anticipated awards 1
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - Identify a panel antibodies that have the potential to detect HBV core antigen in clinical samples.
  - Validate and develop a serological assay for quantitative detection of HBV core antigen
  - Validate the performance characteristics of the assay using commercial panels of serum samples from HBV-infected persons.
  - Validate the performance characteristics of the assay using with prospectively obtained serum samples from HBV-infected persons.
  - Establish protocols to scale up production of validated assay.

CDC / National Center for Immunization and Respiratory Diseases (NCIRD) – (031) Transcutaneous immunization against rotavirus using a dissolvable microneedle patch

- Number of anticipated awards 1
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - The goal of this project is to conduct formulation and process development and a feasibility study to manufacture a dissolving microneedle patch for skin immunization against rotavirus. This program area will provide small business companies with opportunities to apply for necessary funds and work with CDC scientists to further optimize the fabrication process and prepare a dissolving microneedle patch for clinical trials of a patch IRV.
  - Phase I Activities and Expected Deliverables
    - 1. Develop an outline for the project goals described above.
    - 2. Develop a draft scalable manufacturing process for a dissolving microneedle patch, including formulation and fabrication of IRV and necessary assays.

CDC / National Center for Immunization and Respiratory Diseases (NCIRD) – (032) Thermostable Dry Powder Live Attenuated Influenza Vaccine for Nasal Delivery

- Number of anticipated awards 1-3
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - The goal of the proposed research is to develop a thermostable dry powder LAIV for nasal delivery as a platform technology and assess immunogenicity following nasal powder vaccination in a ferret model. It is expected that this platform technology of thermostable dry powder nasal vaccine will be expanded to use for other vaccines.

Deadline for receipt of ALL Proposals

FRIDAY October 16, 2015

5:00 PM Eastern Daylight Time

Electronic submission must be complete.

No paper submissions.

National Institutes of Health
Office of Extramural Research

More Information

Get Connected!

- Subscribe to the SBIR/STTR Listserv:
  - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: **subscribe SBIR-STTR your name**
- NIH Guide for Grants and Contracts (weekly notification) http://grants.nih.gov/grants/guide/listserv.htm
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