



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

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[Original Synopsis](#)

Presolicitation
 Jul 02, 2015
 3:21 pm

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Jul 24, 2015
 2:32 pm
 Solicitation

[Changed](#)

Aug 11, 2015
 4:24 pm

[Changed](#)

Sep 17, 2015
 3:59 pm

[Changed](#)

Oct 08, 2015
 9:53 am

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Solicitation Number: PHS-2016-1
Notice Type: Solicitation

Synopsis:

Added: Jul 02, 2015 3:21 pm Modified: Oct 08, 2015 9:51 am [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.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS), THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) SMALL BUSINESS INNOVATIVE RESEARCH (SBIR) PROGRAM SOLICITATION PHS 2016-1 with a closing date of October 16, 2015, for receipt of proposals, soon will be available electronically through the NIH Small Business Research Funding Opportunities (<http://sbir.nih.gov>) Web site and at fedbizopps.gov. The SBIR Phase I, Fast-Track, Direct to Phase II Contract Solicitation will be available ONLY via electronic means. Printed copies of the Solicitation will not be distributed. Potential offerors are encouraged to check the NIH Small Business Research Funding Opportunities Web site and fedbizopps.gov for updates on the program. Any updates or corrections to the Solicitation will be posted there.

The purposes of the SBIR program are to: (a) stimulate technological innovation in the private sector; (b) strengthen the role of small business in meeting Federal research/research & development (R/R&D) needs; (c) increase the commercial application of Federally-supported research results; (d) foster and encourage participation by socially and economically disadvantaged small business concerns and women-owned business concerns; and improve the return on investment from Federally-funded research for economic and social benefits to the Nation. For purposes of the SBIR program, a small business concern is any business concern that, on the date of award, (1) is organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor; (2) is in the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there must be less than 50 percent participation by foreign business entities in the joint venture; (3) more than 50% directly owned and controlled by one or more individuals (who are citizens or permanent resident aliens of the United States), other business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the United States), or any combination

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 Jul 24, 2015
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 Sep 17, 2015
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- [Amendment 3](#)
 Oct 08, 2015
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GENERAL INFORMATION

Notice Type:
Solicitation

Original Posted Date:
July 2, 2015

Posted Date:
October 8, 2015

Response Date:
Oct 16, 2015 5:00 pm Eastern

Original Response Date:
Oct 16, 2015 5:00 pm

Archiving Policy:
Manual Archive

Original Archive Date:
-

Archive Date:
-

Original Set Aside:
Total Small Business

Set Aside:
Total Small Business

Classification Code:
A -- Research & Development

NAICS Code:
541 -- Professional, Scientific, and Technical Services/541712 -- Research and Development in the Physical, Engineering, and Life

of these; OR more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these. No single venture capital operating company, hedge fund, or private equity firm may own more than 50% of the concern AND (4) has, including its affiliates, no more than 500 employees.

Following are the research topics identified in the NIH/CDC SBIR Contract Solicitation PHS 2016-1:

NATIONAL INSTITUTES OF HEALTH (NIH)

NATIONAL CANCER INSTITUTE (NCI): Development of Metabolomics Data Integration Methods and Software; Validation of Mobile Technologies for Clinical Assessment, Monitoring and Intervention; An Electronic Platform for Cognitive Assessment in Cancer Patients; Technologies for Differential Isolation of Exosomes and Oncosomes; Predictive Biomarkers of Adverse Reactions to Radiation Treatment; Molecularly Targeted Radiation Therapy for Cancer Treatment; Signal Amplification to Enable Attomolar Quantitation in Slide-Based or ELISA Biomarker Immunoassays; Identification and Capture of Enriched Tumor Zones with Preservation of Labile Biomarkers from Ultra-Cold Biopsies; Proximity Slide Based Sandwich Immunoassay to Visualize Intramolecular Epitopes of Analytes in Tissue Sections; Highly Innovative Tools for Quantifying Redox Effector Dynamics in Cancer; Modulating the Microbiome to Improve Efficacy of Cancer Therapeutics; Cell and Animal-Based Models to Advance Cancer Health Disparity Research; Cell-Free Nucleic Acid-Based Assay Development for Cancer Diagnosis; Companion Diagnostics for Cancer Immunotherapies.

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS): Development of Stem Cell-based Assay for High-Throughput Screening of Chemicals of Toxicological Concern; Development of Smart Plate Technology.

NATIONAL HEART, LUNG AND BLOOD INSTITUTE (NHLBI): Transcatheter Cavopulmonary Bypass Endograft; Active MRI Transseptal Needle; Bioabsorbable Stents for Neonatal Aortic Coarctation; Early Detection and Monitoring of Cardiac Injury Due to Cardiotoxicity.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA): Development of Novel Compounds to Treat Alcohol Use Disorder.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID): Precision Genome Engineering for HIV Eradication; High-Throughput Assay Platform for Quantifying Latent HIV Reservoirs; Method for the Detection of Minority Populations of Drug Resistant HIV; Simple, Inexpensive Device to Purify DNA from Sputum for Tuberculosis Testing; Telemonitoring for Infectious Diseases: A Remote System for Assessing Patient Parameters and Specimen Analysis; Innovative Oral Formulations for Anti-Infective Drugs; Vaccines against Pathogens with Small Market Potential.

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA): Development of Primer and Reference Tool to Assess Neonatal Abstinence Syndrome; Therapeutic Cannabidiol Pulmonary Delivery Device (e.g. Nebulizer, Vaporizer or Inhaler); "The Pain Mobile": Remote Pain Management System.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

CENTER FOR GLOBAL HEALTH (CGH): Diagnostic Tools to Support the Elimination and Control of Neglected Tropical Diseases.

NATIONAL CENTER FOR EMERGING ZOO NOTIC AND INFECTIOUS DISEASES (NCEZID): De novo assembly of arthropod genomes of public health importance; Detecting Lower Intestinal Microbiome Disruption and Multidrug Resistant Organisms.

NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS, STD, AND TB PREVENTION (NCHHSTP): Serologic measurement of hepatitis B virus

Sciences (except Biotechnology)

cccDNA; Serologic detection and quantification of hepatitis B core antigen.

NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (NCIRD): Thermostable Dry Powder Live Attenuated Influenza Vaccine for Nasal Delivery.

Note: The PHS 2015-2 Omnibus Solicitation of the National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration, and Administration for Children and Families for Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) GRANT Applications, where investigator-initiated ideas are encouraged, is open and is available at the same Web site noted above with a due dates of September 5, 2015, January 5, 2016, and April 5, 2016.) To understand better the differences between grants and contracts, see LINKURL:<https://sbir.nih.gov/apply> LINKURL:<https://sbir.nih.gov/> LINKDESC: National Institutes of Health Small Business (SBIR/STTR) Research Funding Opportunities. E-mail: sbir@od.nih.gov

For general information regarding the NIH/CDC SBIR program, please refer to:

Office of Extramural Programs, Office of Extramural Research
National Institutes of Health
Email: sbir@od.nih.gov
Phone: 301-435-2688

Questions regarding this specific contract solicitation should be directed to the 'Primary Point of Contact' and/or 'Secondary Point of Contact' designated in this Notice.



Please consult the list of [document viewers](#) if you cannot open a file.

Solicitation 1

Type: Solicitation
Posted Date: July 24, 2015

[PHS2016-1.pdf](#) (1,836.84 Kb)

Description: 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

Amendment 1

Type: Mod/Amendment
Posted Date: August 11, 2015

[Amendment_1_-_PHS2016-1.pdf](#) (10.00 Kb)

Description: Amendment 1 - Correct NAICS Code

Amendment 2

Type: Mod/Amendment
Posted Date: September 17, 2015

[Amendment_2_Solicitation_PHS2016-1.pdf](#) (265.39 Kb)

Description: Amendment 2

Amendment 3

Type: Mod/Amendment
Posted Date: October 8, 2015

 [Amendment 3 - PHS2016-1.pdf](#) (27.02 Kb)

Description: Amendment 3

Contracting Office Address:

Office of Acquisitions
5601 Fishers Lane
3rd Floor, MSC 9821
Bethesda, Maryland 20892
United States

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Solicitation #:

PHS-2016-1

Procurement Type:**Modification/Amendment****Date Posted:**

October 8, 2015

Title:

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

ATTACHMENTS

Amendment 3

Is this package sensitive/secure? No

[Amendment 3 - PHS2016-1.pdf](#) (27.02 Kb)**Description:** Amendment 3

Amendment #3
Solicitation PHS2016-1

AMENDMENT THREE (3)

OFFICE OF ACQUISITIONS

National Institute of Allergy and Infectious Diseases (NIAID)
5601 Fishers Lane, Room 3D35, MSC 9821
Rockville, MD 20852

Solicitation Number: PHS2016-1

Date of Solicitation Issuance: 07/24/2015

Date of Amendment No.1 Issuance: 08/11/2015

Date of Amendment No.2 Issuance: 09/17/2015

Date of Amendment No. 3 Issuance: 10/08/2015

Number of Pages: 3

NIAID Points of Contact:

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George Kennedy, Contracting Officer
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Phone: 240-669-5170

The hour and date specified for receipt of Offers remains unchanged.

Offerors must acknowledge receipt of the amendment by Amendment number(s) and date of the amendment. Include a statement of acknowledgement in your proposal submission. Failure of acknowledgement may result in rejection of your offer.

Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

PURPOSE OF SOLICITATION AMENDMENT

This Amendment corrects the description for NIH / NIDA Topic 158, entitled “Development of Primer and Reference Tool to Assess Neonatal Abstinence Syndrome.” This Amendment only affects NIH / NIDA Topic 158.

Section 12 Component Instructions and Technical Topic Descriptions, *National Institute on Drug Abuse (NIDA), Topic 158, Development of Primer and Reference Tool to Assess Neonatal Abstinence Syndrome*, is revised to reflect that the second set of Activities and Expected Deliverables included in the original solicitation are designated for Phase II. The corrected Activities and Expected Deliverables are as follows:

Phase I Activities and Expected Deliverables:

Technical Requirements

1. Assemble a consultant team and determine availability of data, references, educational and clinical guidelines, and presentation strategies. *Offerors are expected to have in house capabilities or the established practice or*

experience to contact consultative and CME educational services, neonatal centers, hospitals, professional associations and medical practitioners including but not limited to neonatal providers, nurses, pediatricians, and pain prescription physicians.

2. Develop a curriculum for education modules and interactive resources. An electronic Tool should adapt the skill-building multimodal Primer and serve as a bed-site Reference Tool for neonatal and pediatric providers.

A Primer and Reference Tool proposed in response to this solicitation should provide the repository of necessary information in following areas:

- a. *Epidemiology and pathophysiology of NAS.*
 - b. *The clinical phenomenon of NAS symptoms. Clinical signs, frequency, severity and duration of NAS. Mechanisms of opioids withdraw. Clinical facts of multi-drug exposures and their impact to NAS development and representation.*
 - c. *Interpretation of the Modified Finnegan Score system. Guidelines in assessment and scoring.*
 - d. *Overview of available and appropriate toxicology tests to determine the exposure level. All drug screening procedures should contain corresponding references to the test sensitivity, efficiency, time for analysis, cost and diagnostic limitations.*
 - e. *Description of pharmacologic and non- pharmacologic interventions. Interactive referral and references how to select the appropriate therapy based on the symptoms appearance and NAS scoring. The materials should describe the importance of breastfeeding in stable mothers.*
3. Define and collect all reference materials such as medical publications, scientific references, best-practice guidelines, and other downloadable tools. A Tool may be built with the option for interactive questions.
 4. Identify an electronic platform for the software implementation. A Tool's App should have full compatibility with both Flash and FULL compatibility with HTML5 standards.
 5. Develop a detailed project plan for Phase II activities which includes, but is not limited to:
 - a. Project Gantt
 - b. Task linked budget for Phase II Activities
 - c. Mock Ups outlining of Phase I Deliverables 2 (a-e) and Description of the Software
 - d. Plan for the case study recording
 - e. Examples of surveys to be used in Phase II Activities
 - f. Plan for piloting, evaluation, and refinement of draft modules
 - g. Plan to address FDA-regulations if a Tool is to be disseminated as a NAS scoring and a clinical/treatment reference device w/wo compatibility with electronic medical records (EMR) software.

Phase II Activities and Expected Deliverables:

Technical Requirements

1. Develop a multimodal awareness building program of a Primer and Reference Tool:
 - a. Collect case presentations (video and descriptive) to supplement tool's modules and address the challenges in NAS symptoms recognition and interpretation;
 - b. Create reliable software as required. Code the device as needed.

2. Conduct a Pilot study of the draft module with professionals representing the target audience to a Primer and Reference Tool. Conduct community's feedback survey and analyze data.
3. Revise and improve software in response to perceived needs. Complete the web-based lesson context, iterative design and development of the software operation tools.
4. Conduct efficiency study and evaluate the effectiveness of a Primer and Reference Tool. Complete satisfaction and acceptance testing.
5. Prepare strategy for implementation and dissemination.