

AMENDMENT OF SOLICITATION

Solicitation Number: PHS 2015-1

Amendment Number: 1

AMENDMENT ONE (1)

Issued by:

National Institute of Allergy and Infectious Diseases (NIAID)
Office of Acquisitions
6700-B Rockledge Drive, Suite 300
Bethesda, MD 20892

Solicitation Number:

PHS 2015-1

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Attachments:

PHS 2015-1 – Amendment 1

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**The hour and date specified for receipt of Offers remains unchanged, 4:30 PM Eastern
Prevailing Time on November 5, 2014.**

Offerors MUST acknowledge receipt of the amendment by Amendment number(s) and date of the amendment.

FAILURE OF YOUR ACKNOWLEDEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED 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:

The purpose of this amendment is to provide corrections and revisions to Sections 3.1, 3.2, 6.4, 8.3, 9, 10, and 12 of the subject solicitation.

Accordingly, Solicitation PHS 2015-1 is revised as follows:

Section 3.1 General Definitions, *Direct to Phase II*, is revised to read as follows:

Direct to Phase II. A new pilot authority under P.L. 112-81 that allows NIH to issue a Phase II award to a small business concern that did not receive a Phase I award for that research/research & development, if the small business had performed the Phase I stage-type of research through other funding sources (non SBIR/STTR). Certain NIH topics will allow Direct to Phase II SBIR proposals in this solicitation.

Section 3.2 Definitions (Relating to R&D), is revised to add the following definition:

Investigational Device Exemption (IDE). An IDE is a regulatory submission that permits clinical investigation of devices. This investigation is exempt from some regulatory requirements. The term “IDE” stems from the description in 21Code of Federal Regulations (CFR) 812.1.

Section 6.4 Award Decisions, is revised to read as follows:

For proposals recommended for award, the awarding component considers the following:

1. Ratings resulting from the scientific/technical evaluation process;
2. Areas of high program relevance;
3. Program balance (i.e., balance among areas of research);
4. Availability of funds, and.
5. Cost/Price

The government anticipates that prospective offerors will develop unique proposals in response to the topics of research set forth in this solicitation. The agency is not under any obligation to fund any proposal or make any specific number of contract awards in a given research topic area. The agency may also elect to fund several or none of the proposals

received within a given topic area. SBIR contract projects do not require establishing a competitive range but an order of merit ranking and cost analysis is performed before reaching source selection decisions

Section 8.3 Fast Track and Direct to Phase II Proposal Instructions (NIH Only), Item 4, Paragraph (C) Research Plan for Phase II (FAST TRACK or Direct to Phase II) Research Plan, is revised to add Item 9, as follows:

- 9) **Subcontractors/Consultants.** Involvement of a university or other subcontractors or consultants in the project may be appropriate and is permitted. If such involvement is intended, it should be described in detail and identified in the cost proposal. In addition, supported by appropriate letters from each individual confirming his/her role in the project must be included. Small business concerns must perform a minimum of one half for Phase II of the research and/or analytical effort (i.e., total contract price less profit/fee) conducted under the resulting contract. The Contracting Officer must approve deviations from this requirement in writing after consultation with the agency SBIR Program Manager/Coordinator.

Section 9, Summary of HHS Components Anticipated Number of Awards, is revised as follows:

| HHS Components | Anticipated No. of Awards | Anticipated Time of Award |
|--|----------------------------------|---|
| National Institutes of Health (NIH) National Cancer Institute (NCI) | 20-31 | Scientific and Technical Merit Review: March-May 2015 Anticipated Award Date: August-September 2015 |
| National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS) | 4-8 | Scientific and Technical Merit Review: March-May 2015 Anticipated Award Date: September 2015 |
| National Institutes of Health (NIH) National Heart, Lung, and Blood Institute (NHLBI) | 11 | Scientific and Technical Merit Review: February-April 2015 Anticipated Award Date: July-September 2015 |
| National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID) | 4-7 | Scientific and Technical Merit Review: March 2015 Anticipated Award Date: August 2015 |
| National Institutes of Health (NIH) National Institute on Drug Abuse (NIDA) | 3-4 | Scientific and Technical Merit Review: March 2015 Anticipated Award Date: August 2015 |
| Centers for Disease Control and Prevention (CDC) | 1-2 | Scientific and Technical Merit Review: May-June 2015 |

| HHS Components | Anticipated No. of Awards | Anticipated Time of Award |
|---|----------------------------------|---|
| Center for Global Health (CGH) | | Anticipated Award Date: August 2015 |
| Centers for Disease Control and Prevention (CDC) National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) | 1 | Scientific and Technical Merit Review: May-June 2015 Anticipated Award Date: August 2015 |
| Centers for Disease Control and Prevention (CDC) National Center for Emerging Zoonotic and Infectious Diseases (NCEZID) | 1 | Scientific and Technical Merit Review: May-June 2015 Anticipated Award Date: August 2015 |
| Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDs, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) | 3 | Scientific and Technical Merit Review: May-June 2015 Anticipated Award Date: August 2015 |
| Centers for Disease Control and Prevention (CDC) National Center for Immunization and Respiratory Diseases (NCIRD) | 4 | Scientific and Technical Merit Review: May-June 2015 Anticipated Award Date: August 2015 |

Section 10, Contracting Officers and Addresses for Delivery of Contract Proposals, is revised as follows:

The information provided for the **NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)** is revised from

Mr. Bryan Jones, Phone: 301-594-1852, E-mail: bryan.jones@nih.gov

to

Mr. Sean Dalenberg, Contracting Officer
Office of Acquisitions
NIDA COAC
6701 Democracy Blvd, Suite 1084
Bethesda, MD 20892-4874*

*Change the zip code to 20817 if hand-delivered or delivered by an express or other courier service to the NCATS.

The office title provided for the **NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)** is revised from

Review Branch
Division of Extramural Research Activities
National Heart, Lung, and Blood Institute

to

Office of Scientific Review
Division of Extramural Research Activities
National Heart, Lung, and Blood Institute

The acronyms used to identify Centers provided for the **CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)** are revised as follows

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION
(**NCCDPHP**)

NATIONAL CENTER FOR EMERGING ZOOBOTIC AND INFECTIOUS DISEASES (**NCEZID**)

NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS, STD, AND TB PREVENTION
(**NCHHSTP**)

NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (**NCIRD**)

Section 12 Component Instructions and Technical Topic Descriptions, is revised to correct the following Topic numbers:

National Center for Advancing Translational Sciences (NCATS)

Exploring the Potential of CRISPR/CAS Genome-editing Tools, is revised from Topic number 007 to **009**

Assay Development for High-Throughput Screening of Chemicals of Toxicological Concern, is revised from Topic number 009 to **010**

Simple and Robust Reaction Progress Analyzer, is revised from Topic number 341 to **011**

Online Real Time Metals Analysis at Low ppm Level, is revised from Topic number 342 to **012**

National Heart, Lung, and Blood Institute (NHLBI), Limited Amount of Award, is revised to read as follows:

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, the NHLBI may not fund a proposal and does not intend to fund proposals for more than the budget listed for each topic.

National Institute of Allergy and Infectious Diseases (NIAID)

Simple, Inexpensive Unit for Removing Cells from Small Amounts of Blood in Resource-Limited Settings, is revised from Topic number 031 to **032**

Centers for Disease Control and Prevention (CDC)

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

Multiplex Assay for Simultaneous Detection of Hepatitis and Other Viruses, is revised from Topic number 032 to **044**

Improved Antibody Preparation for Post-Exposure Prophylaxis Against Hepatitis A, is revised from Topic number 033 to **045**

National Center for Immunization and Respiratory Diseases (NCIRD)

Thermostable Dry Vaccine Formulation for Microneedle Administration, is revised from Topic number 027 to **029**

Thermostable Oral Vaccines to Combat Enteric Diseases, is revised from Topic 029 to **030**

The revised solicitation: “PHS 2015-1 – Amendment One”, is attached hereto, incorporating the revisions identified above.

End of Amendment 1