

Amendment #3
Solicitation PHS2016-1

AMENDMENT THREE (3)

OFFICE OF ACQUISITIONS

National Institute of Allergy and Infectious Diseases (NIAID)
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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.