

Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office

Comparison and Validation of Screening Tools For Substance Use Among Pregnant Women

RFA-DP-15-003

Application Due Date: 02/24/2015

Comparison and Validation of Screening Tools For Substance Use Among Pregnant Women

RFA-DP-15-003

TABLE OF CONTENTS

Part 1. Overview Information

- Key Dates
- Required Application Instructions
- Executive Summary

Part 2. Full Text

- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office (NCCDPHP ERPO)
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Funding Opportunity Announcement (FOA) Title

Comparison and Validation of Screening Tools For Substance Use Among Pregnant Women

Activity Code

AMENDMENT I. QUESTIONS FROM POTENTIAL APPLICANTS AND CDC RESPONSES added to Section VIII. Other Information, February 9, 2015

Activity Code: CDC-R21

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-15-003

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.068

Category of Funding Activity:

Health

FOA Purpose

The purpose of this FOA is to solicit proposals for a study to compare and validate substance use screening tools for pregnant women in the U.S. Such tools are to be used by providers caring for pregnant women to identify substance use during pregnancy with a focus on illicit and prescription drugs, and to inform the clinical management for substance-using pregnant women.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-DP-15-003, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**
Letter of Intent Due Date:	**01/23/2015**
Application Due Date:	**02/24/2015**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: **04/20/2015**

Secondary Review: **06/05/2015**

Estimated Start Date: **09/01/2015**

Expiration Date: **02/25/2015**

Due Dates for E.O. 12372: **Executive Order 12372 does not apply to this program.**

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Executive Summary

- **Purpose.** The purpose of this FOA is to solicit proposals for a study to compare and validate substance use screening tools for pregnant women in the U.S. Such tools are to be used by providers caring for pregnant women to identify substance use during pregnancy with a focus on illicit and prescription drugs, and to inform the clinical management for substance-using pregnant women.
- **Mechanism of Support.** Grant
- **Funds Available and Anticipated Number of Awards.** NCCDPHP intends to fund one (1) award and to commit approximately $1,200,000 in total (including both direct and indirect costs) over the two-year project period. An award issued under this FOA is contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of the award may also vary. The total amount awarded will depend upon the number, quality, duration, and cost of the applications received.
- **Budget and Project Period.** An applicant may request a project period of up to two (2) years. The estimated total funding (including both direct and indirect costs) is $600,000 for the first year (12-month budget period). The estimated total funding (direct and indirect costs) for the entire project period is $1,200,000. The project period will run from 9/1/2015 to 8/31/2017.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III,1 are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may include more than one PI; however, the first PI listed will be the "contact PI" for all correspondence.
- **Number of Applications.** Eligible applicant institutions may submit more than one application, provided that each application is scientifically distinct.
- **Application Type.** New
- **Special Date(s).** None
- **Application Materials.** See Section IV.1 for application materials.

- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

This FOA will be posted at http://www.cdc.gov/chronicdisease/about/foa.htm

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

This program is authorized under Section 317(k)(2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2) and Section 301(a) of the Public Health Service Act, 42 U.S.C. 241(a).

1. Background and Purpose

The nature of this research opportunity is to conduct a study to compare and validate substance use screening tools for pregnant women in the U.S. with a focus on illicit and prescription drugs. The results of this study will help health providers caring for pregnant women to identify substance use during pregnancy and will inform clinical management for substance-using pregnant women.

Background

The 2012 National Survey on Drug Use and Health showed that among pregnant women approximately 5.9% had used illicit substances, 8.5% had consumed alcohol in the month before the survey, and nearly 16% smoked cigarettes. A five-fold increase in antepartum maternal opiate use, coincident with an "epidemic" of opiate prescription abuse between 2000 and 2009, has also been reported, with women being as likely as men to abuse opiate medications. Many pregnant women will continue to smoke cigarettes, drink alcohol, or use other substances throughout pregnancy and after delivery, unless these practices are recognized and addressed.

Prenatal cigarette use has deleterious effects on fetal development and long-term adverse consequences on postnatal development. Alcohol is a known teratogen with physical and behavioral effects gathered under the non-diagnostic umbrella term, Fetal Alcohol Spectrum Disorders (FASD). Moreover, prenatal alcohol exposure has been associated with lifelong consequences for the individual, family, and society. No safe threshold for prenatal alcohol exposure has been established. Although additional research is needed to confirm causal connections, exposure to illicit substances and non-prescription use of psychotropic medications is generally associated with adverse birth outcomes (e.g. preterm birth, low birth weight, and small for gestational age infants). While opioids have no demonstrated teratogenic or cytotoxic effects during pregnancy, fluctuating opioid concentrations in the maternal blood may lead to fetal withdrawal or overdose. In addition, illicit drug-dependent pregnant women are at increased risk of medical complications such as infectious diseases, malnourishment, and psychosocial problems such as inadequate obstetric care.

The identification of prenatal tobacco, alcohol, and other substance use is challenging. Healthcare professionals may be reticent to inquire about these practices and patients may be reluctant to disclose them because of stigma, denial, or change in behavior after pregnancy confirmation. Fears about legal and other sanctions may also contribute to non-disclosure. Finally, whereas the development and evaluation of screening measures for prenatal smoking and alcohol use are more advanced, the validity, reliability, and clinical utility of standardized questionnaires in screening for illicit drug use during pregnancy is not commensurate. The US Preventive Services Task Force (USPSTF) has issued several recommendations with regard to tobacco, alcohol, and illicit drug use by adult women, and concluded that there is currently insufficient evidence to evaluate the benefits and harms of screening for illicit drug use in clinical subpopulations including pregnant women because the validity, reliability, and clinical utility of

standardized questionnaires in screening for illicit drug use during pregnancy have not been adequately evaluated.

Purpose

The purpose of this FOA is to solicit proposals to conduct a research study to validate and compare the performance of substance use screening tools that are already available in the literature and can be used among pregnant women seeking medical services (e.g. antenatal or delivery care) in clinical settings in the United States. Examples of such screening tools include: 4Ps and related screening tool version (e.g. 5Ps screening tool adapted by the Massachusetts Institute for Health and Recovery in 1999 from 4Ps, in wide use in Massachusetts, California, Maine, Virginia, and South Carolina, and available at: http://www.mhqp.org/guidelines/perinatalPDF/IHRIntegratedScreeningTool.pdf); Substance Use Risk Profile – Pregnancy Scale (SURP-P); CRAFFT (Car, Relax, Alone, Forget, Friends, Trouble); National Institute for Drug Abuse (NIDA) Quick Screen.

Thus, the focus of this funding opportunity is not on development of new screening tools, but on the validation of already available screening tools for substance use in pregnant women and comparison of their performance on identifying illicit and prescription drugs. The performance of existing screening tools should be compared against each other for identification of each substance of interest (i.e. illicit and prescription drugs). Investigators will then be able to recommend the tool or tools best suited for screening for illicit and prescription drugs in pregnant women.

Healthy People 2020 and other National Strategic Priorities

This research will help meet national public health goals and objectives as it addresses the four "Healthy People 2020" priority areas listed below:

- MICH-6 Reduce maternal illness and complications due to pregnancy;
- MICH-10 Increase the proportion of pregnant women who receive early and adequate prenatal care;
- MICH-11 Increase abstinence from alcohol, cigarettes, and illicit drugs among pregnant women;
- MICH-16 Increase the proportion of women delivering a live birth who received preconception care services and practiced key recommended preconception health behaviors.

The project specifically addresses the problem of substance use, an increasingly prevalent condition among the US population and a priority topic for CDC, NCCDPHP, and the Division of Reproductive Health.

- Prescription drug abuse is an agency priority as recently highlighted in a CDC Vital Signs report (http://www.cdc.gov/vitalsigns/).
- This research is aligned with NCCDPHP performance goals to define, conduct, and promote public health research in reproductive health.
- This FOA addresses three (3) Division of Reproductive Health priorities:
  1) to improve women's reproductive health from menarche through menopause;
  2) to improve pregnancy health and care, and one key strategic area of focus: science to practice (to identify and implement effective strategies for promoting science to practice and translation); and
  3) to improve fetal, newborn and infant health.

Public Health Impact

Given the increasing use of substances during pregnancy, identification of women at risk is a critical need; pregnancy may present a window of opportunity for intervention. However, identification of prenatal substance use is challenging. Many pregnant women will continue to smoke cigarettes, drink alcohol, or use other substances throughout pregnancy and after delivery unless these practices are recognized and addressed. This research will identify the substance use screening tools that best perform in clinical settings to identify illicit and prescription drug use by pregnant women. Wide implementation of substance use screening in pregnant women could result in better maternal and infant health outcomes and reduction in healthcare costs associated with pregnancy, delivery, and neonatal care.

Relevant Work

During a CDC-sponsored Expert Meeting on perinatal drug abuse organized in September 2012, the lack of validated screening tools for substance use in pregnant women was identified as a key gap in knowledge and practice. Given CDC's interest in preventing substance use during pregnancy, addressing this knowledge gap represents a program priority.

2. Approach

The goal of this FOA is to conduct a study that compares and validates substance use screening tools for pregnant women in the US (for example, 4Ps and related screening tool version (e.g. 5Ps); Substance Use Risk Profile – Pregnancy Scale (SURP-P); CRAFFT; National Institute for Drug Abuse (NIDA) Quick Screen). Applicants may propose comparison of any of the screening tools already available in the literature provided that an adequate sample size is available to compare psychometric properties between all proposed screening tools with respect to illicit and prescription drug use. It is expected that applicants will propose to conduct the study in one or more clinical settings offering services to pregnant women (e.g. antenatal or delivery care).

Objectives/Outcomes

Objective 1: Design a study that compares and validates substance use screening tools for pregnant women in the U.S. (for example, 4Ps and related version (e.g. 5Ps); Substance Use Risk Profile – Pregnancy Scale (SURP-P); CRAFFT; NIDA Quick Screen). The study population should be representative of the distribution of pregnant women in the U.S population in terms of age and race/ethnicity. The substances of interest that can be assessed include alcohol, tobacco, and illicit and prescription drugs, but the focus should be on screening for illicit and prescription drugs. The study design should include:

- Development of the research protocol, a data analysis plan, and a process evaluation of key milestones of the project;
- Identification and description of the study sites and study population including how the FOA eligibility criteria are met and how women will be recruited and enrolled by type of substance used;
- Description of methods of identification of substance use; inclusion of a plan and justification for use of biological testing for illicit or prescription drugs for all or part of the sample is required;
- Determination of sample size requirements to detect clinically-meaningful differences between all the screening tools selected for comparison.

Objective 2: Implement the study and analyze data to compare and validate the use of selected substance use screening tools:

- Determine data collection methods;
- Implement data collection;
- Ensure that all women testing positive for any substance receive referral to appropriate care and treatment;
- Develop a data analysis plan that includes:

- determination of psychometric properties for all screening tools selected for assessment and comparison;
- comparison of psychometric properties between the selected screening tools;
- identification of best performing screening tool for use of illicit and prescription drugs during pregnancy.

Objective 3: Develop a dissemination plan for the results and study findings, including publishing results in peer-reviewed journals. The plan should include an assessment of the tools tested and a set of recommendations to inform the use, adoption, and potential for scaling-up use of any tested tools in primary care and obstetric settings.

Target Population

The target population is pregnant women ages 15-49 years. The study population must include women in all trimesters of pregnancy.

Collaboration/Partnerships

The applicant may consider developing partnerships in the community(ies) where the study will take place. As such, the applicant may propose a multi-site study, in which case a description of all study sites as well as collaboration letters/agreements should be included with the application.

Evaluation/Performance Measurement

The applicant is expected to develop: 1) an evaluation plan that includes process evaluation of key milestones of the project, and 2) a plan to validate screening tools, including the comparison of psychometric properties between all selected tools with a focus on identification of illicit and prescription drugs.

Translation Plan

The application should address how research findings will be disseminated to key stakeholders together with a set of recommendations to inform the use, adoption, and potential for scaling-up use of any tested tools in primary care and obstetric settings.

References

Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

Hayes MJ, Brown MS. Epidemic of prescription opiate abuse and neonatal abstinence. *JAMA*. 2012; 307: 1974-1975.

Hackshaw A, Rodeck C, Boniface S. Maternal smoking pregnancy and birth defects: a systematic review based on 173687 malformed cases and 11.7 million controls. Human *Reproduction Update*, 2011; 17: 589-604.

Monshouer K, Huizink AC, Harakeh Z et al. Prenatal smoking exposure and the risk of behavioral problems and substance use in adolescence: the TRAILS study. *Eur Addict Res*, 2011; 17: 342-350.

Riley EP, Infante A, Warren KR. Fetal alcohol spectrum disorders: an overview. *Neuropsychol Rev*, 2011; 21: 73-80.

Winklbaur B, Kopf N, Ebner N et al. Treating pregnant women dependent on opioids is not the same as

treating pregnancy and opioid dependence: a knowledge synthesis for better treatment for women and neonates. *Addiction*. 2008; 103: 1429-1440.

Gouin K, Murphy K, Shah PS, and the Knowledge Synthesis Group on Determinants of Low Birth Weight and Preterm Births. *American Journal of Obstetrics and Gynecology.* 2011; 204: 340.e1-12.

Roussote F, Soderberg L, Sowell E. Structural, metabolic, and functional brain abnormalities as a result of prenatal exposure to drugs of abuse: evidence from neuroimaging. *Neuropsychol Rev*. 2010; 20: 376-397.

Substance abuse reporting and pregnancy: the role of the obstetrician-gynecologist. Committee Opinion No. 473. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2011; 117: 200-1.

U.S. Preventive Services Task Force. *Screening for Illicit Drug Use: U.S. Preventive Services Task Force Recommendation Statement.* January 2008. http://www.uspreventiveservicestaskforce.org/uspstf08/druguse/drugrs.htm

U.S. Preventive Services Task Force. Counseling and interventions to prevent tobacco use and tobacco-caused disease in adults and pregnant women: US Preventive Services Task Force Reaffirmation Recommendation Statement. *Ann Intern Med.* 2009; 150: 551-555.

USPSTF A and B Recommendations. U.S. Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm.

Section II. Award Information

Funding Instrument Type: Grant

A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: $1,200,000

NCCDPHP intends to commit approximately $600,000 (including both direct and indirect costs) in FY 2015 to fund one (1) applicant for the first 12-month budget period. The estimated total funding (direct and indirect) for the entire two (2) year project is $1,200,000.

Anticipated Number of Awards: 1

An applicant may request up to $600,000 for the first 12-month budget period, including both direct and indirect costs.

If an applicant requests a funding amount greater than the ceiling of the award range for the first year ($600,000), HHS/CDC will consider the application non-responsive and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling: $600,000 Per Budget Period

Award Floor: $0 Per Budget Period

Total Project Period Length: 2 year(s)

Throughout the project period, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions
Historically Black Colleges and Universities (HBCUs)
Tribally Controlled Colleges and Universities (TCCUs)
Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

Eligible applicants must meet the following criteria:

a. Have an established relationship with study site(s) allowing access to the study population;
b. Have the ability to enroll a sufficient number of pregnant women in order to detect differences between all the screening tools selected for validation and comparison over the 2-year project period;
c. The PI of the proposed study must have served as PI or co-PI on at least one other study assessing screening tools for substance use during pregnancy; the study may have involved primary data collection or be a secondary data analysis;
d. The research team must include at least one obstetrician and one psychiatrist.

4. Justification for Less than Maximum Competition

None

5. Responsiveness

Evidence for the special eligibility criteria listed in number 3 above must be presented in Appendix A of the application. If your application is incomplete or non-responsive to these requirements, it will not enter into the review process.

a. Applicants must provide evidence of an established relationship with the study site(s) granting access to the study population in the form of signed letters or written agreements with each study site;
b. Applicants should report, by substance type, the number and percentage of substance-using pregnant women receiving care at each proposed site where women will be recruited and enrolled into the study;
c. Applicants must provide evidence of the principal investigator's previous research on at least one other study assessing screening tools for substance use during pregnancy that involved primary data collection or secondary data analysis as evidenced in the Research & Related Senior/Key Person section of the SF424 (R&R). To address this request, please include the abstract from the study

publication;
d. The applicant must provide evidence that the project team will include an obstetrician and a psychiatrist, as evidenced in the Research & Related Senior/Key Person section of the SF424 (R&R).

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato. int/AC135Public/Docs/US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (**SAM**) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/#1.
- Grants.gov
- eRA Commons

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date**. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.

If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Multiple applications per institution are allowed, provided that each application is scientifically distinct.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/ 424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components.

3. Letter of Intent

Due Date for Letter of Intent: **01/23/2015**

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 CIO staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the applicant
Descriptive title of proposed research
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this funding opportunity

The letter of intent should be sent to:

Sue Shaw, MPH
National Center for Chronic Disease and Health Promotion
Extramural Research Program Operations and Services (ERPOS)
Centers for Disease Control and Prevention
4770 Buford Highway, NE M/S F-80
Atlanta, GA 30341
Telephone: (770) 488-6142
Email: zgx7@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. Introduction to Application (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. Research Strategy – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
4. Inclusion Enrollment Report (Renewal and Revision applications ONLY)
5. Progress Report Publication List (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects
7. Inclusion of Women and Minorities

8. Targeted/Planned Enrollment Table (for New Application ONLY)
9. Inclusion of Children

Other Research Plan Sections

10. Vertebrate Animals
11. Select Agent Research
12. Multiple PD/PI Leadership Plan.
13. Consortium/Contractual Arrangements
14. Letters of Support
15. Resource Sharing Plan(s)
16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

Research Plan

The applicant's research plan should address activities that will be conducted over the entire 2-year project period, and should include the following items:

Introduction/Background

- Describe the demographics (age, race/ethnicity, insurance status) of the pregnant subjects served by the site(s) where the study will be implemented; include rates of substance use during pregnancy by type of substance;
- Describe the site(s) from which pregnant women will be recruited; if available, include any clinic protocol specific to screening for substance use during pregnancy. Provide signed letter(s) of support from proposed site(s).
- Demonstrate capacity to recruit the estimated number of pregnant women required for an adequate comparison of all selected screening tools. Capacity to recruit can be demonstrated by providing numbers and percentages of substance-using pregnant women attending care at proposed study sites in previous years or for previous, similar research studies.

Specific Aims

- Specify overall aims or objectives for the study
- Specify selected screening tools and provide a justification for their selection
- Specify how substance use indicators will be measured

Research strategy

- Describe the proposed study to compare and validate substance use screening tools among pregnant women;
- Identify and describe the substance use screening tools that will be validated and how they address the intent of the FOA;
- Describe inclusion criteria for study participants;

- Describe how the proposed study approaches and methodologies will be integrated into ongoing services at the proposed site(s);
- Describe how the proposed study will appeal to the target population and be culturally appropriate, including justification for incentives that will be used during the study;
- Provide information on sample size calculations;
- Describe approach for recruitment;
- Describe method of data collection, management and quality assurance;
- Describe if/how self-reported information will be verified/validated; biological testing for illicit and prescription drug use is required for at least a sub-sample of all study participants;
- Describe the information technology (equipment, software, expertise) to be used;
- Describe how study data will be analyzed to compare psychometric properties of all selected screening tools; if more than one site is proposed, include plans for data sharing and data pooling;
- Describe dissemination plan, including planned manuscript(s);
- Describe expected contributions to the field.

Staffing and Milestones for Development and Implementation Phases

- Provide list of study tasks and a timeline for the study;
- Describe key milestones and/or measurable outputs that will be used to indicate progress toward having an Institutional Board Review (IRB)-approved protocol and all study materials pilot-tested, revised, and study staff trained;
- Identify key milestones and staffing needs for study implementation (e.g. recruitment and enrollment, data collection, data management, data analysis, manuscript preparation);
- Describe the proposed management and staffing plan for the study;
- Describe experience and expertise of key proposed staff, including ability to conduct the proposed study;
- Describe the research team's experience recruiting and collecting data from the target population;
- Describe the research team's experience assessing screening tools and their performance in pregnant women;
- Demonstrate commitment to collaborate through letter(s) of support from proposed study site(s), and identify proposed roles for study staff;
- Include any potential study limitations or challenges to accomplishing the study objectives.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/ grants/funding/424/ SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http:// grants.nih. gov/grants /guide/url_redirect .htm? id=11123).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the

system errors cannot be resolved, applicants must contact CDC PGO TIMS at 770-488-2700; www.pgotim@cdc.gov for guidance at least 3 calendar days before the deadline date.

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions:
If an application submission was unsuccessful, ***the applicant*** must:

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "***rejected***," do #2a or #2b.

2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed.
    b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/24/2015**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http:// www. whitehouse.gov/ omb/ grants_spoc).

11. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individuals/entities are subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to coordinate an OMB/PRA approval request.

12. Other Submission Requirements and Information

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process,

visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders:
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding _errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit _app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (http:// www.cdc.gov/ about/ organization/ mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact
Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- What is the potential or actual impact of the research on public health in the US?
- Will the work be influential in that it will open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?
- If successful, do the research results have the potential to be scalable and reach a large portion of the population at risk?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- Does the PI provide evidence of being PI or co-PI of at least one past assessment of (a) substance use screening tool(s) in the pregnant population?
- Does the applicant demonstrate knowledge and experience with recruiting, enrolling, and collecting data from the target study population in clinical settings?
- Do staffing plans include, at a minimum, an obstetrician and a psychiatrist?
- Does the research team demonstrate experience working with the site(s) and collaborating on research studies with staff where the study will be implemented?
- Have previous research results provided high quality outputs and contributed to improvements in public health practice and population health?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- Does the application challenge and seek to shift current public health practice paradigms or approaches?
- Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to CDC?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from

research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

- Does the application draw on the peer-reviewed literature and the applicant's own research to justify the proposed study design?
- Does the applicant describe their approach for assessing and validating screening tools?
- Does the applicant ensure that the study is culturally appropriate and integrated into site(s) services?
- If more than one site is proposed, are the proposed sites appropriately chosen to meet the study objective and provide results generalizable to the US population?
- Are the participant recruitment and study enrollment procedures at all sites comparable, well described and adequate?
- Does the applicant provide power calculations demonstrating that the proposed sample size is sufficient to detect clinically meaningful differences in the performance of all selected substance use screening tools?
- Does the applicant present an adequate plan for data management, including the linkage of screening questionnaire data with laboratory/biological test results for illicit and prescription drugs?
- Does the applicant describe how study data will be analyzed to compare the performance of all selected screening tools?
- Is the proposed timeline sufficiently detailed, complete, and realistic for a 2-year project period (i.e. include key tasks and staff responsible for study protocol development, study implementation, adequate milestones for measuring progress towards completion of these tasks?
- Does the application describe how the results from the research will be disseminated and used to inform the adoption and potential scaling-up in real-world settings?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- Does the applicant have access to qualified personnel with realistic and sufficient percentage-time commitments relative to each phase of the study timeline?
- Does the applicant provide evidence that they can recruit the estimated number of substance-using pregnant women needed for the study?
- Are the roles and responsibilities of the study site(s) and their staff in the project sufficiently described in the application and/or in the letters of support?
- Does the applicant describe the information technology (equipment, software, expertise) available for the study?
- If more than one site is proposed, does the applicant describe plans for data sharing and data pooling?
- Does the application describe physical facilities and procedures for ensuring the confidentiality of the data?
- Does the application describe procedures for securing the integrity and disposal of

biological specimens?
- Does the project utilize critical partnerships or collaborations to accomplish the aims of the funding opportunity?
- Does the project support key stakeholder involvement throughout the research process?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 , the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements

(http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (http://www.cdc.gov/maso/Policy/Policy_women.pdf and http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1) and the policy on the Inclusion of Persons Under 21 in Research (http://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section

(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plans
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar25. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/od/pgo/funding/budgetguide.htm.

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.

As part of the scientific peer review, all applications:

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Diversity and representativeness of the study population.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (http:// www.hhs.gov/ asfr/ogapa/aboutog/ hhsgps107.pdf).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http:// www.hhs.gov/ asfr/ogapa/ aboutog/ hhsgps107.pdf).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate, as well as any additional requirements included in the FOA.

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

AR-1: Human Subjects Requirements

AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-17: Peer and Technical Reviews of Final Reports of Health Studies –; ATSDR

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Release and Sharing of Data

AR-26: National Historic Preservation Act of 1966

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, “;Federal Leadership on Reducing Text Messaging while Driving”;,

October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR-31: Distinguishing Public Health Research and Public Health Nonresearch

AR-32: ;FY 2012 Enacted General Provisions

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

AR-23: Compliance with 45 C.F.R. Part 87

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.archives.gov/.

To view brief descriptions of relevant CDC requirements visit: http:// www.cdc.gov/ od/pgo/funding/ grants /additional_ req.shtm.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications

This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:

http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol_ memo.html)

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, www.USASpending.gov (http:// www.usaspending. gov/). For the full text of the requirements, please review the following website: https:// www.fsrs.gov/.

Plain Writing Act

The Plain Writing Act of 2010 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http:// www.plainlanguage.gov/ plLaw/index.cfm.

Tobacco and Nutrition Policies

The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

  - http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf

  - http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm

  - http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

4. Cooperative Agreement Terms and Conditions of Award

The award mechanism is a grant.

The PD(s)/PI(s) will have the primary responsibility for:

- Implementing the study and accomplishing all activities described in the research plan;
- Assuring and maintaining confidentiality of all relevant data and documents;
- Ensuring that the research protocol complies with the terms and conditions of human subjects protection by preparing and coordinating the submission of the research protocol to all needed local IRB(s) pertaining to all study sites; grantee is responsible for obtaining IRB approval for all collaborators; and
- Maintaining an adequate management and staffing plan to support all project activities.

CDC staff will not have substantial programmatic involvement but will retain stewardship role in awards. The awardee will determine the research approach and develop the research protocol for the study, aligning the design and activities with the intent of the funding opportunity. CDC will provide scientific consultation and technical assistance upon request to support the intent of the announcement.

An HHS/CDC agency program official will be responsible for the normal scientific and

programmatic stewardship of the award. The Scientific Program Official will:

- Be named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award;
- Monitor performance against approved project objectives; and
- Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

5. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over $25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf) for additional information on this reporting requirement.

Annual Reports are required and should include the same information as requested for the Yearly Non-Competing Grant Progress Report (PHS 2590), excluding the New Budget Period Budget, as described below in B. Content of Reports.

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, http:// www. cdc.gov/ od/pgo/ funding/ forms.htm and at http:// grants.nih.gov/grants/ funding/2590/ 2590.htm, **is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period**

ends.

3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress report should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm) http:// grants.nih.gov/grants/ funding/2590/2590.htm: Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project

  a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

  b) Leadership/Partnership: list project collaborations and describe the role of external partners.
- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include*:

  - How will the scientific findings be translated into public health practice or inform public health policy?
  - How will the project improve or effect the translation of research findings into public health practice or inform policy?
  - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
  - How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include*:

  - How will this project lead to improvements in public health?
  - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
  - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an

estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:
    - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
    - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

2. Annual Federal Financial Reporting

The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC grantees are now available at http:// grants.nih.gov/ grants/forms.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: http://www. cdc.gov/od/pgo/ funding/grants/eramain. shtm.

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: http://era.nih.gov/commons/. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: http:// era.nih.gov/ commons /index.cfm.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post

submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)
Procurement and Grants Office
Telephone 770-488-2700
Email: PGOTIM@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)
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National Center for Chronic Disease Prevention and Health Promotion
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
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Financial/Grants Management Contact(s)
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Centers for Disease Control and Prevention
Chronic Diseases and Birth Defects Services Branch
2920 Brandywine Road, Mailstop E09
Atlanta, GA 30341
Telephone: 770-488-2932
Email: cdenard@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations
Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

This program is authorized under Section 317(k)(2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2) and Section 301(a) of the Public Health Service Act, 42 U.S.C. 241(a).

AMENDMENT I. QUESTIONS FROM POTENTIAL APPLICANTS AND CDC RESPONSES

1. Is there a minimum number of pregnant women who must be screened per year for this grant? I have carefully reviewed the grant announcement and have not been able to find anything more definitive than "an adequate sample size".

> **Response:** The FOA does not have a specific requirement for a minimum number of women to be screened. It does provide some guidance to this issue: In Part 2. Section I, Approach, under Objective 1. the FOA states that the study design should include "Determination of sample size requirements to detect clinically-meaningful differences between all the screening tools selected for comparison." Additionally, in Part 2. Section V. Application Review Information, one of the review criteria under Approach includes "Does the applicant provide power calculations demonstrating that the proposed sample size is sufficient to detect clinically meaningful differences in the performance of all selected substance use screening tools?

2. The RFA clearly stated that the interest was in validating existing screens and not developing new ones. However, could we make wording changes to existing screens (e.g., changing the screen from lifetime use to pregnancy use) if need be? Similarly, could we change the scaling of the response format from Likert scale to Yes/No given the purpose to screen for further in depth assessment?

> **Response:** The focus of this funding opportunity is on the validation of already available screening tools for substance use in pregnant women and comparison of their performance on identifying illicit and prescription drugs. In developing a proposal, applicants determine the final content and approach they plan to use to address the FOA's intent, goals, and objectives. This could potentially include modifications to one or more of the existing screening tools he/she proposes to compare and validate.

3. What does the statement "The study population must include women in all trimesters of pregnancy" mean? Does it mean that women must be screened in all trimesters of pregnancy or does it mean that in a cross-sectional design, the sample must include women in all trimesters of pregnancy?

> **Response:** The study population must include women in all trimesters of pregnancy means that the study population should be representative of women who obtain prenatal care throughout all 3 trimesters of pregnancy.

4. Do the statements regarding primary interest in illicit and prescription drugs include marijuana since we are in a state where marijuana is illegal?

> **Response:** Yes, the statements regarding primary interest in illicit and prescription drugs do include marijuana.

5. Is CDC interested in comorbidity? Should we be screening for mental health?

> **Response:** Part 2, Section I. Funding Opportunity Description, item 2. Approach, includes the

following statement under Objective 2. “Ensure that all women testing positive for any substance receive referral to appropriate care and treatment.”

6. Is CDC interested in resident/medical/graduate student involvement in research? Is this an important score driving factor?

Response: The FOA includes the following requirements regarding the research team in the Special Eligibility Requirements section (Part 2. Section III. Eligibility Information, item 3. Special Eligibility Requirements): the research team must include at least one obstetrician and one psychiatrist. Evidence that the project team will include an obstetrician and a psychiatrist must be included in the Research & Related Senior/Key Person section of the SF424 (R&R). Besides the above requirement, the composition of the research team is determined by the applicant.

7. My question is since I work under a grant through the ___ can I apply for this grant that is being offered through the CDC?

Response: This is an open competition funding opportunity, thus any institution or organization can apply. Decisions to submit an application rests with the PI and their institution or organization.

8. My question relates to the Special Eligibility Requirements listed on page 9 of the RFA. This criteria states that “The PI of the proposed study must have served as PI or co-PI on at least one other study assessing screening tools for substance use during pregnancy; the study may have involved primary data collection or be a secondary data analysis.” Our situation is …. I hope that this is sufficient to meet this criteria as I am excited about submitting a proposal. One additional question I have is whether I should list my colleague who has expertise in comparing and validating substance use measures (though not with a pregnant population and not under her own grant) as a co-investigator or a co-PI.

Response: The special eligibility requirement does specify that the PI of the proposed study must have served as PI or co-PI on at least one other study assessing screening tools for substance use during pregnancy. Please note that in the Responsiveness section, it outlines that evidence of the proposed PI’s previous research on at least one other study assessing screening tools for substance use during pregnancy involving primary data collection or secondary data analysis should be included in the Research & Related Senior/Key Person section of the SF424 (R&R). Additionally, it outlines that an abstract from the study publication must be provided. The abstract from the publication comparing substance use measures that you mentioned in your question can be included in that section. The proposed PI’s experience and how the special eligibility requirements have been met should also be documented in that section.

Eligibility will be determined after applications have been submitted and the special eligibility and responsiveness requirements are reviewed. Regarding your question about including your colleague as a co-investigator or co-PI, the special eligibility requirements refer only to the proposed PI.