

Centers for Disease Control and Prevention

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

Evaluation of a Stepped Care Approach for Perinatal Depression Treatment in Obstetrics and Gynecology Clinics

RFA-DP-15-005

Application Due Date: 02/25/2015

Evaluation of a Stepped Care Approach for Perinatal Depression Treatment in Obstetrics and Gynecology Clinics

RFA-DP-15-005

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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

Evaluation of a Stepped Care Approach for Perinatal Depression Treatment in Obstetrics and Gynecology Clinics

Activity Code

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

Activity Code - U01

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-15-005

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

93.068

Category of Funding Activity:

Health

FOA Purpose

The purpose of this FOA is to: 1) determine the effectiveness of a stepped care approach to reducing depression symptomology and increasing treatment rates; 2) determine the feasibility of implementing a stepped care approach to depression treatment in obstetric clinics; and 3) develop recommendations for implementing best practice strategies for incorporating a stepped-care approach in obstetrics clinics. Results of this FOA may inform national guidelines regarding depression care for perinatal women.

Key Dates

Publication Date: **To receive notification of any changes to RFA-DP-15-005, 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: **01/26/2015**

Application Due Date: **02/25/2015**

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: **09/30/2015**

Expiration Date: **02/26/2015**

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: 1) determine the effectiveness of a stepped care approach to reducing depression symptomology and increasing treatment rates among pregnant and postpartum women; 2) determine the feasibility of implementing a stepped care approach to depression treatment in obstetric clinics; and 3) develop recommendations for implementing best practice strategies for incorporating a stepped-care approach in obstetric clinics. Results of this FOA may inform national guidelines regarding depression care for pregnant and postpartum women.
- **Mechanism of Support.** The funding mechanism is a cooperative agreement.
- **Funds Available and Anticipated Number of Awards.** NCCHDPHP intends to fund one (1) award and to commit approximately $2,500,000 in total (including both direct and indirect costs) over the 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 each award may also vary. The total amount awarded will depend upon the quality, duration of project, and costs of the applications received.
- **Budget and Project Period.** An applicant may request a project period up to five (5) years. The estimated funding (including both direct and indirect) for the first year (12 month budget period) is $500,000 and the estimated total funding (including both direct and indirect) for the entire project period is $2,500,000. The project period will run from 9/30/2015 to 09/29/2020.
- **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 contain more than one PI. However, the first PI listed will be the "contact PI" for all correspondence.
- **Number of Applications.** Only one application per institution (normally identified by having a unique

DUNS number) is allowed.
- **Application Type.** New
- **Special Date(s).** None
- **Application Materials.** SeeSection 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 317K of the Public Health Service Act 42 U.S.C. 247b-12 and Section 301(a) of the Public Health Service Act, 42 U.S.C. 241(a).

1. Background and Purpose

Among women of reproductive age, approximately 1 out of 10 women suffer from past-year depression (Ko et al., 2012). Depression is one of the most common causes of maternal morbidity and approximately 15% of women experience symptoms before, during, or after pregnancy (Dietz et al., 2007). Depression is associated with anxiety, increased rates of alcohol and drug abuse, and may also be associated with adverse reproductive outcomes, including decreased fertility, pre-term delivery, low birth weight infants, and impaired maternal functioning and infant development. Effective treatments for depression, such as counseling/behavioral therapy and prescription medication, are available. However, fewer than half of depressed women with diagnoses receive any treatment (Ko et al., 2012) and racial/ethnic disparities in receiving care have been documented (Kozhimannil et al., 2011).

Studies evaluating mandates for universal screening (e.g.., New Jersey legislation and federal Healthy Start programs) have not shown improvements in depressive symptomology or treatment rates (Kozhimanill et al., 2011; Yonkers et al., 2009). Only three intervention studies have documented high rates of screening, diagnosis and therapy initiation, as well as declines in maternal depressive symptoms (Leung et al., 2011; Melville et al., 2014, Yawn et al., 2012). These studies incorporated multiple components such as: implementation of screening procedures and care at a woman's usual care site, care to begin immediately after a positive screen, provision of staff educational sessions and support tools for diagnosis, and other system changes to ensure women receive comprehensive care. However, two of these studies were among postpartum women only, one conducted in Hong Kong (Leung et al., 2011) and the other at a U.S. family medicine practice (Yawn et al 2012). In the third study, the authors applied many eligibility criteria that resulted in enrollment of only 32% of women who screened positive for depression and only 7% of the study population was pregnant (Melville et al., 2014). Therefore, it is unclear whether these components of care are feasible and pragmatic to incorporate in the majority of obstetric clinics serving prenatal and postpartum women.

The American College of Obstetricians and Gynecologists (ACOG) encourages women to visit their Ob/Gyn annually for well-woman visits (American College of Obstetricians and Gynecologists, 2012) and research shows that women are 4 times as likely to attend a behavioral health treatment visit if the provider is located at the same site as their obstetrical provider (Smith et al., 2009). However, ACOG does not currently recommend universal screening for perinatal depression due to lack of effective screening and referral/treatment approaches to improve women's mental health. Additionally, the U.S. Preventive Services Task Force (USPSTF) recommends depression screening for adults only when staff-assisted depression care supports are in place to ensure accurate diagnosis, effective treatment, and follow-up; however, the USPSTF recommendations have not been rigorously examined among pregnant and postpartum women. Offering

treatment at the obstetric care visit may improve treatment uptake and outcomes. Stepped care is defined as initial treatment provided at the obstetric clinic, progress assessed routinely, and referral for more intensive treatment if a woman does not adequately respond to initial treatment. More research is needed to evaluate the effectiveness and feasibility of a stepped care approach to depression diagnosis and treatment among pregnant and postpartum women in obstetric clinics. Results of this FOA may inform national guidelines regarding depression care for perinatal women.

Healthy People 2020 and other National Strategic Priorities

This research addresses several Healthy People 2020 priority area(s):

a. Maternal, Infant, and Child Health (MICH) objectives:

i. **MICH-10** Increase the proportion of pregnant women who receive early and adequate prenatal care.
ii. **MICH-6** Reduce maternal illness and complications due to pregnancy (complications during hospitalized labor and delivery).
iii. **MICH-34 (developmental)** Decrease the proportion of women delivering a live birth who experience postpartum depressive symptoms.

b. Mental Health and Mental Disorders (MHMD) objectives:

i. **MHMD-4** Reduce the proportion of persons who experience major depressive episodes (including postpartum depression).
ii. **MHMD-9** Increase the proportion of adults with mental health disorders who receive treatment,and
iii. **MHMD-11**Increase depression screening by primary care providers.

The proposed research addresses one of CDC's NCCDPHP core focus areas, or domains, "health system interventions to improve the effective delivery and use of clinical and other preventive services to prevent disease, detect diseases early, and reduce or eliminate risk factors and mitigate or manage complications." Additionally, the research addresses CDC's Division of Reproductive Health's priority to improve women's reproductive health from menarche through menopause, and three key DRH strategic areas of focus: 1) Chronic Disease Prevention and Health Promotion in Women of Reproductive Age; 2) Maternal Mortality and Complications of Pregnancy; and 3) Infant Morbidity and Mortality.

Public Health Impact

Among women of reproductive age, approximately 1 out of 10 women suffer from past-year depression, or 1.2 million women annually (Ko et al., 2012). Depression is associated with adverse reproductive health outcomes. Maternal depression may be associated with adverse reproductive health outcomes. However, fewer than half of depressed women receive treatment. A successful intervention for a stepped care approach to treating pregnant and postpartum women with depression would provide a model for incorporation in obstetric practices nationally. Such evidence could also inform national recommendations aimed at reducing the public health burden of perinatal depression.

Relevant Work

Refer to **Background and Purpose** and **Healthy People 2020 and other National Strategic Priorities** sections.

2. Approach

The research goals of this FOA are: 1) to conduct a pragmatic randomized control trial that evaluates whether a stepped care approach to screening and provision of treatment for pregnant and/or postpartum women, conducted at her normal place of care, is effective and feasible compared to referral to treatment and 2) to develop recommendations for implementation of a stepped care approach at obstetric practices across the U.S. Stepped care is defined as initial treatment provided at the obstetric clinic, progress assessed routinely, and referral for more intensive treatment if a woman does not adequately respond to initial treatment.

Objectives/Outcomes

Objective 1: To design a randomized controlled trial among depressed pregnant and postpartum women that compares depressive symptomology and treatment rates between an intervention group that receives a stepped care approach to treatment and a control group receiving usual care. The study should also evaluate the effectiveness and feasibility of the stepped care approach.

- The intervention must include a stepped-care approach, where, for the majority of depressed pregnant and postpartum women, screening and initial treatment both occur at a woman's usual (single) site of obstetric care. Women are monitored for progress, and more intensive treatment is provided, through referral, if necessary, for those who do not respond to initial treatment.
- The research design must be a randomized control trial. The study inclusion and exclusion criteria should yield a sample that is reflective of pregnant and/or postpartum women at risk for perinatal depression, with the aim of producing results generalizable to the larger population of depressed pregnant and postpartum women. Thus, the study population should have racial/ethnic and socioeconomic diversity, including multiple racial and ethnic groups and levels of socioeconomic status. Inclusion criteria should be pregnant and postpartum women who screen positive for depression. Exclusion criteria should be minimal and the study population should reflect that of the obstetric practice(s); rather than excluding women with common comorbidities to depression (e.g. inter-personal violence, substance use, and post-traumatic stress disorder) the intervention protocol should include contingencies for these women.
- The standard of care for women who screen positive for depression should reflect what is currently being implemented at the clinic(s) where the women are receiving prenatal/postpartum care. However, in the study design, investigators should consider the need to modify the standard of care to meet study objectives; for example, may need to implement universal screening for depression to capture depression prevalence.
- To determine effectiveness of the stepped care approach, outcomes of interest at a minimum should include reduction in depressive symptomology and/or remission of depression and treatment uptake and adherence. Secondary outcomes may include: complications to treatment engagement and retention, suicide ideation/attempts; functioning, quality of life, and health status.
- To determine feasibility of the stepped care approach in an obstetric clinical setting, process measures (e.g., number of clinicians trained; cost of intervention per patient and/or per clinic, time spent per patient to provide intervention, and number of referrals) should be monitored.
- The proposed sample size should be large enough to detect a difference in depressive symptomology and treatment rates within the intervention and standard care groups.

Objective 2: To implement the study and analyze data to assess all outcomes including depressive symptomology and treatment rates, feasibility and process measures.

- Establish a protocol for training clinic staff to provide the stepped care approach intervention.
- Evaluate depressive symptomology and treatment rates using stepped care approach compared to standard of care.
- Evaluate process measures (e.g., number of staff trained, time spent per patient to provide intervention, and number of referrals) to inform implementation process and future recommendations.

Objective 3: To disseminate study findings and, based on those findings, make recommendations on implementation and sustainability of a stepped-care approach in obstetric clinics.

- Summarize results of the project and prepare manuscripts in collaboration with CDC consultants. Develop recommendations on implementation and sustainability, addressing pre-implementation needs, successful best-practice components, and solutions to challenges that obstetric clinics may experience when implementing a stepped-care approach to enhance care for women with depression.
- Develop and implement a plan to disseminate the recommendations to obstetric clinics and other stakeholders (e.g., ACOG, USPTF).

Timeline – The anticipated timeline for the project consist of 3 phases over 5 years.

Phase 1: Development (Months 1-12)

- Determine primary and secondary research questions for analysis.
- Design stepped care approach intervention with best practices for screening and treatment from the literature.
- Design study and develop data collection instruments.
- Develop the research protocol for the study and submit to human subjects review.
- Register the trial with ClinicalTrials.gov, if necessary.
- Prepare OMB package, if necessary.

Phase 2: Intervention implementation (Months 13-48)

- Finalize intervention materials.
- Recruit and train staff to provide stepped care approach intervention and to conduct study.
- Pilot test intervention and revise design, if needed.
- Enroll women into the study, conduct intervention, and follow participants through at least 12 months.
- Conduct quality assurance of intervention implementation and data collection.

Phase 3: Study findings, publications, and dissemination (Months 49-60)

- Complete study data collection (by 51 months).
- Analyze data to assess depressive symptomology, treatment uptake and retention, feasibility of intervention, and cost per patient of intervention.
- Prepare and submit results to peer-review journals.
- Share de-identified data with CDC staff for secondary analyses.
- Draft and disseminate recommendations for implementation at obstetric clinics.

Target Population

The target population of this study will be all pregnant and postpartum females who screen positive for depression.

Collaboration/Partnerships

In addition to CDC, the applicant is expected to collaborate/partner with selected obstetric clinics to reach the study population. In addition, applicants may identify mental health professionals for consultation and/or referral of study participants if further treatment is needed.

Evaluation/Performance Measurement

The applicant is expected to develop an evaluation of key process milestones and outcomes such as the following:

- Number of clinicians trained, cost of intervention per patient and/or per clinic, and time spent per patient to provide the intervention.
- Depressive symptomology and treatment rates using stepped care approach compared to standard of care.

Translation Plan

The applicant should address how research findings and recommendations will be disseminated to key stakeholders (e.g. obstetric providers, ACOG, researchers) who would benefit from the knowledge gained from the study.

OMB/PRA may apply.

Reference list:

American College of Obstetricians and Gynecologists. Well-woman visit. Committee Opinion No. 534. Obstet Gynecol 2012;120:421–4.

Dietz, P.M., et al., Clinically identified maternal depression before, during, and after pregnancies ending in live births. Am J Psychiatry, 2007. 164(10): p. 1515-20.

Ko, J.Y., et al., Depression and treatment among U.S. pregnant and nonpregnant women of reproductive age, 2005-2009. J Womens Health (Larchmt), 2012. 21(8): p. 830-6.

Kozhimannil K.B. et al., New Jersey's efforts to improve postpartum depression care did not change treatment patterns for women on Medicaid. Health Aff (Millwood). 2011;30(2):293-301.

Kozhimannil K.B. et al., Racial and Ethnic Disparities in Postpartum Depression Care Among Low-Income Women. Psychiatr Serv. 2011; 62(6): 619-625.

Leung, S.S., et al., Outcome of a postnatal depression screening programme using the Edinburgh Postnatal Depression Scale: a randomized controlled trial. J Public Health (Oxf), 2011.

Smith, M.V. et al. Success of mental health referral among pregnant and postpartum women with psychiatric distress. Gen Hosp Psychiatry. 2009;31(2):155-62.

Yawn, B.P., et al., TRIPPD: a practice-based network effectiveness study of postpartum depression screening and management. Ann Fam Med, 2012. 10(4): p. 320-9. 33(2): p. 292-301.

Yonkers K.A. et al., Depression screening of perinatal women: an evaluation of the healthy start depression initiative. Psychiatr Serv. 2009;60(3):322-8.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

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: $2,500,000

Anticipated Number of Awards: 1

NCCDPHP intends to commit approximately $500,000 (including both direct and indirect costs) in FY2015 to fund one (1) applicant for the first 12-month budget period. The estimated total funding (direct and indirect) for the entire five (5) year project is $2,500,000.

If an applicant requests a funding amount greater than the ceiling of the award range for the first year ($500,000), 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: $500,000 Per Budget Period

Award Floor: $0 Per Budget Period

Total Project Period Length: 5 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

- Applicants must have the support of one or more obstetric clinics in which the project will be implemented.
- The principal investigator of the project must have experience as an investigator or co-investigator in conducting a randomized control trial among pregnant and/or postpartum women, experience conducting clinical research on mental health topics, and experience disseminating the findings in peer-reviewed publication(s).
- The applicant must have, as part of the research team, an obstetrician and a mental health specialist (e.g. psychiatrist, psychologist, or counselor with appropriate credentials).

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.

- Letter of support from obstetric clinic(s) affirming their participation in the study, and a description of their patient population.
- The applicant must provide evidence of the principal investigator's previous research conducting a randomized control trial among pregnant or postpartum women and experience in the mental health field, in the form of peer-reviewed publications on this subject matter, as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).
- The applicant must provide evidence that the project team will include an obstetrician and mental health specialist (e.g. psychiatrist, psychologist, or counselor with appropriate credentials) 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.

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

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: **01/26/2015**

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 Prevention and Health Promotion
Extramural Research Program Operations and Services
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 5-year project period and should include the following items:

Introduction/ Background

- Describe the demographics (e.g., number, age, race/ethnicity, income, insurance status) of the clients/patients served by the site(s) where the intervention will be implemented and evaluated to demonstrate a diverse racial/ethnic population with varying socioeconomic levels. Include prevalence of depression among patients at study site(s). Include other clinical and community demographic data that might be relevant.
- Describe the current practice for depression screening and treatment at study site(s).
- Demonstrate capacity to recruit the estimated number of women screening positive for depression required for an adequately powered randomized controlled trial to examine

meaningful differences in depressive symptomatology and treatment uptake.

Specific Aims

- Specify overall aims or objectives for intervention development, implementation, evaluation, and dissemination of findings and recommendations.
  Specify primary and secondary outcomes, how they will be measured, and expected effect size.

Research Strategy

- Describe approach for randomization and specify the unit of randomization (e.g., clinic, individual). If randomization is at the individual level, describe how feasibility [at the clinic level will be assessed].
- Describe inclusion/exclusion criteria of study participants.
- Describe how the proposed intervention will be implemented at study site(s). Include a description of usual care at the unit of control (e.g., clinic, individual) and whether additional care components will be implemented to enable appropriate comparison of the stepped-care approach among women who screen positive for depression (e.g., implementing universal screening at control site or among all women).
- Describe the components that will be incorporated into the stepped-care approach at the intervention site from best practices identified in the literature (e.g., established relationships between obstetric providers and mental health professionals; care provided immediately after a positive screen; system level support to promote stepped collaborative care [e.g., linked medical records between obstetric and mental health professionals]; case-management approach; reminders in the electronic medical record for screening and documentation; and staff initial and ongoing training [nurse, physician, etc.]).
- Describe approach for recruitment and retention of the study participants.
- Describe how primary outcomes (i.e., reduction in depressive symptomatology and/or remission of depression and treatment uptake and adherence) and any secondary outcomes (e.g., complications to treatment engagement and retention, suicide ideation/attempts; functioning, quality of life, and health status) will be assessed.
- Describe measures of feasibility, including process measures (e.g., number of clinicians trained; cost of intervention per patient and/or per clinic, time spent per patient to provide intervention, and number of referrals).
- Describe method and measures for data collection, management, and quality assurance. Include participant burden (e.g., time) for each data measurement. It is important that the intervention and its data components be sufficient to determine effectiveness of the intervention, as well as realistic and pragmatic for incorporation in other obstetric clinics.
- Describe a timeline for conducting follow-up assessments, after a positive screening for depression.
- Describe the protocol to address the needs of women with co-morbidities, such as inter-personal violence, substance use, and post-traumatic stress disorder, and the clinical protocol to address the most severe cases.
- Describe how data will be analyzed to demonstrate effectiveness and feasibility of the intervention, using appropriate statistical methods.
- Describe plans for working collaboratively with CDC staff on the design, analyses, and dissemination of the study.
- Describe how de-identified data will be shared with CDC collaborators for analyses.
- Describe how the RCT findings will be translated into recommendations for implementation and sustainability in other obstetric clinics and how these recommendations will be

disseminated to stakeholders.

Staffing and Milestones for Development and Implementation Process

- Describe experience and expertise of key proposed staff, including team's experience in developing, evaluating and disseminating findings from RCTs examining effectiveness and feasibility of a clinical intervention and experience working with the target population (i.e., pregnant and postpartum women) and within the site(s) where the study will take place.
- Identify tasks and provide a timeline for key milestones and protocol development activities to occur in the first 12-months of the project. Include milestones that will be used to demonstrate progress toward having an Institutional Review Board (IRB) - approved protocol and, if required, an OMB approved protocol.
- Identify key milestones and staffing needs for implementation of the RCT and evaluation in subsequent years of funding (e.g., training of clinic staff to deliver the intervention, recruitment, enrollment, and follow-up of patients, intervention delivery, data collection, management, and analysis, and report writing).
- Describe the staffing plan for the 5-year project period. Include project organizational charts with key personnel.

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: **02/25/2015**

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.

Funds will be restricted until IRB and OMB/PRA (if needed) approvals are obtained

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?

- Does the work address a scientific problem of great importance to public health research and/or practice?
- What is the potential or actual impact of the research on public health in the US and/or globally?
- Will the work be influential in that it will change the scientific approach or public health practice, and how will this improve and be of value to public health?
- If successful, is the intervention scalable and does it have the potential to reach a large portion of population at risk?
- If effective, can other obstetric clinics realistically replicate the stepped-care approach with reasonable effort?

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?

- Do the investigators have a successful track record in conducting RCTs and working in the field of perinatal mental health?
- Is there evidence of successful past collaborations with the proposed research team?
- Has the Principal Investigator engaged in previous research that has provided high quality outputs and contributed to improvements in public health practice and population health?
- Does the applicant demonstrate knowledge and experience with recruiting and collecting data from the target study population in clinic settings?

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?

- Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to CDC?
- Does the project have the potential to increase efficiency or lead to cost savings?

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 applicant draw on the peer-reviewed literature and the applicant's own research to justify the proposed components of the stepped care approach intervention? Specifically, are the included components of the proposed stepped care approach supported by the literature as best practices?
- Are the participant recruitment strategy, study enrollment procedures, and retention strategies well described and adequate?
- Is the study population diverse in race/ethnicity and socioeconomic levels, as evidenced by payer status and other clinical or community demographic data?
- Does the applicant specify an adequate protocol to address the needs of women who have comorbid conditions (e.g., substance use, post-traumatic stress disorder) and those with severe cases of depression?
- Does the applicant specify how they will screen for depression and what measures they will use to collect data for primary and secondary study outcomes? Are these data collection measures sufficient to meet the objectives of the study while being minimally burdensome to the patient so as to make the study as pragmatic and

generalizable as possible to other obstetric clinics?

- Does the applicant provide power calculations demonstrating that the proposed sample size, taking into account anticipated attrition and unit of randomization (e.g., clinic, individual), is sufficient to detect clinically meaningful differences?
- Does the applicant present an adequate plan for data management?
- Does the applicant describe how the data will be analyzed to address key research questions?
- Is the proposed timeline sufficiently detailed, complete, and realistic for a 5-year project period? (i.e., includes key tasks and staff for intervention development, protocol development, implementation of RCT, and adequate milestones for measuring progress towards completion of these tasks?)
- Does the applicant discuss plans to disseminate results of the study and subsequent recommendations for implementation to stakeholders?

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 persuasive evidence that they can recruit and retain the estimated number of women who screen positive for depression for this project?
- Does the applicant describe the site(s) and staff and explain the typical patient flow, and typical staff workload that will contribute to and be affected by the implementation of the project and data collection to evaluate the intervention?
- Does the applicant describe the roles and responsibilities of the clinic and research staff involved in the project (e.g., training of clinic staff to deliver the intervention, recruitment and follow-up of patients, data collection, management and analysis)?
- Does the applicant describe the information technology (equipment, software and expertise) available to the project (e.g., computers, software and programmer for assessment or other applications, software and expertise for statistical analyses)?
- Does the application describe physical facilities and procedures for ensuring confidentiality of data?
- Does the project utilize critical partnerships or collaborations (e.g., establish relationships to mental health professionals for care of most severe cases) to achieve study's objectives?

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 of study population by race/ethnicity and socioeconomic status.

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-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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 following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

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

- Providing oversight of the management and administrative aspects of the project including maintaining an adequate staffing plan to support project activities.
- Developing all materials required for IRB submission (e.g., protocols, consent forms, data collection materials, recruitment materials). The protocols must be designed to adequately describe implementation and evaluation of the proposed intervention and meet Office of Human Research Protections (OHRP) standards.
- Collaboratively developing the protocol with CDC.
- Submitting the protocol for human subjects review.
- OMB/PRA requirements may apply. If OMB applies, develop OMB submission package and coordinate with CDC to obtain and maintain appropriate approvals through the life cycle of the award.
- Grantee will obtain local and site IRB approval for all collaborators.
- Developing recruitment strategies to enroll adequate numbers of the proposed study sample.
- Developing and implementing stringent safeguards for protecting the rights and confidentiality of records.
- Working collaboratively with CDC to develop and finalize the research protocol, the research agenda, the data sharing agreement that details data use, access, and sharing of de-identified

data with CDC collaborators, publication plan, and review of analyses.
- Implementing the intervention, within the context of the evaluation/research study.
- Identifying, recruiting, obtaining informed consent, and enrolling and retaining an adequate number of participants in the research, as determined by the study protocols.
- Collecting all study data and ensuring data entry, security, and quality/accuracy.
- Working collaboratively with CDC staff on the design, analyses, and dissemination of study results, including sharing de-identified data with CDC for secondary analyses. As part of this effort, submit manuscript(s) through CDC clearance before submission to a peer-reviewed journal.
- Using appropriate statistical techniques to analyze data.
- Timely submission of de-identified data to lead CDC Investigator(s) over a secure data network.
- Participating in monthly conference calls with CDC collaborators and provide progress updates.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- An agency program official will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. There are two separate CDC scientific roles – Scientific Collaborator (SC) and the Scientific Program Official (SPO).

In this cooperative agreement, a NCCDPHP SC is a partner with scientific and programmatic involvement during the conduct of the project through technical assistance, advice, and coordination. The SC will:

- Use his/her experience in studies of this nature to advise the project on specific questions regarding the project.
- Provide scientific consultation and technical assistance in the development, implementation, and conduct of the study.
- Assist in the development of the research protocol and data collection instruments for Institutional Review Board (IRB) review and other required reviews and approvals.
- Obtain IRB approvals as required by CDC, if CDC is engaged in research involving human subjects. Local, and possibly CDC IRB approval will be needed for activities under this award.
- Provide assistance on and participate in data analysis, interpretation, and reporting of findings in the literature.
- Participate in monthly, or more frequent, conference calls and annual, or more frequent, site visits with awardee.

An HHS/CDC agency program official will be responsible for the normal scientific and programmatic stewardship of the award. The SPO 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.

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)

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
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Email: zgx7@cdc.gov

Peer Review Contact(s)

Moises (Chris) Langub, PhD
National Center for Chronic Disease and Health Promotion
Extramural Research Program Office
Centers for Disease Control and Prevention
4770 Buford Highway, NE M/S F-46
Atlanta, GA 30341
Telephone: (770) 488-3585
Email: eeo6@cdc.gov

Financial/Grants Management Contact(s)

Charles Denard
Procurement and Grants Office
Centers for Disease Control and Prevention
Procurement and Grants Office
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.

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations; Section 317K of the Public Health Service Act, 42 U.S.C. 247b-12 and Section 301(a) of the Public Health Service Act, 42 U.S.C. 247b-12 and 241(a).

Appendix A
Questions from Potential Applicants and Answers by CDC

1. My question is whether to proceed with myself as PI, or look to OBGYN or midwifery for more experienced PIs?

> **Response**: We cannot make recommendations regarding roles of staff on a proposed project; the applicant must make those determinations. We can provide information from the FOA that is relevant to your staffing question. The Special Eligibility Criteria outlines that the principal investigator of the project must have experience as an investigator or co-investigator in three areas: conducting a randomized control trial among pregnant and/or postpartum women, conducting clinical research on mental health topics, and disseminating the findings in peer-reviewed publication(s). In the Responsiveness section, the RFA states that the evidence of the principal investigator's previous research, conducting a randomized control trial among pregnant or postpartum women, and experience in the mental health field, in the form of peer-reviewed publications on this subject matter, should be shown in the Research & Related Senior/Key Person Section from the SF424 (R&R).

2. Our questions are whether there will be another deadline for this FOA or the Feb 25th date is the last one at this time. Is it truly one award?

> **Response:** This announcement is a Request for Applications (RFA), indicating one-time funding, not an ongoing open announcement. The application due date is 02/25/2015, no later than 5:00 PM U.S. Eastern Time. NCCDPHP intends to fund one (1) award and to commit approximately $2,500,000 in total (including both direct and indirect costs) over the 5-year project period that will run from 9/30/2015 to 09/29/2020.

3. I would be very interested to learn if another RFA for this opportunity will be announced for next year (or similar opportunities).

> **Response:** This announcement is a Request for Applications (RFA), indicating one-time funding. We do not have any information regarding future funding. For other federal funding opportunities, please continue to refer to www.Grants.gov.

4. Is there a preference for the depression measure or preferred tools for the evaluation component of the grant?

> **Response:** The FOA does not require use of specific depression measures nor does it identify preferred evaluation tools. In the Goals and Objectives section of the FOA, it does describe outcomes to determine effectiveness of the stepped care approach (at a minimum should include reduction in depressive symptomatology and/or remission of depression and treatment uptake and adherence) and secondary outcomes may include: complications to treatment engagement and retention, suicide ideation/attempts; functioning, quality of life, and health status. Also, to determine feasibility of the stepped care approach in an obstetric clinical setting the FOA notes examples of process measures (e.g., number of clinicians trained; cost of intervention per patient and/or per clinic, time spent per patient to provide intervention, and number of referrals).

5. Does the grant allow for funding the position of a dedicated therapist within the OB/GYN clinic (at MSW level)?

> **Response:** The Special Eligibility Criteria states that the applicant must have, as part of the research team, an obstetrician and a mental health specialist (e.g. psychiatrist, psychologist, or counselor with appropriate credentials). The applicant must provide evidence that the project team will include an obstetrician and mental health specialist (e.g. psychiatrist, psychologist, or counselor with appropriate credentials) as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R). No further requirements are specified in the FOA regarding support

for the research team or project partners.

6. Is the focus of the study adult women of childbearing age or are girls under the age of 18 to be included?

Response: The target population for this study will be all pregnant and postpartum females who screen positive for depression. Objective 1. of the FOA states that the study inclusion and exclusion criteria should yield a sample that is reflective of pregnant and/or postpartum women at risk for perinatal depression, with the aim of producing results generalizable to the larger population of depressed pregnant and postpartum women. Section V.2. of the FOA suggests additional criteria that reviewers will use in evaluating applications, including the proposed plans for inclusion of women, minorities, and children. Applicants should note the hyperlink to the CDC policy regarding inclusion of persons under 21 in research.

7. Can women receive incentives for participating in the RCT?

Response: In the Research Plan section of the FOA (Part 2, Section IV, Item 5) applicants are asked to describe their approach for recruitment and retention of the study participants. The funding opportunity announcement does not prohibit the use of incentives.

8. My team has experience in conducting ___. However, there is no single member of the team that has conducted an RCT in pregnant or postpartum women with mental health issues. I have conducted a few RCT's in the past and other members of my team have conducted research in ___ and ___. Would this be an impediment to applying for the grant?

Response: The announcement is seeking applicants with experience in multiple areas. The Special Eligibility Criteria outlines that the principal investigator of the project must have experience as an investigator or co-investigator in three areas: conducting a randomized control trial among pregnant and/or postpartum women, conducting clinical research on mental health topics, and disseminating the findings in peer-reviewed publication(s). In the Responsiveness section, the RFA outlines that the evidence of the principal investigator's previous research conducting a randomized control trial among pregnant or postpartum women and experience in the mental health field, in the form of peer-reviewed publications on this subject matter, should be shown in the Research & Related Senior/Key Person Section from the SF424 (R&R).

9. Does the CDC require or recommend a Data and Safety Monitoring Board for DP15-005?

Response: Having a Data and Safety Monitoring Board is not required to apply for funding under DP15-005. However, during the development phase, the successful applicant will be required to develop a research protocol for submission to the human subjects review, register the trial with ClinicalTrials.gov (if necessary), and prepare an OMB package (if necessary). These processes may require systems are in place for data protection and monitoring.

Also, in Part. 2. Section V. Application Review Information, Protections for Human Subjects, the FOA states that 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.

10. Please let us know if my collaborator is eligible as the PI for this RFA. My collaborator is currently conducting a _____ to compare the effect of _____. The study is still ongoing and has not completed yet and the study is not a ____ to compare across four groups.

Response: Eligibility will be determined after applications have been submitted and the special

eligibility and responsiveness requirements are reviewed. Therefore, the decision to include an individual as a PI rests with the applicant. Below is the special eligibility criteria and responsiveness requirements. Please note that the FOA does not specify a Phase III randomized control trial. The FOA also does not specify if study experience is related to an ongoing or completed study; it does specify that evidence of principal investigator's previous research conducting a randomized control trial among pregnant or postpartum women and experience in the mental health field be provided in the form of peer-reviewed publications on the subject matter.

Special Eligibility Criteria:

- Applicants must have the support of one or more obstetric clinics in which the project will be implemented.
- The principal investigator of the project must have experience as an investigator or co-investigator in conducting a randomized control trial among pregnant and/or postpartum women, experience conducting clinical research on mental health topics, and experience disseminating the findings in peer-reviewed publication(s).
- The applicant must have, as part of the research team, an obstetrician and a mental health specialist (e.g. psychiatrist, psychologist, or counselor with appropriate credentials).

Responsiveness to the Special Eligibility Criteria:

- Letter of support from obstetric clinic(s) affirming their participation in the study, and a description of their patient population.
- The applicant must provide evidence of the principal investigator's previous research conducting a randomized control trial among pregnant or postpartum women and experience in the mental health field, in the form of peer-reviewed publications on this subject matter, as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).

11. The announcement states "For this announcement, applicants may not include collaborators or consultants from foreign institutions." on page 11 of the PDF. Would this restriction also apply to a foreign collaborator who will not be paid off the grant?

Response: In Part 1. Section III. Eligibility, the FOA does state that foreign organizations are not eligible to apply, foreign components of U.S. organizations are not eligible to apply, and applicants may not include collaborators or consultants from foreign institutions. The funding source is unrelated to this eligibility requirement.

12. I wanted to confirm whether tuition was an acceptable direct cost on this award?

Response: As stated in the FOA, 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. We encourage you to review this document to determine how your specific circumstances apply to the requirements. Page II-41 discusses Compensation for Students.

13. The ___ is preparing a letter of intent and application for RFA-DP-15-005 "Evaluation of A Stepped Care Approach for Perinatal Depression Treatment." I see in the RFA that multiple PI's are allowable, but wondering about multi-site proposals. Can you advise about the fit with the RFA of use of multiple sites?

Response: The funding announcement does not prohibit applications proposing the use of multi-sites.

14. The title of this RFA is "Evaluation of a Stepped Care Approach for Perinatal Depression Treatment in Obstetrics and Gynecology Clinics" yet the purpose seems solely to focus on pregnancy. If we respond to RFA, can we include gyn patients (all reproductive age gyn patients) as

a secondary aim or is this over-reaching the purpose of this RFA?

Response: Part 2, Section I. of the FOA includes a description of the intent of the FOA. The decision to include additional aims rests with the applicant.