



Centers for Disease Control and Prevention

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

Pregnancy Risk Assessment Monitoring System (PRAMS)

RFA-DP-16-001

Application Due Date: 11/20/2015

Pregnancy Risk Assessment Monitoring System (PRAMS)

RFA-DP-16-001

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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

Pregnancy Risk Assessment Monitoring System (PRAMS)

Activity Code

Amendment I. made November 6, 2015

- **Section I.2 Approach** - For Components C and D, information is added about the anticipated length of the surveys.
- **Section III.3 Special Eligibility Requirements** - For Components A, B, D, information is added about sampling.
- **Section VIII. Other Information** - Added Appendix A. Questions from Potential Applicants and CDC Responses

Cooperative Agreement U01

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-16-001

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

93.946

Category of Funding Activity:

Health

FOA Purpose

The Purpose of this FOA is to assist state public health agencies in collecting population-based data on maternal and child health indicators of high scientific quality that can be used to monitor and evaluate the impact of programs and policies that influence maternal and infant health. This will be accomplished by funding 4 separate components of activities:

- 1) **Component A: Core Surveillance** to implement the Pregnancy Risk Assessment Monitoring System (PRAMS) surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy in 50 states, and to use PRAMS survey methods and supplements to monitor emerging issues that may arise during the data collection cycle, including the response to post-disaster or pandemic surveillance needs.
- 2) **Component B: Point-in-time Surveillance** to establish a point-in-time (e.g. one time, one birth year) surveillance on selected maternal behaviors and experiences that occur prior to, during, and after pregnancy and early infancy for entities with a small birth population (<20,000 annually), a lack of electronic birth records, or inadequate resources to maintain ongoing surveillance.

3) **Component C: Stillbirth Surveillance Pilot** to expand Core PRAMS methods and sampling to conduct a pilot survey among women who experienced a stillbirth and provide essential data for monitoring stillbirth and related factors such as prenatal, obstetric and postpartum health care. The information collected can fill data gaps and inform efforts to prevent the occurrence of stillbirth and improve care and support to those who experience pregnancy loss.

4) **Component D: Family history of breast and ovarian cancer survey** to expand Core PRAMS methods and sampling to collect data on family history of breast and ovarian cancer in women who recently delivered a live birth, adding valuable information to the current surveillance, medical evaluation, and cancer prevention efforts focused on identifying populations at risk, including women of reproductive age.

Key Dates

Publication Date: To receive notification of any changes to RFA-DP-16-001, 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: 10/26/2015

Is a LOI: Recommended but not Required

Application Due Date: 11/20/2015

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: 01/20/2016

Secondary Review: 03/01/2016

Estimated Start Date: 05/01/2016

Expiration Date: 11/21/2015

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.** This FOA solicits applications to support state public health agencies to: 1) establish or maintain surveillance of selected maternal behaviors and experiences that occur prior to, during, and after pregnancy in 50 states; 2) provide a high quality data source for ongoing monitoring of risk factors for maternal and infant health; 3) use PRAMS methods and survey supplements to address emerging issues that may arise during the data collection cycle, including the response to post-disaster or pandemic surveillance needs; and 4) ensure data collection results are available to inform state and national program and policies, facilitate partnerships, and demonstrate the utility of PRAMS as a data source for state and national surveillance for women who have recently had a live birth.

The activities in the FOA will be conducted under 4 separate funding components:

- 1) **Component A: Core Surveillance** to implement the Pregnancy Risk Assessment Monitoring System (PRAMS) surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy in 50 states by establishing new sites and maintaining existing sites, and to use PRAMS survey methods and supplements to monitor emerging issues that may arise during the data collection cycle including the response to post-disaster or pandemic surveillance needs.
- 2) **Component B: Point-in-time Surveillance** to establish a point-in-time (e.g. one time, one birth year) surveillance on selected maternal behaviors and experiences that occur prior to, during, and after pregnancy and early infancy for entities with a small birth population (<20,000 annually), a lack of electronic birth records, or inadequate resources to maintain ongoing surveillance.
- 3) **Component C: Stillbirth Surveillance Pilot** to expand Core PRAMS methods and sampling to conduct a pilot survey among women who experienced a stillbirth and provide essential data for monitoring stillbirth and related factors such as prenatal, obstetric and postpartum health care. The information collected can fill data gaps and inform efforts to prevent the occurrence of stillbirth and improve care and support to those who experience pregnancy loss.
- 4) **Component D: Family history of breast and ovarian cancer survey** to expand Core PRAMS methods and sampling to collect data on family history of breast and ovarian cancer in women who recently delivered a live birth, adding valuable information to the current surveillance, medical evaluation, and cancer prevention efforts focused on identifying populations at risk, including women of reproductive age.

- **Mechanism of Support.** Cooperative agreement (U01)
- **Funds Available and Anticipated Number of Awards.** Total funding is expected to be \$37,190,000 (direct and indirect) over the five-year project period to support up to 61 anticipated awards.

Component A (Core Surveillance):

Estimated Funding (per year): \$7,000,000

Estimated Number of Awards: 50

Average amount of each award: \$140,000

Component B (Point-in-Time Surveillance):

Estimated Funding (per year): \$400,000

Estimated Number of Awards: 4

Average amount of each award: \$100,000

Component C (Stillbirth Surveillance Pilot):

Estimated Funding (per year): \$80,000

Estimated Number of Awards: 2

Average amount of each award: \$40,000

Component D (Family History of Breast and Ovarian Cancer Survey):

Estimated Funding (per year): \$150,000

Estimated Number of Awards: 5
Average amount of each award: \$30,000

- **Budget and Project Period.** The estimated total funding for the first year (12 month budget period) is \$7,630,000.00 and the estimated total funding (direct and indirect) for the entire project period is \$37,190,000. The project period for each Component of funding is as follows:

Component A (Core Surveillance): 5 years – 05/01/2016 to 04/30/2021

Component B (Point-in-Time Surveillance): 3 years – 05/01/2016 to 04/30/2019

Component C (Stillbirth Surveillance Pilot): 3 years – 05/01/2016 to 04/30/2019

Component D (Family History of Breast and Ovarian Cancer Survey): 5 years – 05/01/2016 to 04/30/2021

- **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.A.](#) are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may include more than one PI; however, the first PI listed on the application 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 for each **Component** of funding.
- **Application Type.** New
- **Special Date(s).** CDC will conduct one teleconference for prospective applicants. This session will provide information about the FOA and will answer questions pertinent to preparing applications in response to this FOA.

Teleconference Date: October 14, 2:00 – 4:30 pm EST

Web link: <https://webconf.cdc.gov/lfl0/13HSD4H9>

Call-in Number: (855) 644-0229 Toll Free

Participant Code: 997938

- **Application Materials.** See [Section IV.1](#) for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Information about the Pregnancy Risk Assessment Monitoring System (PRAMS) is available at <http://www.cdc.gov/prams/>

This funding opportunity announcement 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], as amended.

1. Background and Purpose

The Pregnancy Risk Assessment Monitoring System (PRAMS) is a surveillance project of the Centers for Disease Control and Prevention (CDC) conducted in collaboration with numerous state and local health departments that was initiated in 1987 because infant mortality rates were no longer declining as rapidly as they had in prior years (1). PRAMS allows states to collect data on maternal attitudes, behaviors and experiences before, during and after pregnancy. The states use PRAMS data to inform maternal and child health programs by monitoring health behaviors, access to care, and receipt of services. For example, PRAMS data have been used to monitor various targets in Healthy People 2020, preconception health and health care indicators, and selected performance measures for various public health programs and initiatives. There is legislative support for PRAMS as follows:

The *Prematurity Research Expansion and Education for Mothers who Deliver Infants Early (PREEMIE) Act* supports the use of PRAMS to track pregnancy outcomes and help prevent preterm birth. Language in other bills have also supported the use of PRAMS to collect data on health and morbidity during pregnancy (2,4).

The purpose of PRAMS is to collect state-specific, population-based data on maternal and child health indicators of high scientific quality that can inform programs and policies related to maternal and infant health. The overall goal of PRAMS is to reduce maternal and infant morbidity and mortality by collecting information that can be used to inform:

- Maternal and infant health programs
- Health policies
- Maternal behaviors

This new funding cycle aims to: 1) establish or continue surveillance of selected maternal attitudes, behaviors and experiences that occur prior to, during, and after pregnancy in 50 states by establishing new PRAMS sites and maintaining existing PRAMS sites; 2) provide a high quality data source for ongoing monitoring of risk factors for maternal and infant health; 3) use PRAMS survey supplements (questions added to the end of the PRAMS survey in the middle of a data collection cycle) to explore and monitor issues that may arise during the data collection cycle, including the response to post-disaster or pandemic surveillance needs; and 4) ensure data collection results are available to inform state and national programs and policies, facilitate partnerships, and demonstrate the utility of PRAMS as a data source for state and national surveillance.

As the health system and patient centered health care services continue evolving in states under the Affordable Care Act, surveys with state-based sampling like PRAMS become increasingly valuable resources for self-reported information from patients on access to care and receipt of services. To increase PRAMS flexibility and meet emerging needs, PRAMS has transformed key aspects of its structure and function (5), including:

- Revision of the questionnaire to enhance PRAMS ability to be used to monitor the impact of the health system changes on maternal and infant health and behaviors and assist in efforts to translate science into public health practice.
- Implementation of the web-based centralized PRAMS Integrated Data collection System (PIDS), with the capacity to support web-based survey administration, supplemental questions on emerging issues, and future linkages to other electronic data sources.
- Improvement of data accessibility through the launch of an upgraded web-based data query system (PRAMStat) with the capacity to support sharing of surveillance data to broader audiences.

Together, these changes enhance the PRAMS infrastructure and add the flexibility necessary to support an expansion of PRAMS to become a national surveillance system. Importantly, the changes create the capacity for expansion beyond traditional surveillance methodology to increase sampling of high-risk populations and to increase responsiveness to emerging issues. These changes also create the opportunity to expand the use

of PRAMS data beyond public health professionals and researchers to health care providers.

Healthy People 2020 and other National Strategic Priorities

Healthy People 2020: PRAMS data are used to monitor progress towards 10 objectives related to Maternal, Infant, and Child Health (3 of which are developmental) (6):

- MICH-16.2 – Increase the proportion of women delivering a live birth who took multivitamins/folic acid prior to pregnancy
- MICH-16.3 – Increase the proportion of women delivering a live birth who did not smoke prior to pregnancy
- MICH-16.4 – Increase the proportion of women delivering a live birth who did not drink alcohol prior to pregnancy
- MICH-16.5 – Increase the proportion of women delivering a live birth who had a healthy weight prior to pregnancy
- MICH-16.6 – Increase the proportion of women delivering a live birth who used contraception postpartum to plan their next pregnancy
- MICH-18 – Reduce postpartum relapse of smoking among women who quit smoking during pregnancy
- MICH-20 – Increase the proportion of infants who are put to sleep on their backs
- MICH-16.1 (Developmental) – Increase the proportion of women delivering a live birth who discussed preconception health with a health care worker prior to pregnancy
- MICH-19 (Developmental) – Increase the proportion of women giving birth who attend a postpartum care visit with a health worker
- MICH-34 (Developmental) – Decrease the proportion of women delivering a live birth who experience postpartum depressive symptoms.

Title V and CoIIN: The states use PRAMS data to inform maternal and child health programs by monitoring health behaviors, access to care, and receipt of services. For example, PRAMS data have been used to monitor preconception health and health care indicators, and selected performance measures for various programs and initiatives such as the Title V Maternal and Child Health (MCH) Program and The Collaborative Improvement and Innovation Network (CoIIN) to Reduce Infant Mortality (7,8).

CDC Winnable Battles: To keep pace with emerging public health challenges and to have an impact on the leading causes of death and disability, the CDC embarked on an initiative to achieve measurable impact in a short time for topics that are described as Winnable Battle areas. CDC's Winnable Battles are areas with potential for large-scale public health effects and for which effective strategies exist to address them (9). PRAMS data can be used in the assessment of a several Winnable Battles as they relate to maternal and child health:

- HIV
- Motor Vehicle Injuries
- Nutrition, Physical Activity, and Obesity
- Breastfeeding (part of the Nutrition, Physical Activity, and Obesity Winnable Battle)
- Teen Pregnancy
- Tobacco

Public Health Impact

Data gathered by PRAMS will be used to: 1) document trends in adverse birth outcomes and other reproductive health and MCH outcomes; 2) identify subpopulations at greatest risk for the adverse birth outcomes, and inform prevention strategies and program development; 3) inform the Title V needs assessment process to help states plan for and allocate MCH block grant funds and to provide background information for states that apply for other grant funds; 4) develop and evaluate programs and policies that support improvement of maternal and child health; 5) investigate merging issues in reproductive health; and 6) support health professionals to incorporate the latest research findings into their standards of practice.

Relevant Work

Epidemiologic surveillance efforts that quantify disease and risk factors, and identify opportunities for prevention, are central to CDC's planning and evaluation efforts. CDC expects that PRAMS will continue to reflect its essential character and purpose, which is to provide statistically representative, state-specific information on maternal attitudes, behaviors and experiences useful for state-level public health program planning and evaluation. Examples of numerous previous applications of PRAMS data to impact state-level programs and policies have been documented (10-13). Further, as mentioned above, enhancements to PRAMS to increase its flexibility will expand its potential uses (5).

2. Approach

PRAMS is currently supported in 40 states and New York City. For some entities, this FOA will allow continuation of existing data collection efforts within the context of the new PRAMS infrastructure (see key transformations mentioned above). For others that do not have PRAMS, this FOA may mark the beginning of efforts to collect self-reported information on maternal and child health through this new infrastructure.

Several opportunities exist to expand beyond core PRAMS surveillance by conducting surveillance of special populations, such as stillbirths, and conducting surveillance on special topics new to PRAMS such as cancer risk.

To meet the goals of the FOA, this announcement includes 4 separate funding components:

- 1) Component A: Core Surveillance
- 2) Component B: Point-in-time Surveillance
- 3) Component C: Stillbirth Surveillance pilot
- 4) Component D: Family History of Breast and Ovarian Cancer Survey

Component A: Core Surveillance

5-year project period

The Pregnancy Risk Assessment Monitoring System collects state- and population-based information on selected maternal behaviors and experiences that occur prior to, during, and after pregnancy. Component A is for both new and previously funded PRAMS projects that plan to conduct ongoing core PRAMS surveillance. These states may also use PRAMS methods and survey supplements to respond to emerging issues that arise during the data collection cycle including the response to post-disaster or pandemic surveillance needs.

Applicants may apply for Component A or B, but not both.

Component B: Point-in-time Surveillance

3-year project period

Component B is for eligible entities that plan to conduct point-in-time (e.g. one time, one birth year) PRAMS surveillance on selected maternal behaviors and experiences that occur prior to, during, and after pregnancy. Component B is for entities with a small birth population (<20,000 annually), a lack of electronic birth records, or inadequate resources to maintain ongoing Core Surveillance, as specified in Component A above.

Applicants may apply for Component A or B, but not both.

Component C: Stillbirth Surveillance pilot 3-year project period

Stillbirth is defined as fetal deaths at 20 weeks of gestation or more. A number of factors associated with stillbirth include advanced maternal age, black race, smoking, pre-gestational diabetes, chronic hypertension, fetal growth impairment, and assisted reproductive technology. In the U.S., stillbirths occurs in 1 out of every 200 pregnancies (14).

Since its inception over 25 years ago, PRAMS has been instrumental in surveillance of maternal and neonatal health care, as well as risk factors for preterm birth and infant mortality. Women with stillbirth can be identified through vital records, utilizing similar methodologies currently in use to sample women with live births for PRAMS. Expanding PRAMS to include stillbirths could provide States with much-needed and timely data for surveillance of stillbirth factors related to prenatal and obstetric health care (e.g., for obesity, hypertension, and diabetes) and postpartum health care following pregnancy loss.

The expansion of PRAMS sampling to include women who experience a stillbirth has been a longstanding topic of interest for experts in the maternal and child health field. Thus CDC's Division of Reproductive Health, in collaboration with researchers from Emory University, subject matter experts, and women who experienced stillbirths, has developed a PRAMS-like survey for mothers with stillbirths. Formative research was conducted, including interviews with experts, focus groups with women who experienced a stillbirth, and stakeholder meetings with experts in the field, and as a result, a final stillbirth surveillance questionnaire was developed that is now available for piloting in the field. Component C is for conducting a pilot of the stillbirth surveillance questionnaire **which will allow CDC to collaborate with states to refine the survey methods. The list of questions will be provided at the start of the project period. It is anticipated that they will be similar in length to the core PRAMS survey located at <http://www.cdc.gov/prams/questionnaire.htm>.**

*Only applicants applying **for Component A** may apply for **Component C**. To be funded for **Component C**, applicants must have a responsive application for **Component A** and receive **Component A** funding.*

Component D: Family History of Breast and Ovarian Cancer Survey 5-year project period

In 2011, 220,097 women in the United States were diagnosed with breast cancer and it is the most common cancer in women (excluding some kinds of skin cancer), regardless of race or ethnicity (15). Although ovarian cancer accounts for only about 3% of all cancers in women, it causes more deaths than any other cancer of the female reproductive system; each year in the United States, about 20,000 women get ovarian cancer and about 14,500 die from it (16). A positive family (medical) history of certain types of cancer can increase the risk of cancer. This increased risk may be due to genetic factors, shared lifestyle factors or other family traits. Therefore, taking a family history is considered an integral part of the medical evaluation, particularly important in genetic risk evaluation and risk management protocols that may ultimately help in the design of strategies to reduce cancer-associated mortality (17).

From 2003 to 2008, CDC's Office of Public Health Genomics awarded cooperative agreements to four state health departments to integrate genomics knowledge (e.g., genetic risk factors) and tools (e.g., family history assessments) into state chronic disease prevention programs and core public health functions. These genomics programs have focused on building infrastructure and partnerships, training the public health workforce, educating the general public, using surveillance surveys to assess integration of genomics with existing public health programs, and promoting genomics screening tools (18).

Through collaboration with CDC's Division of Reproductive Health and Division of Cancer Prevention and Control, an additional set of survey questions to assess family history of cancer risk and genetic screening has been developed. Including questions on the family history of breast and ovarian cancer in PRAMS provides

an opportunity to identify women of reproductive age that might be high-risk or genetically predisposed to these cancers, and provide valuable information on cancer screening referrals and provision of genetic counseling to improve maternal health. **Component D** is for collecting data on the family history of breast and ovarian cancer with the new set of survey questions, **using core surveillance methods. The questions are under development and will be provided at the start of the project period. It is anticipated that the list of questions in the survey supplement will not exceed 15.**

*Only applicants for **Component A** may apply for **Component D**. To be funded for **Component D**, applicants must have a responsive application for **Component A** and receive **Component A** funding.*

Over the course of the project period there may be other opportunities to support enhanced PRAMS activities. CDC may fund these based on program priorities and availability of funding. Examples of such activities include but are not limited to:

1. Enhancements which may require oversampling of specific populations, for the evaluation of intervention programs targeting maternal and child health such as state or community programs for which the activities could be supported or evaluated by PRAMS data.
2. Enhancements to data collection methodology to be responsive to special circumstances such as natural or man-made disasters that occur in geographic areas that may adversely affect pregnant women or reproductive health services.
3. Questionnaire supplements in response to infectious disease epidemics that may adversely affect pregnant women such as influenza, Ebola, anthrax, or others that may arise
4. Questionnaire supplements on topics related to non-infectious diseases that can inform programs and policies related to CDC or State priorities:
 - Family history of chronic diseases (e.g., diabetes, hypothyroidism) in women of reproductive age who deliver a live infant
 - Maternal PKU (Phenylketonuria) or Sickle-cell disease
 - Infertility and the use of new ovarian stimulation protocols and technologies
 - Availability and use of new family planning and contraception methods
 - Environmental exposure to toxins
 - Emerging tobacco products (e.g. e-cigarettes and vaping) to support states prevention efforts
 - Marijuana use to support State monitoring and surveillance needs
 - Assessment of the referral patterns to delivery hospitals to inform perinatal regionalization efforts
4. Enhancements for special analytic studies or data linkages to assess data quality or validity.
5. Expansion of PRAMS sampling methodology:
 - PRAMS stillbirth surveillance in additional states
 - PRAMS follow-back survey for toddlers
 - Use of PRAMS methods to collect information about the experiences, health, and behaviors of fathers of recently delivered live-born infants.

To participate in PRAMS, grantees must agree to share a pre-determined, pre-approved list of variables with CDC for release via a proposal process to researchers for analytic purposes, without additional state approval requirements. CDC will provide a PRAMS Data Sharing Agreement at time of award that outlines the details of the agreement. Compliance with this data sharing agreement is required.

Objectives/Outcomes

Component A: Core Surveillance:

Objectives

1. To implement state-specific population-based surveillance on selected maternal attitudes, behaviors and experiences that occur prior to, during, and after pregnancy.
2. To collect population-based data of high scientific quality using the CDC PRAMS protocol and methods.
3. To conduct comprehensive analyses of PRAMS data based on a written analysis plan designed to inform programmatic activities and public health practice.
4. To translate and disseminate analytic results into useable information for public health action that can guide program development and evaluation in collaboration with a state-level steering committee.
5. To have the capability to respond to post-disaster or pandemic surveillance needs that may arise during the data collection cycle by implementing a PRAMS survey supplement or oversample.

Expected outcomes:

1. PRAMS sites will have statistically representative, high quality data to monitor risk factors for maternal and infant health. High quality data is based on an achievable response rate target set for all participating states.
2. PRAMS sites will have access to data on a variety of topics for analysis and providing feedback to public health and health system leaders as they establish priorities for the states.
3. Sites (with at least one year of weighted data) will have used PRAMS data to inform public health programs and policies, and health care system changes.
4. PRAMS data will be available to CDC, state public health agencies, providers and external researchers for complex studies surrounding maternal and infant health.

Component B: Point-in-time Surveillance

Objectives

1. To establish a point-in-time (e.g. one time, one birth year) surveillance on selected maternal attitudes, behaviors and experiences that occur prior to, during, and after pregnancy for entities with a small birth population (<20,000 annually), a lack of electronic birth records, or inadequate resources to maintain ongoing surveillance.
2. To collect population-based data of high scientific quality using the CDC PRAMS Point-in-time protocol and methods.
3. To conduct comprehensive analyses of PRAMS data based on a written analysis plan designed to inform programmatic activities and public health practice.
4. To translate and disseminate analytic results into useable information for public health action that can guide program development and evaluation in collaboration with a state-level steering committee.

Expected outcomes

1. PRAMS Sites will have statistically representative, high quality data to monitor risk factors for maternal and infant health. High quality data is based on an achievable response rate target set for all participating states.
2. PRAMS Sites will have access to data on a variety of topics for analysis and providing feedback to health system leaders as they establish priorities for the states.
3. Sites (with at least one year of weighted data) will have used PRAMS data to inform public health programs and policies, and health care system changes.
4. PRAMS data will be available to CDC, state public health agencies, providers and external researchers for complex studies surrounding maternal and infant health.

Component C: Stillbirth Surveillance Pilot

Objectives

1. To establish state-specific population based stillbirth surveillance by expanding core PRAMS methods and sampling to collect data on selected maternal attitudes, behaviors and experiences among women who experienced a stillbirth (i.e. fetal death at 20 weeks gestation or more).
2. To pilot test existing stillbirth survey questions and methods based on results of existing formative research; assess success and barriers to inform efforts to implement stillbirth surveillance in other states.
3. To conduct comprehensive analyses of the stillbirth data based on a written analysis plan designed to inform programmatic activities and public health practice related to stillbirth.
4. To translate and disseminate analytic results into useable information for public health action that can guide program development and evaluation in collaboration with a state-level steering committee.

Expected outcomes

1. PRAMS Sites will have collected essential data for stillbirth surveillance including related factors such as preconception and prenatal behaviors and experiences, and health care access and content.
2. PRAMS Sites will have enhanced their existing Core surveillance activities and complemented vital records data by adding information directly from women not available otherwise.
3. PRAMS Sites will have access to data on stillbirths and a variety of topics for analysis and providing feedback to health system leaders as they establish priorities for the states.
4. PRAMS data will be available to CDC, state public health agencies, providers and external researchers to increase knowledge about stillbirths, inform efforts to prevent stillbirths, and improve care and support to those who experiencing this adverse pregnancy outcome.
5. The results of the project will inform future efforts to conduct surveillance of stillbirths on a broader scale.

Component D: Family history of breast and ovarian cancer survey

Objectives

1. To implement a survey of CDC-developed questions to collect data on family history of breast and ovarian cancer, cancer screening referrals, and provision of genetic counseling.
2. To collect population-based data of high scientific quality using the CDC PRAMS protocol and methods.
3. To conduct comprehensive analyses of cancer risk data based on a written analysis plan designed to inform or change programmatic activities and public health practice specific to the topic of family history of breast and ovarian cancer.
4. To translate and disseminate analytic results into useable information for public health action that can guide program development and evaluation in collaboration with a state-level steering committee.

Expected outcomes

1. PRAMS Sites will have collected data to add to states' existing surveillance efforts on genomics and cancer.
2. PRAMS Sites will have access to data on cancer risk and a variety of topics for analysis and to provide feedback to health system leaders as they will set forth priorities for the states.
3. PRAMS Sites will have increased knowledge on cancer risk among women who deliver a live born infant.
4. PRAMS data will be available to CDC, state public health agencies, providers and external researchers for complex studies surrounding maternal cancer risk.

5. Results from the supplemental data collection will be used to inform state and national program and policies, facilitate partnerships, and demonstrate the utility of PRAMS as a data source for state breast and ovarian cancer surveillance.

Target Population

Components A, B & D: This FOA addresses the potentially vulnerable population of women recently delivering a live birth and their infants.

Component C: This FOA addresses the vulnerable population of women with a recent stillbirth.

Collaboration/Partnerships

The applicants are expected to develop substantial collaborations and partnerships with a variety of program partners and stakeholders that use and promote PRAMS data as follows:

Components A & B

- Assure active cooperation and collaboration among participating organizational units such as MCH, Vital Records, and Data Processing units.
- Form and support a state-level steering committee consisting of key internal and external stakeholders; steering committee members provide feedback on the content of the questionnaire, connect the PRAMS project to organizations that can use PRAMS data, and may provide support to the analysis and dissemination of results from the PRAMS survey.
- Collaborate with CDC and other participating states to revise the common survey questions at agreed-upon intervals to evaluate state MCH programs and priorities.
- Develop and implement a written analysis plan, to be updated annually, reflecting the evaluation of programmatic activities, including potential partners and collaborators in and outside of the health departments.

Component C:

- Assure active cooperation and collaboration among participating organizational units such as MCH, Vital Records, and Data Processing units.
- Form and support a state-level steering committee consisting of key internal and external stakeholders. The steering committee membership should include fetal death review panel members and birth defects program professionals.
- Develop and implement a written analysis and dissemination plan specific to stillbirth surveillance, to be updated annually, reflecting the evaluation of programmatic activities, including potential partners and collaborators in and outside of the health departments.

Component D:

- Assure active cooperation and collaboration among participating organizational units such as MCH, Vital Records, and Data Processing units.
- Form and support a state-level steering committee consisting of key internal and external stakeholders. The steering committee membership should include genetic counselors and oncologists, primary care and cancer-genomics public health professionals.
- Develop and implement a written analysis and dissemination plan specific to the history of cancer among women of reproductive age who deliver a live birth, to be updated annually, reflecting the evaluation of programmatic activities, including potential partners and collaborators in and outside of the health departments.

Evaluation/Performance Measurement

The applicants are expected to, in collaboration with CDC, effectively collect data, monitor the quality of their data, and make use of these data in informing policies and programs:

Components A & B

1. Ensuring stable surveillance operations by:
 - Following CDC's surveillance protocol
 - Cross training of staff in carrying out the routine data collection operations
 - Documenting the operational details
2. Ensuring data quality by:
 - Initial checking of data files generated by sampling program
 - Examining data collection operations from PIDS-generated reports
 - Monitoring response rates; CDC PRAMS has set the minimum acceptable response rate (i.e. 65% for 2007-2011 and 60% for 2012) for inclusion of PRAMS data in multi-state comparison reports.
3. Analyzing data by:
 - Identifying an individual at the state level who is dedicated to performing data analysis using software designed for complex survey data
 - Identifying analysis priorities and analysis plans.
4. Using and disseminating data by:
 - Developing linkages within the state health department and other partners
 - Promoting use of data with both public and private organizations.
 - Distributing PRAMS results to inform maternal and child health policies.
 - Documenting efforts to translate data into useable information for public health action. For this FOA, grantees are required to submit with their annual report, two (2) examples of how data were used to inform policies or programs that address maternal and infant health. Documentation is required annually for grantees with a weighted data set and will be required for newly funded states 1 year after receipt of the first weighted dataset. Grantees will use a "Data to Action" template.

Component C:

1. Ensuring stable surveillance operations by:
 - Following CDC's stillbirth surveillance protocol
 - Cross training of staff in carrying out the routine data collection operations
 - Documenting the operational details
2. Ensuring data quality by:
 - Initial checking of data files generated by sampling program
 - Examining data collection operations from PIDS-generated reports
3. Analyzing data by:
 - Identifying an individual at the state level who is dedicated to performing data analysis using software designed for complex survey data
 - Identifying analysis priorities and analysis plans related to stillbirth.
4. Using and disseminating data by:
 - Developing linkages within the state health department and other partners with expertise in stillbirth and fetal deaths.
 - Promoting use of data with both public and private organizations.
 - Distributing PRAMS results to inform maternal and child health policies.

Component D:

1. Ensuring stable surveillance operations by:
 - Following CDC's surveillance protocol developed for Component D.

- Cross training of staff in carrying out the routine data collection operations
 - Documenting the operational details
2. Ensuring data quality by:
 - Initial checking of data files generated by sampling program
 - Examining data collection operations from PIDS-generated reports
 3. Analyzing data by:
 - Identifying an individual at the state level who is dedicated to performing data analysis using software designed for complex survey data
 - Identifying analysis priorities and analysis plans related to cancer risk.
 4. Using and disseminating data by:
 - Developing linkages within the state health department and other partners with expertise in genomics or cancer.
 - Promoting use of data with both public and private organizations.
 - Distributing PRAMS results to inform maternal and child health policies.

Translation Plan

Applicants are expected to develop a research translation and dissemination plan to ensure surveillance findings are translated into policies or programs that address maternal and infant health. The plan should:

Components A & B

- Describe the data needs and priority topics for PRAMS analysis.
- Describe existing partnerships and any planned partnerships for dissemination and translation and how findings will be disseminated through various channels, including steering committee members, health policy makers, and health providers and translated into public health action.

Component C:

- Describe the data needs and priority topics for PRAMS analysis related to stillbirth surveillance.
- Describe existing partnerships and any planned partnerships for dissemination and translation of the stillbirth surveillance data and how findings will be disseminated through various channels, including steering committee members, health policy makers, and health providers and translated into public health action to reduce stillbirth occurrence.

Component D:

- Describe the data needs and priority topics for PRAMS analysis related to breast and ovarian cancer.
- Describe existing partnerships and any planned partnerships for dissemination and translation of the cancer surveillance data and how findings will be disseminated through various channels, including steering committee members, health policy makers, and health providers and translated into public health action to promote cancer prevention among women of reproductive age.

OMB/PRA is expected to apply.

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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: \$37,190,000

The estimated total funding for the entire project period is \$37,190,000 (direct and indirect). \$7,630,000 is the estimated total for the first year (12-month budget period) to fund up to 61 awards in four components.

Component A (Core Surveillance):

Estimated Funding (per year): \$7,000,000

Average amount of each award: \$140,000

Component B (Point-in-Time Surveillance):

Estimated Funding (per year): \$400,000

Average amount of each award: \$100,000

Component C (Stillbirth Surveillance Pilot):

Estimated Funding (per year): \$80,000

Average amount of each award: \$40,000

Component D (Family History of Breast and Ovarian Cancer Survey):

Estimated Funding (per year): \$150,000

Average amount of each award: \$30,000

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

Anticipated Number of Awards: 61

Component A (Core Surveillance): Estimated Number of Awards is 50

Component B (Point-in-Time Surveillance): Estimated Number of Awards is 4

Component C (Stillbirth Surveillance Pilot): Estimated Number of Awards is 2

Component D (Family History of Breast and Ovarian Cancer Survey): Estimated Number of Awards is 5

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

Award Ceiling: \$175,000 Per Budget Period

See below for Award Ceiling by Component:

Component A (Core Surveillance): \$175,000 (total direct and indirect costs); This ceiling is for the first 12-month project period.

If an applicant requests a funding amount greater than the ceiling of the award range for the first year (\$175,000), 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.

Component B (Point-in-Time Surveillance): \$125,000 (total direct and indirect costs); This ceiling is for the first 12-month project period.

If an applicant requests a funding amount greater than the ceiling of the award range for the first year (\$125,000), 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.

Component C (Stillbirth Surveillance Pilot): \$40,000 (total direct and indirect costs); This ceiling is for the first 12-month project period.

If an applicant requests a funding amount greater than the ceiling of the award range for the first year (\$40,000), 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.

Component D (Family History of Breast and Ovarian Cancer Survey): \$30,000 (total direct and indirect costs); This ceiling is for the first 12-month project period.

If an applicant requests a funding amount greater than the ceiling of the award range for the first year (\$30,000), 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.

Award Floor: \$0 Per Budget Period

Components A, B, C and D: Award floor is \$0.

Total Project Period Length: 5 year(s)

Component A (Core Surveillance):

Proposed Award Start Date: May 1, 2016

Project Period: 5 years

Component B (Point-in-Time Surveillance):

Proposed Award Start Date: May 1, 2016

Project Period: 3 years

Component C (Stillbirth Surveillance Pilot):

Proposed Award Start Date: May 1, 2016

Project Period: 3 years

Component D (Family History of Breast and Ovarian Cancer Survey):

Proposed Award Start Date: May 1, 2016

Project Period: 5 years

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

III. Eligibility Information

1. Eligible Applicants

Eligibility Category: State governments
County governments
City or township governments

Special district governments
Native American tribal governments (Federally recognized)
Others (see text field entitled "Additional Information on Eligibility" for clarification)

Additional Eligibility Category:

Other:

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

Additional Information on Eligibility - Eligibility is limited to official State, local or territorial public health agencies designated as registration areas for vital statistics, federally or state recognized American Indian or Alaska Native Tribal (AI/AN) governments (with at least 1,000 births annually), and Tribal Epidemiology Centers, as a Bona Fide Agent for a tribal government.

Applicants whose jurisdiction includes a Tribal Epidemiology Center (TEC) are encouraged, but not required, to work with the TEC on surveillance of their American Indian/Alaska Native populations.

Throughout this document, the terms "state" or "site" apply to any local, state, territory, or tribe that meets the eligibility requirements.

Special Eligibility Requirements

- Applicants may apply for **Component A, Core Surveillance** or **Component B Point-in-Time**, not both.
- To receive an award, applicants applying for **Component C or Component D** must also apply for and receive **Component A** funding. A separate application must be provided for each Component and each application will be peer-reviewed and evaluated separately.
- Applicants should clearly indicate the Component for which they are applying and should include at the beginning of the title, the respective component under which the application should be considered (i.e. **Component A, Component B, Component C or Component D**).

Component A: Core Surveillance - All applicants for Component A must provide:

- 1) Written assurance, signed by the head of the state's Vital Statistics unit, that:
 - a) Vital Statistics will work collaboratively with the organizational units housing and collaborating on PRAMS to support the PRAMS program;
 - b) The recipient PRAMS program will have timely (i.e. two to four months after delivery) access to edited birth certificate information for sampling on a monthly basis;
 - c) The recipient program will identify and commit a person from the Vital Statistics unit to act as a liaison to the PRAMS program to develop and maintain the **sampling** program and make any modifications needed throughout the life of the program;
 - d) The final birth tape will be available to CDC by December 1 of the year following the data collection year (i.e. 2017 for 2016 data collection), and the birth tape will include all the elements required by CDC for data weighting;
 - e) Any changes in the vital statistics system, such as with file layouts or adoption of any new birth certificate format, will be communicated in writing to the recipient PRAMS program in a timely fashion.
- 2) A joint letter of commitment from the State Directors of the Maternal and Child Health (MCH), the Data Processing units and/or other organizational units where the PRAMS project may be housed indicating that:
 - a) They will work collaboratively to support the PRAMS program; this letter should identify which unit will be the lead in implementing the PRAMS program, and what roles each unit will play; and
 - b) PRAMS questionnaire and operational variables are available to CDC without restriction, and CDC may distribute these variables to internal and external stakeholders and researchers via a proposal process.
- 3) Applicants who will be working with a Tribal Epidemiology Centers (TEC) should include a letter of support from the TEC that describes the nature of the working relationship (e.g., data sharing agreements, steering committee appointments, assistance with TECs, assistance in locating survey participants, or dissemination of data).
- 4) Applicants with projects that span more than one state or territory must provide all of the above listed supporting materials from each state and territory involved.

Evidence of these Special Eligibility Requirements should be placed in Appendix A of the application. If the application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

Component B: Point-in-time Surveillance - All applicants for Component B must provide:

- 1) Written assurance, signed by the head of the state's Vital Statistics unit, that:
 - a) Vital Statistics will work collaboratively with the organizational units housing and collaborating on PRAMS to support the PRAMS program;
 - b) The recipient PRAMS program will have timely (i.e. two to four months after delivery) access to edited birth certificate information for sampling on a monthly basis;
 - c) The recipient program will identify and commit a person from the Vital Statistics unit to act as a liaison to the PRAMS program to develop and maintain the **sampling** program and make any modifications needed throughout the life of the program;
 - d) The final birth tape will be available to CDC by December 1 of the year following the year of

data collection (i.e. 2017 for 2016 data collection), and the birth tape will include all the elements required by CDC for data weighting;

e) Any changes in the vital statistics system, such as with file layouts or adoption of any new birth certificate format, will be communicated in writing to the recipient PRAMS program in a timely fashion.

2) A joint letter of commitment from the State Directors of the Maternal and Child Health (MCH), the Data Processing units and/or other organizational units where the PRAMS project may be housed indicating that:

a) They will work collaboratively to support the PRAMS program; this letter should identify which unit will be the lead in implementing the PRAMS program, and what roles each unit will play; and

b) PRAMS questionnaire and operational variables are available to CDC without restriction, and CDC may distribute these variables to internal and external stakeholders and researchers via a proposal process.

3) Applicants who will be working with a Tribal Epidemiology Centers (TEC) should include a letter of support from the TEC that describes the nature of the working relationship (e.g., data sharing agreements, steering committee appointments, assistance with TECs, assistance in locating survey participants, or dissemination of data).

4) Applicants with projects that span more than one state or territory must provide all of the above listed supporting materials from each state and territory involved.

Evidence of these Special Eligibility Requirements should be placed in Appendix A of the application. If the application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

Component C: Stillbirth Surveillance Pilot - All applicants for Component C must provide:

1) Written assurance, signed by the head of the state's Vital Statistics unit, that

a) Vital Statistics will work collaboratively with the organizational units housing and collaborating on PRAMS to support the sampling and data collection of mothers who experienced a stillbirth, including identifying variables required for sampling and weighting;

b) The recipient PRAMS program will have access to edited fetal death certificate information at least nine to twelve months after death for sampling;

c) The recipient program will identify and commit a person from the Vital Statistics unit to act as a liaison to the PRAMS program to develop and maintain the sampling program and make any modifications needed throughout the life of the program;

d) The final fetal death file will be available to CDC by December 1 of the second year following year of data collection (i.e. by 2018 for 2016 data collection), and the fetal death file will include all the elements required by CDC for data weighting;

e) Any changes in the vital statistics system related to the fetal death file, such as with file layouts or formats, will be communicated in writing to the recipient PRAMS program in a timely fashion

f) Vital statistics will work collaboratively with organizational units supporting PRAMS and the CDC to:

i) Identify a specific set of fetal death certificate variables and define the acceptable groupings of these variables for release to researchers by CDC as part of a standard PRAMS Analytic Research File.

- ii) To develop and approve a data sharing agreement.
- 2) A joint letter of commitment from the State Directors of the Maternal and Child Health (MCH), the Data Processing units and/or other organizational units where the PRAMS project may be housed indicating that:
 - a) They will work collaboratively to support the sampling of stillbirths from the fetal death file; this letter should identify which unit will be the lead in implementing the PRAMS program, and what roles each unit will play; and
 - b) PRAMS questionnaire and operational variables are available to CDC without restriction, and CDC may distribute these variables to internal and external stakeholders and researchers via a proposal process.
 - 3) Applicants who will be working with a Tribal Epidemiology Centers (TEC) should include a letter of support from the TEC that describes the nature of the working relationship (e.g., data sharing agreements, steering committee appointments, assistance with TECs, assistance in locating survey participants, or dissemination of data).
 - 4) Applicants with projects that span more than one state or territory must provide all of the above listed supporting materials from each state and territory involved.

Evidence of these Special Eligibility Requirements should be placed in Appendix A of the application. If the application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

Component D: Family History of Breast and Ovarian Cancer Survey - All applicants for Component D must provide:

- 1) Written assurance, signed by the head of the state's Vital Statistics unit, that:
 - a) Vital Statistics will work collaboratively with the organizational units housing and collaborating on PRAMS to support data collection related to the family history of breast and ovarian cancer;
 - b) The recipient PRAMS program will have timely (i.e. two to four months after delivery) access to edited birth certificate information for sampling on a monthly basis;
 - c) The recipient program will identify and commit a person from the Vital Statistics unit to act as a liaison to the PRAMS program to develop and maintain the **sampling** program and make any modifications needed throughout the life of the program;
 - d) The final birth tape will be available to CDC by December 1 of the year following the year of data collection (i.e. 2017 for 2016 data collection), and the birth tape will include all the elements required by CDC for data weighting;
 - e) Any changes in the vital statistics system, such as with file layouts or adoption of any new birth certificate format, will be communicated in writing to the recipient PRAMS program in a timely fashion.
- 2) A joint letter of commitment from the State Directors of the Maternal and Child Health (MCH), the Data Processing units and/or other organizational units where the PRAMS project may be housed indicating that:
 - a) They will work collaboratively to support the PRAMS program; this letter should identify which unit will be the lead in implementing the PRAMS program, and what roles each unit will play; and
 - b) PRAMS questionnaire and operational variables are available to CDC without restriction, and

CDC may distribute these variables to internal and external stakeholders and researchers via a proposal process.

- 3) Applicants who will be working with a Tribal Epidemiology Centers (TEC) should include a letter of support from the TEC that describes the nature of the working relationship (e.g., data sharing agreements, steering committee appointments, assistance with TECs, assistance in locating survey participants, or dissemination of data).
- 4) Applicants with projects that span more than one state or territory must provide all of the above listed supporting materials from each state and territory involved.

Evidence of these Special Eligibility Requirements should be placed in Appendix A of the application. If the application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

4. Justification for Less than Maximum Competition

The following organizations are eligible to receive funding under this funding announcement:

- Federally recognized or state-recognized American Indian/Alaska Native tribal governments
- Tribal epidemiology centers (TECs), as a Bona Fide Agent, for a Federally recognized or state-recognized American Indian/Alaska Native tribal government
- State and local governments or their Bona Fide Agents

These agencies are designated as registration areas for vital statistics and are the only agencies qualified to perform the activities under the proposed funding announcement because implementation of the activities requires access to vital records information for sampling. The office of vital records is the official office to record all births and deaths within the jurisdiction. In addition, and equally important, these agencies have the ability to conduct the following required activities to participate in PRAMS:

1. Design a State-wide PRAMS program that assures access to essential vital records information on a timely basis by being able to draw a sample from birth certificates within two to four months after delivery and a sample from fetal deaths certificates within nine to twelve months after death;
2. Develop a cycle of sampling and data collection in accordance with the protocol and PRAMS software;
3. Develop, maintain, and make available, using the standardized PRAMS protocol, electronic files on birth or death certificate information of the sampling frame and of sampled women, data collection activities, and questionnaire data for assuring timely data management, sampling, cleaning, and weighting; and
4. Assure that a final birth tape is available by December 1 of the year following data collection and the final death file is available by December 1 of the second year following data collection. The final vital statistics files are needed for weighting the annual data set. The final weighted is returned to the State for analyses.

5. Responsiveness

Documentation 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.

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%20for%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](https://www.Grants.gov)
- [eRA Commons](https://www.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 for each **Component** of funding.

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 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.

Applicants should clearly indicate the **Component** for which they are applying and should include at the beginning of the title, the respective component under which the application should be considered (i.e. **Component A**, **Component B**, **Component C** or **Component D**).

3. Letter of Intent

Due Date for Letter of Intent: **10/26/2015**

Is a LOI: Recommended but not Required

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 above and 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
Name of **Component (i.e. A, B, C or D)**

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: zg7@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

- Applicants must submit a separate application for each Component of funding.
- Applicants should clearly indicate the Component for which they are applying and should include at the beginning of the title, the respective **Component** under which the application should be considered (i.e. A [Core], B [Point-in-time Surveillance], C [Stillbirth Pilot], etc.).
- For each **Component**, the applicant's research plan should address activities that will be conducted over the entire project period and should include the following items:

Component A (Core Surveillance):

5-year project period

Background and Need

1. Describe the composition of the birth population, giving the numbers of overall births and births in each sub-population of interest. Describe the scope and severity of the problems of poor pregnancy outcomes, including infant mortality, low birth weight, and related risk factors such as inadequate prenatal care or unintended pregnancy. This may apply on a statewide basis or to high risk sub-populations in defined geographical areas and may be assessed in relation to relevant national rates, state program activities, Maternal and Child Health Bureau indicators, or the "Healthy People 2020 Objectives".
2. Describe how the proposed research will improve or have an impact on population health
3. Describe the reproductive health and maternal and child health priorities for the state and how PRAMS data can be integrated into the state's activities to address those priorities and evaluate state programs.
4. Identify gaps in needed information concerning adverse pregnancy and infant outcomes, pregnancy and infant risk factors, and describe how PRAMS data can be used to fill these gaps and aid in program development.
5. Describe how data from PRAMS will complement the use of vital records or other MCH data by increasing understanding of previously identified maternal and infant health problems, identifying new

problems, and evaluating programs designed to address these problems.

Profile of State Birth Registration Process

1. Describe the state process for registering births. Include each step from collection of information at the birth site, having an initial computerized file, and having a clean, edited file from which other information can be drawn. Present a time line for the cleaning of critical variables, such as name, address, and date of birth. Document that the birth certificate information is available within two to four months after the date of birth.
2. Describe the schedule on which birth certificate information will be available for sampling.
3. Describe the extent to which you can link birth certificate data to other data sources, e.g., infant deaths, Supplemental Nutrition Program for Women, Infants, and Children (WIC), Medicaid, or Hospital Discharge Data (for mother and/or infant).
4. Describe any state laws or policies that place restrictions on the release of vital records data for surveillance purposes and indicate the impact of these laws or policies on PRAMS. Include in your description the impact of these laws and policies on the re-release of birth certificate variables to internal and external stakeholders or researchers for analytic purposes, and describe a plan for addressing any restrictions, if applicable.
5. Describe any state laws or policies that place restrictions on the temporary secure upload of information to the CDC certified software system for use by internal state PRAMS staff to contact sampled women, and describe a plan for addressing any restrictions.
6. Describe any plans for dealing with revisions of the birth certificate.

Plan of Operation

1. Describe how the major project components, such as data analysis, staffing plan, procedures development, and steering committee, will be developed and implemented within the first year of funding.
2. Include any potential study limitations or challenges to accomplishing the study objectives.
3. Describe the planned approach for establishing, maintaining, or achieving expected response rates throughout the project period. Document a plan of action to ensure achievement of response rates meeting the CDC threshold in any population or sub-population (i.e. 65% for 2007-2011 and 60% for 2012) including plans for overcoming data collection barriers.
4. Provide examples of previous data collection efforts, including past experiences with PRAMS, PRAMS-like or other surveillance systems. Describe progress implementing PRAMS, PRAMS-like or other surveillance activities and any barriers that precluded complete and successful implementation of the project (e.g. sources of contact information, staffing patterns, and response rates).
5. Document the extent to which PRAMS, PRAMS-like or other surveillance data have been analyzed and used for health program planning, program evaluation, policy development, and resource allocation. Provide a list of abstracts, presentations, publications (e.g. fact sheets, surveillance reports, journal articles, etc.), and specific examples of dissemination and translation of PRAMS, PRAMS-like or other surveillance data from within the last 3 years.
6. Describe capacity to implement a survey supplement (questions added to the end of the PRAMS survey in the middle of a questionnaire Phase) to explore and monitor issues that may arise during the data collection cycle including the response to post-disaster or pandemic surveillance needs.

Management and Staffing Plan

1. Describe the proposed management and staffing plan for the study. It is strongly recommended that a minimum of two full-time equivalents be committed to working on daily operations and coordination of PRAMS.
 - Include a state level staffing plan (roles, percentage of time on project) that identifies and

describes the state staff, including who contributes to PRAMS throughout the Project Period. Also, specify a person in Vital Records indicating the percentage of their time dedicated to PRAMS. For existing PRAMS projects, include roles, the proportion of their time spent on PRAMS, and a summary of their accomplishments on previous PRAMS, PRAMS-like or other surveillance systems.

- Identify key milestones and staffing needs for study implementation (e.g. data collection, data management, data analysis, data translation and dissemination).
- Describe plans for maintaining Project Activities when staff vacancies occur.
- Document (with curriculum vitae) and describe experience and expertise of proposed staff, including ability to conduct the proposed study. Describe the research team's experience collecting data from the target population. Dedicated staff should possess a specific set of skills that includes but is not limited to surveillance and surveys, epidemiology and research, statistical methods employed when weighted survey data are used, translation of study findings, collaboration and partnership.
- Describe the organizational capabilities of the project leadership and the institutional capabilities that exist
- Document (with curriculum vitae) and describe the experience of project leadership overseeing or conducting PRAMS, PRAMS-like, or other surveillance activities at the state health department, and level of performance in achieving project aims.

2. Include project and agency organizational charts with key personnel. It is highly recommended that staff dedicated to PRAMS are housed together and supervised by the same entity.

Analysis and Translation plan

1. Describe the specific roles and responsibilities of staff responsible for identifying analysis priorities, developing analysis plans, and analyzing PRAMS data.
2. Describe a plan for data use that integrates the MCH priorities that can be addressed by PRAMS and will be used for program planning, program evaluation, policy development, and resource allocation.
3. Describe how data will be disseminated through various channels, including steering committee members, health policy makers, and health providers and translated into public health action.
4. Describe a plan for reporting effective use of PRAMS data to CDC.

Collaboration

1. Describe plans for developing substantial collaborations and partnerships with a variety of program partners and stakeholders for the use and promotion of PRAMS data.
 - Include plans to assure active cooperation and collaboration among participating organizational units such as MCH, Vital Records, and Data Processing units.
 - Describe the state-level steering committee consisting of key internal and external stakeholders, including members' affiliations and areas of expertise, frequency of meetings, and a summary of activities or meetings conducted. If individuals have not been identified, specify the process by which individuals will be identified to ensure members have content specific expertise.
 - Describe the role of steering committee and other partners in the analysis, dissemination and translation of PRAMS data.
2. Describe plans for collaborating with CDC and other participating states to revise the common survey questions at agreed-upon intervals in order to evaluate state MCH programs and priorities.

Timetable

1. Provide a timeline for key milestones and protocol development activities to occur in the first 12-months of the five-year project. Include milestones that will be used to demonstrate progress

- toward having an Institutional Review Board (IRB) approved protocol.
2. Identify key milestones for the remainder of the project period.

Budget

1. Provide a detailed budget and line-item justification of all operating expenses that are consistent with the planned activities of the project for the first 12-months and include at least one trip per year to Atlanta, GA.

Component B (Point-in-Time Surveillance): 3-year project period

Background and Need

1. Describe the composition of the birth population, giving the numbers of overall births and births in each sub-population of interest. Describe the scope and severity of the problems of poor pregnancy outcomes, including infant mortality, low birth weight, and related risk factors such as inadequate prenatal care or unintended pregnancy. This may apply on a statewide basis or to high risk sub-populations in defined geographical areas and may be assessed in relation to relevant national rates, state program activities, Maternal and Child Health Bureau indicators, or the “Healthy People 2020 Objectives”.
2. Describe how a point-in-time survey would meet the needs of the state (e.g., a small birth population [$<20,000$ births annually], lack of electronic birth records, inadequate resources to maintain ongoing surveillance).
3. Describe how the proposed research will improve or have an impact on population health.
4. Describe the reproductive health and maternal and child health priorities for the state and how PRAMS data can be integrated into the state’s activities to address those priorities and evaluate state programs.
5. Identify gaps in needed information concerning adverse pregnancy and infant outcomes, pregnancy and infant risk factors, and describe how PRAMS data may be used to fill these gaps.
6. Describe how data from PRAMS will complement the use of vital records or other MCH data by increasing understanding of previously identified maternal and infant health problems, identifying new problems, and evaluating programs designed to address these problems.

Profile of State Birth Registration Process

1. Describe the state process for registering births. Include each step from collection of information at the birth site, having an initial computerized file, and having a clean, edited file from which other information can be drawn. Present a time line for the cleaning of critical variables, such as name, address, and date of birth. Document that the birth certificate information is available within two to four months after the date of birth.
2. Describe the schedule on which birth certificate information will be available for sampling.
3. Describe the extent to which birth certificate data can be linked to other data sources (e.g., infant deaths, Supplemental Nutrition Program for Women, Infants, and Children [WIC], Medicaid, or Hospital Discharge Data [for mother and/or infant]).
4. Describe any state laws or policies that place restrictions on the release of vital records data for surveillance purposes and indicate the impact of these laws or policies on PRAMS. Include in your description the impact of these laws and policies on the re-release of birth certificate variables to internal and external stakeholders or researchers for analytic purposes, and describe a plan for addressing any restrictions, if applicable.
5. Describe any state laws or policies that place restrictions on the temporary secure upload of information to the CDC certified software system for use by internal state PRAMS staff to contact

- sampled women, and describe a plan for addressing any restrictions.
6. Describe any plans for dealing with revisions of the birth certificate.

Plan of Operation

1. Describe how the major project components, such as data analysis, staffing plan, procedures development, and steering committee, will be developed and implemented within the first year of funding.
2. Describe the planned approach for establishing, maintaining, or improving response rates. Document a plan of action to ensure achievement of response rates meeting the CDC threshold in any population or sub-population (65% for 2007-2011 and 60% for 2012). Provide examples of previous data collection efforts, including past experience with PRAMS, PRAMS-like or other surveillance systems.

Management and Staffing Plan

1. Describe the organizational capabilities of the project leadership and the institutional capabilities that exist.
2. Describe the specific roles and responsibilities of participating organizational units, such as MCH, vital records, and data processing units. Provide agency and project organizational charts that shows the location of units participating in PRAMS.
3. Describe the experience of project leadership overseeing or conducting PRAMS or other surveillance activities at the state health department, and level of performance in achieving project aims.
4. Describe the roles, responsibilities, and supervision of key personnel who will be contributing to the PRAMS program during the next budget period. It is highly recommended that staff dedicated to PRAMS are housed together and supervised by the same entity. Also, specify a person in Vital Records indicating the percentage of their time dedicated to PRAMS.
5. Document (with curriculum vitae) the relevant expertise and experience of proposed personnel involved in PRAMS program direction, operational management, and data analysis and dissemination, and their placement within the organization. It is strongly recommended that a minimum of two full-time equivalents at the state level be committed to working on daily operations and coordination of PRAMS. Dedicated staff should possess a specific set of skills that includes but is not limited to surveillance and surveys, epidemiology and research, statistical methods employed when weighted survey data are used, translation of study findings, collaboration and partnership.
6. Document (with curriculum vitae) the experience and expertise of an epidemiologist, statistician, or other analyst who will be dedicated to the analysis and reporting of PRAMS data results.

Analysis and Translation plan

1. Describe the specific roles and responsibilities of staff responsible for identifying analysis priorities, developing analysis plans, and analyzing PRAMS data.
2. Describe a plan for data use that integrates the MCH priorities that can be addressed by PRAMS and will be used for program planning, program evaluation, policy development, and resource allocation.
3. Describe how data will be disseminated through various channels, including steering committee members, health policy makers, and health providers and translated into public health action.
4. Describe a plan for reporting effective use of PRAMS data to CDC.

Collaboration

1. Describe plans for developing substantial collaborations and partnerships with a variety of program partners and stakeholders for the use and promotion of PRAMS data.
 - Include plans to assure active cooperation and collaboration among participating organizational units such as MCH, Vital Records, and Data Processing units.
 - Describe the state-level steering committee consisting of key internal and external stakeholders, including members' affiliations and as areas of expertise, frequency of meetings, and a summary

of activities or meetings conducted. If individuals have not been identified, specify the process by which individuals will be identified to ensure members have content specific expertise.

- Describe the role of steering committee and other partners in the analysis, dissemination and translation of PRAMS data.

2. Describe plans for collaborating with CDC and other participating states to revise the common survey questions at agreed-upon intervals in order to evaluate state MCH programs and priorities.

Timetable

1. Provide a timeline for key milestones and protocol development activities to occur in the first 12-months of the three-year project. Include milestones that will be used to demonstrate progress toward having an Institutional Review Board (IRB) approved protocol.
2. Identify key milestones for the remainder of the project period.

Budget

1. Provide a detailed budget and line-item justification of all operating expenses that are consistent with the planned activities of the project for the first 12-months and include at least one trip per year to Atlanta, GA.

Component C (Stillbirth Surveillance Pilot): 3-year project period

Background and Need

1. Describe the scope and severity of stillbirth in the state overall and within sub-populations of interest.
2. Identify gaps in needed information concerning stillbirth and describe how PRAMS data may be used to fill these gaps.
3. Describe how the stillbirth surveillance activities may be used to improve outreach and collaboration, and the amount and quality of information available related to stillbirths among women of reproductive age.
4. Describe any legislative support to evaluate and assess stillbirths in the state.
5. Describe experience with conducting surveillance of stillbirths or an active stillbirth registry.

Profile of State Fetal Death Registration Process

1. Describe, in detail, the state process for registering fetal deaths. Include each step from initial collection of death information, having an initial computerized file, and having a clean, edited file from which other information can be drawn. Present a time line for the cleaning of critical variables, such as name, address, cause of death, and date of death. Document that the fetal death certificate information is available for sampling within nine to twelve months after the date of death.
2. Describe the schedule on which death certificate information will be available.
3. Describe any state laws or policies that place restrictions on the release of vital records data for surveillance purposes and indicate the impact of these laws or policies on PRAMS. Include in your description the impact of these laws and policies on the re-release of death certificate variables to internal and external stakeholders or researchers for analytic purposes.
4. Describe any plans for dealing with revisions of the fetal death certificate.

Plan of Operation

1. Describe the plan for obtaining resources (including staff and analytic expertise) and expertise to carry out the enhanced activities.
2. Describe how existing resources will be used and/or how new resources will be obtained to ensure

sufficient staffing time and content area expertise for the project

3. Describe how the stillbirth surveillance activities (such as staffing, data analysis, data dissemination and translation, and steering committee) will be developed and implemented.
4. Describe how the state's planned PRAMS structure will be adjusted to accommodate the additional workload related to adding a sample of a special population. Examples of prior experiences with expansion of PRAMS sampling should be described, if applicable. The following areas should be addressed: staffing, sampling, data collection, steering committee, data analysis, and data dissemination.
5. Document (with curriculum vitae) the relevant expertise and experience of proposed personnel involved in PRAMS program direction, operational management, and data analysis and dissemination, and their placement within the organization. It is strongly recommended that a minimum of .5 full-time equivalents at the state level be committed to working on operations and coordination of PRAMS stillbirth surveillance.

Management and Staffing Plan

1. Document the relevant expertise and experience of proposed personnel involved in enhanced activities, and their placement within the organization.
2. Describe relevant experience of proposed personnel as it relates to responsibilities that they will have on the project. Include curriculum vitae and organizational charts.
3. Describe how all units involved with the core PRAMS activities and the stillbirth surveillance pilot will cooperate and collaborate.
4. Describe how the vital records office staff, birth defects registry, and other surveillance program or epidemiology staff will be involved with the project.
5. Provide confirmation of the availability and completeness of fetal death records from the Vital Records Office.

Analysis and Translation plan

1. Describe a plan for data analysis related to stillbirth surveillance.
2. Describe the specific roles and responsibilities of staff responsible for identifying analysis priorities, developing analysis plans, and analyzing PRAMS data.
3. Describe how findings from the stillbirth data collection will be disseminated through various channels, including steering committee members, health policy makers, and health providers and translated into public health action.

Collaboration

1. Describe plans for developing substantial collaborations and partnerships with a variety of program partners and stakeholders for the use and promotion of PRAMS data.
 - Include plans to assure active cooperation and collaboration among participating organizational units such as MCH, Vital Records, and Data Processing units.
 - Describe the current planned structure, composition, and function of the PRAMS Steering Committee, and how it will be revised or adjusted to accommodate the PRAMS stillbirth surveillance pilot and promotion of the stillbirth data. The steering committee membership should include fetal death review panel members and birth defects program professionals.
 - Describe the role of steering committee and other partners in the analysis, dissemination and translation of PRAMS data specific to stillbirth.
2. Describe any prior collaborations with Vital Records, the Birth Defects Registry, or other entities that will be providing support to the project.
3. Describe plans for collaborating with CDC and other participating states to revise the common survey questions at agreed-upon intervals in order to evaluate state MCH programs and priorities.

Timetable

1. Provide a timeline for key milestones and protocol development activities to occur in the first 12-months of the three-year project. Include milestones that will be used to demonstrate progress toward having an Institutional Review Board (IRB)-approved protocol.
2. Identify key milestones for the remainder of the project period.

Budget

1. Provide a detailed budget and line-item justification of all operating expenses that are consistent with the planned activities of the project for the first 12-months and include at least one trip per year to Atlanta, GA.

Component D (Family History of Cancer Survey): 5-year project period

Background and Need

1. Describe the scope and severity of breast and ovarian cancer in the state overall and within sub-populations of interest.
2. Identify gaps in needed information concerning breast and ovarian cancer and describe how PRAMS data may be used to fill these gaps.
3. Describe how the cancer surveillance activities may be used to improve outreach and collaboration, and the amount and quality of information available related to family history of cancer among women of reproductive age.
4. Describe any existing programs in the recipient agency that are funded to help those at high risk for developing hereditary cancer. Include any CDC-funded programs, such as those funded as part of the cooperative agreement, "Enhancing Cancer Genomic Best Practices through Education, Surveillance, and Policy": http://www.cdc.gov/cancer/breast/what_cdc_is_doing/genomics_foa.htm

Plan of Operation

1. Describe the plan for obtaining resources (including staff and analytic expertise) and expertise to carry out the cancer surveillance supplement.
2. Describe how existing resources will be used and/or how new resources will be obtained to ensure sufficient staffing time and content area expertise for the project
3. Describe how the cancer surveillance activities (such as staffing, data analysis, data dissemination and translation, and steering committee) will be developed and implemented.
4. Describe how the state's planned PRAMS structure will be adjusted to accommodate the additional workload related to adding a supplement to the PRAMS survey. Examples of prior experiences with conducting survey supplements should be described, if applicable.

Management and Staffing Plan

1. Document the relevant expertise and experience of proposed personnel involved in enhanced activities, and their placement within the organization.
2. Describe relevant experience of proposed personnel as it relates to responsibilities that they will have on the project. Include curriculum vitae and organizational chart.

Analysis and Translation plan

1. Describe a plan for data analysis related to family history of breast and ovarian cancer.
2. Describe how the research findings may contribute to decreasing overall burden and contributing to improvements in population health.

3. Describe the specific roles and responsibilities of staff responsible for identifying analysis priorities, developing analysis plans, and analyzing PRAMS data.
4. Describe how findings from the cancer surveillance will be disseminated through various channels, including steering committee members, health policy makers, and health providers and translated into public health action.

Collaboration

1. Describe plans for developing substantial collaborations and partnerships with a variety of program partners and stakeholders for the use and promotion of PRAMS data.
 - Include plans to assure active cooperation and collaboration among participating organizational units such as MCH, Vital Records, and Data Processing units.
 - Describe the current planned structure, composition, and function of the PRAMS Steering Committee, and how it will be revised or adjusted to accommodate the PRAMS family history of cancer surveillance project and promotion of the cancer history data. The steering committee membership should include genetic counselors and oncologists, primary care and cancer-genomics public health professionals.
 - Describe the role of steering committee and other partners in the analysis, dissemination and translation of PRAMS data specific to the history of cancer among women of reproductive age who deliver a live birth.
 - Describe any prior collaborations with Vital Records, the Birth Defects Registry, or other entities that will be providing support to the project.
2. Describe any existing collaborations and activities in the recipient agency related to genomics and cancer prevention among women of reproductive age. Include any efforts to build infrastructure and partnerships, provide public health education and training, and use surveys to assess genomics integration with chronic disease prevention. Include any existing plans to collaborate with described partners on the project, analysis, steering committee or other activities.
3. Describe plans for collaborating with CDC and other participating states to revise the common survey questions at agreed-upon intervals in order to evaluate state MCH programs and priorities.

Timetable

1. Provide a timeline for key milestones and protocol development activities to occur in the first 12-months of the five-year project. Include milestones that will be used to demonstrate progress toward having an Institutional Review Board (IRB) approved protocol.
2. Identify key milestones for the remainder of the project period.

Budget

1. Provide a detailed budget and line-item justification of all operating expenses that are consistent with the planned activities of the project for the first 12-months and include at least one trip per year to Atlanta, GA.

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 50 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) (<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; 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: **11/20/2015**

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](http://www.whitehouse.gov/omb/grants_spoc)).

11. Funding Restrictions

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

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

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

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained.
- Human Subjects Education Requirement documentation is provided.

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/ElectronicReceipt/avoiding_errors.htm or http://grants.nih.gov/grants/ElectronicReceipt/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 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).

b. 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?

Components A and B:

- To what extent does the applicant justify the need for this program? Do problems of poor pregnancy outcome exist? What is the severity of poor pregnancy outcomes and do they exist on a statewide basis, within high-risk sub-populations, or defined geographical areas? Can problems of poor pregnancy outcome be assessed in relation to relevant national rates, the Maternal and Child Health Bureau indicators, and the “Healthy People 2020 Objectives”?
- What is the programmatic relevance of PRAMS data to the reproductive health and maternal and child health program priorities?
- To what extent does the applicant describe the surveillance information needed and how it may be used for health program planning, program evaluation, policy development, and resource allocation?
- To what extent does the applicant describe how the research will improve or impact population health?
- To what extent has the applicant used birth certificate data or other data sources, (e.g., infant deaths, Hospital Discharge, WIC, Medicaid, or PRAMS) to identify and analyze maternal and infant health problems and evaluate programmatic activities to address these problems?

Component B:

- To what extent does the applicant justify a point-in-time survey methodology? Is the applicant’s justification based on a small birth population (<20,000 births annually), lack of electronic birth records, or inadequate resources to maintain ongoing surveillance?

Component C:

- To what extent does the applicant justify the need for this program? Does the applicant describe the population of women with stillbirths? Is the applicant’s rationale for conducting the enhanced activities appropriate?
- To what extent does the applicant describe how the stillbirth surveillance activities may be used to improve health outcomes for women with stillbirth experiences?

Component D:

- To what extent does the applicant justify the need for this program? Is the applicant’s rationale for conducting the cancer history survey appropriate?
- To what extent does the applicant describe how the enhanced activities may be used to improve health outcomes for women at high risk for breast or ovarian cancer?

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?

Components A and B:

- Does the applicant document the experience of project leadership and their ability to achieve project aims related to PRAMS or other surveillance activities?
- To what extent are the roles and responsibilities for organizational units supporting PRAMS, such as MCH, vital records and data processing, documented and appear reasonable and appropriate? To what extent are the roles and responsibilities for key personnel and their expertise and experience documented and appear reasonable and appropriate? Has the applicant identified staff with adequate expertise who will be dedicated to PRAMS analysis? Are two full-time equivalents committed to working on PRAMS?
- Does the applicant adequately describe the composition and function of the steering committee? Are the areas of expertise represented on the steering committee appropriate to support analysis, use and translation of PRAMS data?

Component C:

- Does the applicant adequately describe the expertise and experience of the proposed personnel? Does their placement within the organization appear to be appropriate? Is there a .5 full-time equivalent committed to working on PRAMS stillbirth surveillance?
- Does the applicant adequately describe the composition and function of the steering committee? Are the areas of expertise represented on the steering committee appropriate for the stillbirth project?

Component D:

- Does the applicant adequately describe the expertise and experience of the proposed personnel? Does their placement within the organization appear to be appropriate?
- Does the applicant adequately describe the composition and function of the steering committee? Are the areas of expertise represented on the steering committee appropriate to support analysis, use and translation of data related to the family history of breast and ovarian cancer?

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?

Component A, B, C and D:

- Does the applicant propose methods or approaches for data collection, analysis, or translation that are innovative or novel?

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?

Components A and B:

- Is the operational plan adequate to carry out major project components (i.e., mail and telephone operations, data analysis, staffing plan, procedures development, and steering committee)?
- Do the proposed methods appear to be appropriate and are they likely to produce adequate response (i.e. 65% for 2007-2011 and 60% for 2012), from the population, including high-risk sub-populations? Has the applicant provided evidence of previous experience, including PRAMS, with the populations?
- Does the plan for data analysis assure the following: 1. Attention to reproductive health and MCH priorities; 2. Dissemination of findings through multiple channels, to include steering committee members, health policy makers, and health providers; 3. Formation of partnerships for dissemination and translation activities; and 4. A plan for the use of the data for evaluation of MCH programmatic activities?
- Is the timetable specific, measurable, and realistic? To what extent does the timetable incorporate major PRAMS activities and milestones?

Component A:

- If data restrictions are identified related to uploading to CDC certified software, is there a plan to address the restrictions to conduct PRAMS surveillance activities? To what extent is the plan appropriate and achievable to allow for data collection procedures to occur in accordance with the project timeline and meet project goals?
- Does the plan adequately demonstrate capacity and willingness to carry out supplemental data collection to address emerging issues in the future? To what extent does the applicant address planned procedures for implementing a survey supplement?

Component C:

- Is the operational plan adequate to carry out major project components (i.e., staffing, data analysis, data dissemination and translation, and steering committee)?
- Does the plan for obtaining resources and expertise to carry out the stillbirth surveillance activities appear detailed and appropriate?
- Does the applicant describe special features of the stillbirth surveillance activities? To what extent do the stillbirth surveillance activities appear to interface smoothly with the core PRAMS activities?
- To what extent does the plan for data analysis address gaps in knowledge related to stillbirth among women in the state?
- To what extent will findings from analyses be disseminated through various channels and translated into public health action?
- Is the timetable specific, measurable, and realistic? To what extent does the timetable incorporate major PRAMS activities and milestones?

Component D:

- Is the operational plan adequate to carry out major project components (i.e., staffing, data analysis, data dissemination and translation, and steering committee)?
- Does the plan for obtaining resources and expertise to carry out the cancer history survey appear detailed and appropriate?
- Does the plan for data dissemination assure dissemination of findings through multiple channels, to include the steering committee members, health policy makers, and health providers?
- To what extent does the plan for data analysis address gaps in knowledge related to the family history of breast and ovarian cancer among women in the state?
- To what extent will findings from analyses be disseminated through various channels and translated into public health action?

- Is the timetable specific, measurable, and realistic? To what extent does the timetable incorporate major PRAMS activities and milestones?

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?

Components A and B:

- Do state laws and policies support the release of vital records data for surveillance purposes? Is the impact of these laws described as it relates to the release of birth certificate data linked to the PRAMS file to internal and external stakeholders or researchers for analytic purposes?
- Does the applicant's Vital Records Unit have a plan for dealing with revisions of the birth certificate?

Component A:

- How thorough is the state birth registration process? Is the birth certificate information computerized, edited, and available within two to four months after the date of birth?
- Does the vital records information schedule provide timely access to needed data?
- To what extent is the applicant able to link to other data sources (e.g., infant deaths, Hospital Discharge, WIC, or Medicaid)?
- Do state laws and policies support the release of minimal personal identifier information (i.e. mother's name, date of birth, address, and phone number and infant's name and date of birth) to a secure CDC certified software system for use by internal state PRAMS staff to contact sampled women? If data restrictions are identified, is there a description of how PRAMS data collection operations can successfully be conducted in light of the restrictions?
- To what extent has the applicant described the progress to date in carrying out PRAMS, PRAMS-like or other surveillance activities? Does the applicant include a discussion of any barriers that precluded complete and successful implementation of the project?
- To what extent has the program remained fully staffed with vacancies minimized? To what extent do staff contributions, roles, time, and accomplishments in support of the PRAMS, PRAMS-like or other surveillance programs appear reasonable, appropriate, and likely to be successful?
- To what extent has the applicant maintained minimal levels of response (i.e. 65% for 2007-2011 and 60% for 2012) overall and by sub-populations?
- To what extent has available PRAMS, PRAMS-like or other surveillance data been analyzed and linkages been made with other data sources?
- To what extent has the steering committee been engaged and active in supporting the PRAMS, PRAMS-like or other surveillance research agenda and data promotion efforts?
- To what extent has PRAMS, PRAMS-like or other surveillance data been used for health program planning, program evaluation, policy development, and resource allocation? Have specific examples of dissemination and translation been shared and partners in these activities identified?

Component B:

- Does the applicant thoroughly document the state birth registration process? Is the birth certificate information cleaned, edited, and available within two to four months after the date of birth?

Component C:

- To what extent does the applicant document system capacity and readiness to support sampling from

the fetal death file to collect data on the population of women who experience a stillbirth?

- Does the applicant propose methods to improve data collection and research on the vulnerable population of mothers who experience a stillbirth?
- Does the applicant describe any legislative support to evaluate and assess stillbirths in the state?
- Does the applicant have experience with conducting surveillance of stillbirths or operating an active stillbirth registry?

Component D:

- Does the applicant propose methods to improve data collection and research on the population of mothers who have a history of breast or ovarian cancer?
- To what extent does the applicant document system capacity and readiness to support the implementation of a survey to collect data on women with a family history of breast and ovarian cancer?
- Does the applicant describe existing collaborations with genomics or cancer prevention programs that were successful in building infrastructure and partnerships, providing public health education and training, and using surveys to assess genomics integration with chronic disease prevention.
- Does the applicant describe any collaborations among genomics or cancer prevention programs to promote cancer prevention efforts and translate PRAMS findings into cancer prevention strategies for all women including those of reproductive age?

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.

Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Awardees are expected to comply with all applicable CDC and federal policies on public access to publication and data collected with federal funds. CDC/ATSDR Policy on Releasing and Sharing Data is available at <http://www.cdc.gov/maso/Policy/ReleasingData.pdf>.

For the duration of the grant cycle, CDC can release a pre-determined, restricted list of variables via a proposal process to researchers for analytic purposes without additional approval requirements. The list of variables will be approved by the CDC, State Vital Registrars and PRAMS awardees.

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/grants/additionalrequirements/index.html>. 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/grants/interestedinapplying/applicationresources.html>

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.

Additionally for Component A:

- Size of birth population
- Racial or ethnic diversity of surveillance population

Additionally for Component C:

- Racial or ethnic diversity of surveillance population

Additionally for Component D:

- Documented system capacity, established collaborations with genomics or cancer prevention programs, and readiness to implement family history survey
- Racial or ethnic diversity of surveillance population

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

[AR-1: Human Subjects Requirements](#)

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)

[AR-9: Paperwork Reduction Act Requirements](#)

[AR-10: Smoke-Free Workplace Requirements](#)

[AR-11: Healthy People 2020](#)

[AR-12: Lobbying Restrictions](#)

[AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities](#)

[AR-14: Accounting System Requirements](#)

[AR-16: Security Clearance Requirement](#)

[AR-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](#)

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](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/](http://www.usaspending.gov/)). For the full text of the requirements, please review the following website: [https:// www.fsrcs.gov/](https://www.fsrcs.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](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.gsa.gov/graphics/pbs/Guidelines%20for%20Federal%20Concessions%20and%20Vending%20Operations.pdf)

- <http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>
- <http://www.cdc.gov/nutrition/index.html>

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:

Components A and B:

The oversight of all management, administrative, and scientific aspects of the research project

1. Assuring and maintaining confidentiality of all relevant data and documents
2. Ensuring adherence to the surveillance protocol; adapting the state-specific portions of the written procedures to meet state needs. Promptly (within 5 business days) respond to CDC in the event that discrepancies in operational procedures are identified.
3. Obtaining and maintaining the appropriate Institutional Review Board approvals for all institutions or individuals participating in research involving human subjects. Providing certification for any new key personnel or other significant contributors involved in the design or conduct of research involving human subjects that they have completed an educational program in the protection of human subjects.
4. Maintaining an adequate management and staffing plan to support all project activities.
5. Recruiting technical and content experts with proper skills and education to implement the PRAMS surveillance activities. It is preferable that dedicated staff possess a specific set of skills that include but are not limited to surveillance and surveys, epidemiology and research, statistical methods employed when weighted survey data are used, translation of study findings, collaboration and partnership
6. Ensuring staff are trained to use the CDC certified software system for data collection and operational components of the project.
7. Ensuring staff conduct monitoring of the data collection and management efforts. Establishing and maintaining communication with key research partners
8. Initiating or maintaining PRAMS program collaboration with vital records department that assures timely access to needed vital records information. Timely access to birth certificates and death certificates, if applicable, is essential.
9. Assuring active cooperation and collaboration among the participating organizational units such as MCH, Vital Records, and Data Processing units.
10. Assuring that the vital records data linked to the PRAMS analytic dataset are available in a timely

fashion for re-release by the state or CDC to internal and external researchers and stakeholders via a proposal process.

11. Providing assurance that PRAMS questionnaire and operational variables are available to CDC without restriction, and CDC may distribute these variables to internal and external researchers and stakeholders via a proposal process.
12. Collaborating with CDC and other participating states to revise the common questions at agreed-upon intervals in order to evaluate state MCH programs and priorities.
13. Forming or maintaining a state-level steering committee consisting of representatives from organizational units housing and collaborating on PRAMS, other public and private health community representatives, and subject matter experts. Developing and implementing a written analysis plan to reflect the evaluation of programmatic activities, including potential partners and collaborators in and outside of the health departments.
14. Developing strategies to interact and share states' findings with health departments, professional societies, voluntary agencies, universities, Tribal Epidemiology Centers (TECs), other PRAMS states, and other interested individuals and organizations.
15. Documenting and sharing examples of dissemination products and examples of how data have been translated into useable information for public health action.
16. Attending annual project review meetings or site visits, national meetings and any additional working meetings with CDC.

Component C:

1. Using CDC PRAMS protocol and methods to implement PRAMS stillbirth surveillance.
2. Initiating and maintaining PRAMS program collaboration with vital records department that assures timely access to needed vital records information. Timely access to fetal death certificates is essential.
3. Forming a state-level steering committee related to stillbirth surveillance activities consisting of representatives from organizational units housing and collaborating on PRAMS, other public and private health community representatives, and subject matter experts in the area of fetal death.
4. Developing and implementing a written analysis plan to reflect the evaluation of programmatic activities specific to stillbirth surveillance activities, including potential partners and collaborators in and outside of the health departments.
5. Preparing state stillbirth survey including the rationale and relevance of questions for evaluation of programmatic activities.
6. Ensuring staff have proper skills and education to implement the PRAMS stillbirth surveillance activities.
7. Ensuring interviewers are trained to conduct telephone interviewing using the CDC certified software and standard PRAMS procedures. For the stillbirth survey it is recommended that grief counseling or other specialized training be provided to telephone interviewers.
8. Documenting results of pilot research and sharing with CDC and other states in web conferences or meetings.

Component D:

1. Using CDC PRAMS protocol and methods for implementation of supplemental question on the PRAMS survey
2. Adding family history of breast and ovarian cancer supplemental questions to core PRAMS survey
3. Ensuring staff have proper skills and education to implement of the family history questionnaire supplement in a manner that does not compromise core the PRAMS surveillance activities.
4. Forming or maintaining a state-level steering committee consisting of representatives from organizational units housing and collaborating on PRAMS, other public and private health community representatives, and subject matter experts in the area of family history of breast and ovarian cancer.
5. Developing and implementing a written analysis plan to reflect the evaluation of programmatic

activities specific to the topic of family history of breast and ovarian cancer, including potential partners and collaborators in and outside of the health departments.

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:

Components A, B, C and D:

1. Maintain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.
2. Obtain Office of Management and Budget (OMB) approval in accordance with the Paperwork Reduction Act (PRA), if required.
3. Provide model procedures and assist with development of state-specific written procedures. Conduct periodic review of written procedures and provide recommendations for improvement if needed.
4. Provide CDC certified software system for use in data collection procedures and monitoring of PRAMS operational data.
5. Provide training, operations management and ongoing technical support for CDC supported software.
6. Assist with the specification of variable descriptions and format layouts of all data files.
7. Assist with the development of computer programs for sampling and analysis.
8. Provide statistical guidance on development, implementation, and modification of sampling plan.
9. Provide technical assistance to resolve problems in data collection procedures. Conduct regular operational evaluations and provide recommendations for improvements if needed.
10. Provide technical assistance for data editing.
11. Provide technical assistance on implementation of survey supplements to address emerging issues that may arise during the project.
12. Assist the recipient agencies with development and revisions of state-specific and the common questions at agreed-upon intervals in order to evaluate state MCH programs and priorities.
13. Provide recipients with epidemiologic technical assistance including identifying relevant data sources, developing descriptive analyses and preparing reports on a range of topics including stillbirths and family history of breast and/or ovarian cancer.
14. Conduct the statistical weighting and create annual data sets for recipient agencies.
15. Assist recipient agency staff in obtaining training in software to analyze PRAMS data.
16. Provide web-based analysis and query systems for wider access to PRAMS data.
17. Facilitate the dissemination of weighted analytic datasets to researchers via a proposal process.
18. Facilitate dissemination and translation of findings for use in development and evaluation of MCH programs.
19. Organize on-going opportunities for exchange of information on challenges and best practices in establishing surveillance or other enhanced activities.
20. Participate with recipient agencies in workshops, trainings, meetings, and coordinating committees to exchange information among states.
21. Coordinate and participate in the biennial PRAMS National Meeting.
22. Establish and maintain a PRAMS Coordinating Committee comprised of CDC Project Scientists and recipients to promote exchange of information and best practices for program development and evaluation.

Component C:

1. Provide recipients with epidemiologic technical assistance including identifying relevant data sources, developing descriptive analyses and preparing reports on stillbirth related topics.
2. Facilitate dissemination and translation of findings for use in development and evaluation of MCH

- programs, including those related to stillbirth and/or family history of cancer.
3. Organize on-going opportunities for exchange of information on challenges and best practices in establishing state stillbirth surveillance or other enhanced activities.

Component D:

1. Provide recipients with epidemiologic technical assistance including identifying relevant data sources, developing descriptive analyses and preparing reports on topics related to family history of breast or ovarian cancer.
2. Facilitate dissemination and translation of findings for use in development and evaluation of MCH programs, including those related cancer risk.

Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

The NCCDPHP Extramural Research Program Operations and Services (ERPOS) 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.

Areas of Joint Responsibility include:

- Participation in the PRAMS Coordinating Committee:

The PRAMS Coordinating Committee (CC) is comprised of CDC Project Scientists and the State Working Group (SWG). The SWG has been established to help with project planning and to promote exchange of information and best practices for program development and evaluation. CDC Project Scientists and recipients meet to discuss a variety of programmatic, operational and methodologic subjects. Topics include questionnaire revision, national meeting, training activities, software issues, alternative data collections methods, and others. The SWG consists of a primary and secondary representative from 7 defined regions. Primary representatives actively participate in calls and serve as the liaison between the SWG and the states in their assigned region as needed (i.e. take the lead in conveying or gathering information). Secondary representatives participate in calls and backs up the primary representatives as needed. Representation rotates each year so that secondary representatives become primary representatives and each state in the region has an opportunity to participate during the grant cycle. The SWG meets monthly by phone. The frequency of the meetings is subject to change depending on the operational and methodologic issues underway.

Recipients and CDC Project Scientists are expected to participate in the following:

1. Routine conference calls to discuss operational and analytic activities at the state-level
2. All state calls to discuss emerging issues that affect all recipients
3. In-person biennial grantee meetings.

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.fsrc.gov on all subawards over \$25,000. See the HHS Grants Policy Statement ([http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)) for additional information on this reporting requirement.

In addition to the reporting requirements outlined below in **B. Content of Reports**, grantees should include with their **Yearly Non-Competing Grant Progress Report**:

1. Documentation of 2 or more examples of uses of PRAMS data to inform policies or programs that address maternal and infant health (use PRAMS Data to Action template to be provided by CDC PRAMS). For new applicants, this documentation will be required starting with year 3 of the grant.
2. Certification, for any new key personnel or other significant contributors involved in the design or conduct of research involving human subjects, that they have completed an educational program in the protection of human subjects.

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, www.grants.gov and at [http:// grants.nih.gov/grants/ funding/2590/ 2590.htm](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://grants1.nih.gov/grants/funding/2590/2590.htm)) [http:// grants.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](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/grants/interestedinapplying/applicationresources.html>

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (<https://public.era.nih.gov/chl/public/search/commonsRegisteredOrgs.era>). 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](https://commons.era.nih.gov/commons/registration/registrationInstructions.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](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

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

For the following, there must be a staff contact for all participating CIOs:

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

Scientific/Research Contact

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: zg7@cdc.gov

Peer Review Contact

Jayalakshmi Raman, PhD
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) 488-6511
Email: kva5@cdc.gov

Financial/Grants Management Contact(s)

Barry B. Gregory
Grants Management Specialist
Centers for Diseases Control and Prevention
Procurement and Grants Office
Chronic Diseases and Birth Defects Services Branch
Telephone: 770. 488.3073
Email: Kvi3@cdc.gov

Section VIII. Other Information

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

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

Authority and Regulations

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

This program is authorized under Section 317K of the Public Health Service Act, [42 U.S.C. 247b-12], as amended.

APPENDIX A

Questions from Potential Applicants and CDC Responses

1. We have conflicting statutes that may or may not prohibit us from releasing identifying information. We were wondering if there was a list of data elements the CDC needs from the states when we send our birth files or this list is able to edited according to states' needs.

Response: For information on the file layouts for the birth certificate files sent to CDC, please visit Appendix Q of the PRAMS Model Protocol at <http://www.cdc.gov/prams/methodology.htm>.

2. Is it permitted to insert landscape-oriented tables into the Research plan if they adhere to the font and margin parameters in the application guidelines? I have not been able to find anything on this matter in the SF424 (R and R) application guide.

Response: In the SF424 R&R application guide, in Section 2.6 Format Specifications for Text (PDF) Attachments, beginning on page I-27 are directions for Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes.

3. The FOA lists an average award amount of \$140,000 and a ceiling amount of \$175,000 for Component A. Are we allowed to apply up to the ceiling amount? Or is that in place in case we are applying for more than one component?

Response: For Component A, Core Surveillance, the budget ceiling is \$175,000 and floor is \$0.00. If an applicant requests a funding amount greater than the ceiling for the first year (\$175,000), 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.

The average award amount is the anticipated funding each awardee will receive. The funding amount for an awardee may be higher or lower than the average award based on the availability of funds, and the scientific and technical merit of the application. Applicants should submit a budget that is necessary and consistent with their proposed project that does not exceed the ceiling.

4. Based on the following language: 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. Do I as PI need to have an eRA commons account? Or do we just need to have one as an agency?

Response: Yes, 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>. Please contact the eRA Commons Help Desk for questions regarding eRA Commons registration, tracking application status, post submission issues, and 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 register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

5. Is it required or necessary to include in-kind contributions to the Program, in the budget?

Response: Yes. In-kind contributions need to be included in the budget and in the budget justification. For in-kind staff, the percentage time on the project must be included along with the dollar amount.

6. Where do we attach the forms related to the Inclusion of Women & Minorities and Targeted/Planned enrollment?

Response: In the SF424 R&R Application Guide, beginning on page I-13, is PART I.2 Process for Application Submission via Grants.gov, which provides guidance for submission of applications. Also in the SF424 R&R, Section 3.3 Open and Complete Mandatory Documents, beginning on page I-45, are directions to open and complete optional and mandatory documents.

7. Could you please list the items that go in Appendix A?

Response:

- Evidence of the Special Eligibility Requirements should be placed in Appendix A and uploaded as part of the application.
- Applicants may include additional information in Appendix A or create additional appendices for supporting documentation such Indirect Cost Rate Agreement, Letters of Support, Publications (not publicly available), Organizational Charts, Data Use Examples and Charts/diagrams illustrating the Vital Records Registration Process.
- Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices.

8. How will Component D play out in the field in the first year?

Response: When Programs begin data collection, the Component D supplement will be incorporated as part of core PRAMS surveillance.

9. For Component D, does sampling need to be changed?

Response: Core PRAMS sampling methods will be used for Component D. Upon award there will be discussions regarding the methods and Component D questions will be provided.

10. For Component C, is there a sample size requirement? What kind of methods will be used?

Response: The survey methods will be refined and methodology will be provided at the time of award. The FOA does not specify or require applicants to provide information about numbers or methods. Applicants should propose a management and staffing plan that applicants determine are necessary.

11. Can we have access to the slides?

Response: The slides from The October 14, 2015 pre-application conference call are posted on the CDC PRAMS website at <http://www.cdc.gov/prams/funding-opportunities/index.htm> under “More information.”

12. Does the Vital Statistics department need to use SAS for sampling and the sample program?

Response: The FOA does not specify. Applicants should propose their own plans for sampling.

13. At what point is IRB approval required? Is it needed around the time of grant submission?

Response: IRB approval is required before awardees can begin data collection. Funds will be restricted until IRB approvals are obtained and Human Subjects Education Requirement documentation is provided.

14. I would like clarification on the issue of county level data, which could be used to identify tribes/tribal communities. Is county level data included as “unidentified data collected on the PRAMS survey and linked in from the birth certificate to the PRAMS file become part of the final PRAMS weighted dataset?”

Response: For more information on the variables included in the PRAMS analytic research file, please visit the PRAMS Research Dataset Codebook on the PRAMS webpage at <http://www.cdc.gov/prams/researchers.htm>.

15. Are there any line-spacing requirements (single, double)?

Response: The SF424 R&R Application Guide, PART I. 2.6 Format Specifications for Text (PDF) Attachments, which begins on page I-26, provides guidance on the submission of documents, including guidance on font, format, page limits and other relevant information.

The SF424 R&R Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

16. Is it possible to protect tribal identity? In approaching tribes for their collaboration, this will be a topic that will need to be discussed. Although we would share aggregated AI data to include in the state survey for AI, we believe that the Tribes included in the tribal PRAMS would want to remain confidential. Certain identifiers, i.e. county of residence, could make it possible to make community/tribal level identification—will this information receive protection?

Response:

- In the FOA, Section III.3. Special Eligibility Requirements, Components A, B, C, and D include the following requirements:
 - 3) Applicants who will be working with a Tribal Epidemiology Centers (TEC) should include a letter of support from the TEC that describes the nature of the working relationship (e.g., data sharing agreements, steering committee appointments, assistance with TECs, assistance in locating survey participants, or dissemination of data).
 - 4) Applicants with projects that span more than one state or territory must provide all of the above listed supporting materials from each state and territory involved.
- Standard PRAMS does not collect information on tribal identity. If an applicant would like to collect information on tribal identity from respondents, the applicant could specify the terms of the arrangement. However, unidentified data collected on the PRAMS survey and linked in from the birth certificate to the PRAMS file become part of the final PRAMS weighted dataset.

17. Which information of the section, PHS 398 Research Plan, is required? I see Research Strategy highlighted in yellow and the rest isn't.

Response: In the FOA, Section IV. 2. Content and Form of Application, provides guidance on the content of the application. This section states “In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS 398.” Note the PHS 398 should include assurances and certifications, additional data required by the

agency for a complete application. While these are not identical to the PHS 398 application form pages, the PHS 398 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.”

18. The second attachment shows a list of forms that are optional. Which ones to be used for budget justification? And where can I find optional forms?

Response: In the SF424 R&R Application Guide, Section 3.3 Open and Complete Mandatory Documents, beginning on page I-4, provides directions to navigate to the form in the application package and complete all of the Mandatory forms. Complete the form titled SF 424 (R&R) first. Data entered in this form populates other mandatory and optional forms where applicable.

19. Under the budget for Component A (Core Surveillance) the RFA says (page 28): “Provide a detailed budget and line-item justification of all operating expenses that are consistent with the planned activities of the project for the first 12-months and include at least one trip per year to Atlanta, GA.” Should we budget for a trip the first year even though we know that there will not be a meeting that first year, with the understanding that we will have to re-budget the funds later?

Response: In the FOA, Section IV.5 Research Plan, Components A, B, C, and D include a Budget category. For each Component, the Budget category instructs applicants to include at least one trip per year to Atlanta, GA.

20. According to SF424 guidelines (page I-52: http://grants.nih.gov/grants/funding/424/sf424_rr_guide_general_verc.pdf) the “Person to be contacted on matters involving this application” (on the first page of the SF424): “This information is for the Administrative or Business Official, not the PD/PI. This person is the individual to be notified if additional information is needed and/or if an award is made. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the AO profile information contained in the eRA Commons.” Is this the administrative official who submits the PRAMS grant for our agency, or should this be a Business Official (e.g. budget officer for the state)?

Response: In the FOA, Section VII. Agency Contacts, is the telephone number and e-mail address for eRA Commons. Please contact eRA Commons to obtain assistance. 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

21. Whom should the Letter(s) of Support be addressed to? I do not see a name/address in the FOA.

Response: The FOA does not specify to whom letters of support or commitment should be addressed. The Letters of Support should be on letterhead and uploaded into the Appendix as part of the application.

22. We know that we are a "new" application but when reading the guidance, it sometimes asks for information that would come from input provided by the current Project's staff.

Response: In Section IV.5. PHS 398 Research Plan Component, Research Plan, on pages 26-34 of

the FOA, is information applicants should address in the Research Strategy section of the application. The requested information is the same for existing grantees and organizations that have not been funded for PRAMS.

23. Is it a requirement that at least two employees are fully funded by the PRAMS project?

Response: Reference to two full-time equivalents are addressed in several sections of the FOA as follows:

- Section IV. 5 Research Plan, says that it is strongly recommended that a minimum of two full-time equivalents be committed to working on daily operations and coordination of PRAMS.
- Section V.B. Criteria, B. Scored Review Criteria – Two full-time equivalents committed to working on PRAMS is one of the review criteria.
- Section V.4. Review and Selection Process - One of the criteria for making funding decisions, is “Relevance of the proposed project to program priorities.”

24. Where are we to upload the Budget Justification in the Application Package?

Response: The SF424 R&R Application Guide, PART I.2 Process for Application Submission via Grants.gov, provides guidance on submission of budgets.

Consistent with the SF424 R&R Application Guide, Section 4.7 R&R Budget Form, beginning on page I-90, a budget and budget justification is required for first budget period. Estimated budgets for each subsequent year of the project period are also required. A budget justification is not required for years 2-5.

The SF424 R&R Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

CDC guidance for completing a detailed budget is available at http://www.cdc.gov/grants/interested_inapplying/applicationresources.html

25. Will CDC provide access to the PIDS to the telephone follow up collection facility that we (will) contract with? Will CDC do the CATI programming? If yes to the above, are the below statements accurate?

The PIDS is a secure, web-based software system that includes a CATI telephone data collection software to facilitate data collection. CDC will provide access to the PIDS to conduct interviews. CDC will be responsible for the CATI programming

Response: PRAMS has transformed key aspects of its structure and function including implementation of the web-based centralized PRAMS Integrated Data collection System (PIDS), with the capacity to support web-based survey administration, supplemental questions on emerging issues, and future linkages to other electronic data sources.

In the FOA, Section IV. 4. Cooperative Agreement Terms and Conditions of Award, is information on CDC responsibilities for this funding announcement. CDC will provide support for the PRAMS Integrated Data Collection System (PIDS), including the following:

- Provide training, operations management and ongoing technical support for CDC supported software.
- Assist with the specification of variable descriptions and format layouts of all data files.
- Assist with the development of computer programs for sampling and analysis.
- Provide statistical guidance on development, implementation, and modification of sampling

plan.

- Provide technical assistance to resolve problems in data collection procedures. Conduct regular operational evaluations and provide recommendations for improvements if needed.
- Provide technical assistance for data editing.

26. In the Human Subjects Section under “Targeted/Planned Enrollment Table (for New Application ONLY)”: as a new applicant, what should we put in this section if we have not developed a sampling frame by race/ethnicity?

Response: The primary source of guidance on the content of an application is the SF424 (R&R) application guide available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

Section 5.8 Planned Enrollment Report and Cumulative Inclusion Enrollment Report, beginning on page I-145 of the SF424 application guide, provides guidance on the content of the Targeted/Planned Enrollment form.

27. We know that informed consent is obtained with the actual response to the survey, but we are wondering what kind of permission/statute/etc. we have to contact a mother for her to participate in the survey in the first place.

Response: The FOA does not address any specific state statutes regarding data collection. However, in Section I. Funding Opportunity Description Statutory Authority and Section VIII. Other Information Authority and Regulations, it states that this program (PRAMS) is authorized under Section 317K of the Public Health Service Act, [42 U.S.C. 247b-12], as amended.

28. The Grant Application package; Optional – Planned Enrollment Report: Is this the same as the Targeted/Planned Enrollment Table? Then do we use the entire birth cohort data?

Response: In the FOA, Section IV.5. PHS 398 Research Plan Component, item 4. Inclusion Enrollment Report, is for Renewal and Revision applications ONLY. Item 8. Targeted/Planned Enrollment Table is for New Applications ONLY. This FOA is a new application.

Directions for completing the Targeted/Planned Enrollment Table are provided in the SF 424 Application Guide, beginning on page I-145, Section 5.8. Planned Enrollment Report and Cumulative Inclusion Enrollment Report. The SF 424 Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

29. In the Grant Application package; Mandatory - PHS 398 Research Plan – Appendix – 14. Appendix: Leslie Harrison mentioned about attaching Data usage sample and publication. I am assuming these are related to PRAMS. What to do? Do we attached any data usage sample, and any publication?

Response: The funding opportunity announcement does not request applicants to submit data usage examples or publications with the application.

30. In the Grant Application package; Optional –Research & Related Budget – K. Budget Justification: Is this the place we attach the 1st year detailed budget justification and 2nd, 3rd, 4th, and 5th year not so detail budget?

Response: The SF424 R&R Application Guide, PART I.2 Process for Application Submission via

Grants.gov, provides guidance on submission of budgets.

Consistent with the SF424 R&R Application Guide, Section 4.7 R&R Budget Form, beginning on page I-90, a budget and budget justification is required for first budget period. Estimated budgets for each subsequent year of the project period are also required. A budget justification is not required for years 2-5.

The SF424 R&R Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

CDC guidance for completing a detailed budget is available at <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html>

31. In the Grant Application package; Mandatory - SF 424 (R&R) – 21. Cover Letter Attachment: no mention of cover letter on the FOA. Do you attach cover letter?

Response: In the SF424 Application Guide, Section 4.2 SF 424 (R&R) Form, Item 21. Cover Letter Attachment, it states “Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the announcement and/or the agency specific instructions.” The funding opportunity announcement does not request applicants submit a Cover Letter.

32. In the Grant Application package; Mandatory - PHS 398 Research Plan - 3. Research Strategy Page 25: PHS 398 Research Plan, #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. Page 26: Research Plan – Component A (Core Surveillance): 5 year project period has 8 headings: Background and need; profile of state birth registration process; plan of operations; management and staffing plan; analysis and translation plan; collaboration; timetable; and budget. How would you like for us organize using 3 headings under 8 headings???

Response: In the FOA, Section IV.5. PHS 398 Research Plan Component, page 25, item #3, Research Strategy, is one of the documents that will be included in your application.

The Research Plan on pages 26-34 of the FOA, is information applicants should address in the Research Strategy section of the applicant’s application. The applicants’ Research Strategy should be organized under 3 headings: Significance, Innovation and Approach. Under these headings, applicants should include the information requested on pages 26-34 (Research Plan) of the FOA.

Applicants are not required to use the headers that are included on pages 26-34 (Research Plan) of the FOA. CDC included the headers to help organize the information applicants are asked to address in their Research Strategy.

Applicants can decide how they want to organize their responses under the 3 headings of Significance, Innovation, and Approach.

33. In the Grant Application package; Mandatory - PHS 398 Research Plan – Other Research Plan Sections – 12. Letters of Support. Do we attach letters of support here or under 14. Appendix as one of the appendix items?

Response: Applicants should follow 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.

Section 5.5 PHS 398 Research Plan Form, beginning on page I-141 of the SF424 Application guide, includes directions for submitting Letters of Support.

34. On page 19 of the FOA, it says that evidence of Special Eligibility Requirements (letter from Vital Records, etc.) should be placed in Appendix A of the application. Does "appendix A" refer to No. 12, Letters of Support, on the Research Plan form of the application or No. 14, Appendix on that same page? I could not find anything that was specifically referred to as Appendix A.

Response: Evidence of the Special Eligibility Requirements should be placed in Appendix A of the application. Applicants need to create an Appendix A for the Special Eligibility Requirements and upload the document as part of the application. Additional Appendices may need to be created for other supporting documentation. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices.

35. Was the PRAMS conference call on 10/14 recorded? I was not free to listen and want to now. I would share with my colleagues also.

Response: The October 14, 2015 pre-application conference call was not recorded. The slides from the Pre-Application Conference Call for DP16-001 Pregnancy Risk Assessment Monitoring System (PRAMS) are posted on the CDC PRAMS website at <http://www.cdc.gov/prams/funding-opportunities/index.htm> under "More information."

36. In reference to this RFA, who should the joint letters of support be addressed to? The contact person I have is:

Brenda Colley Gilbert, Ph.D., MSPH | Office of Extramural Research
National Center for Chronic Disease Prevention and Health Promotion
4770 Buford Highway, NE, MSK-92 | Atlanta, GA 30341

Response: The FOA does not specify to whom letters of support or commitment should be addressed. They can be addressed to Dr. Colley Gilbert, Director, Extramural Research Programs and Operations (ERPOS). The Letters of Support should be on letterhead and uploaded into the Appendix as part of the application.

37. PRAMS is being transferred from the vital records division to the family health division. Given the information that was provided yesterday, our application still qualifies as "new," despite this move, correct?

Response: The application is still new.

38. For the budget, are we just required to use the Research & Related Budget? Or do we also have to do something with the PHS 398 Modular Budget?

Response: Applicants should complete the R&R Budget Form, not the Modular Budget Form.

39. On the PRAMS pre-application conference call, the financial person said to go by the CDC budget guidelines, but they are a little more granular than the R&R form and do not quite align with the Research and Related Budget form.

Response: Applicants should use the CDC Budget Guidelines document to obtain guidance for completing a detailed justified budget. The Budget Guidelines document is available at <http://www.cdc.gov/grants/interestedinapplying/applicationresources>.

40. Is it true that we need to put in salaries for in-kind staff?

Response: In the FOA, beginning on page I-25, is the PHS 398 Research Plan Component which includes information applicants should include in their application. Each Component includes a Budget category that says applicants are to provide a detailed budget and line-item justification of all operating expenses that are consistent with the planned activities of the project for the first 12-months and include at least one trip per year to Atlanta, GA. If in-kind staff are contributing the project then their information should also be included in the budget for each budget year.

41. The host of the TA call that just concluded indicated the importance of checking box 4a and 4b on the 424 form addressing the Component selected. I cannot see any such boxes that are relevant to the Component selection.

Response: In Section 4.2 of the SF424 R&R Application Guide, page I-48 illustrates the SF424R&R form and it shows in box 4.A. Federal Identifier. In box 4.A. applicants should identify the Component they are applying. In box 4.B. Agency Identifier, applicants should write the title of the Component identified in box 4A.

For Example: Box 4.A. Federal Identifier – Component A
Box 4.B. Agency Identifier – Core Surveillance

For applicants that plan to apply for more than one Component, a separate SF424 R&R form must be completed for each Component. The SF 424 Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

42. Component D: Family History of Breast and Ovarian Cancer Survey. Will the questions be available for data collection for 2016 births?

Response: For Component D, the questions will be provided at the start of the project period.

43. Component D - How many years of data collection do you anticipate?

Response: For Component D, it is anticipated that there will be 4 years of data collection.

44. Component D: Family History of Breast and Ovarian Cancer Survey. Will these questions be incorporated into the PIDS data entry system? If so, who will be responsible for that?

Response: CDC will incorporate the questions into the PRAMS Integrated Data collection System (PIDS).

45. We are also wondering if the organization chart should be included in the PRAMS research plan or as an appendix.

Response: Organizational charts should be included in the appendix.

46. So, just to make sure that I'm interpreting information correctly:

1. The "Research Strategy" (required item #3 under the PHS 398 Research Plan Component) is the document that gets attached. (Y/N)

1a. This document is what has the 25-page limit. (Y/N)

1b. This document is what must be organized using the 3 headings: Significance, Innovation and

Approach. (Y/N)

2. The piece of the FOA that states “Research Plan” (pg. 28) with the content that must be included, but uses optional headers, will be a component of the Research Strategy (not the opposite, as highlighted below). (Y/N)

2a. This content makes sense to include under the Approach heading (except for the Background and Need, which may belong under Significance?), and applicants can organize this information as they see fit, and may elect to use the headers as outlined in the FOA (e.g., Background and Need, Profile of State Birth Registration Process, Plan of Operation, etc.). (Y/N)

Response:

1. Yes. In Section IV.5.PHS 398 Research Plan Component, in the FOA, page 25, item #3, Research Strategy, is one of the documents that will be included in your application.

1a. Yes. Also in Section IV.5.7 Page Limits, on page 34 of the FOA, it states For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages.

1b. Yes. One page 25, it states 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.

2. The Research Plan on pages 26-34 of the FOA, is information applicants should address in the Research Strategy section of the applicant’s application.

2a. Applicants’ Research Strategy should be organized under 3 headings: Significance, Innovation and Approach. Under these headings, applicants should include the information requested on pages 26-34 (Research Plan) of the FOA.

Applicants are not required to use the headers that are included on pages 26-34 (Research Plan) of the FOA. CDC included the headers to help organize the information applicants are asked to address in their Research Strategy. Applicants can decide how they want to organize their responses under the 3 headings of Significance, Innovation, and Approach.

47. Should we have all letters of support, including the joint letter of commitment from the state Directors of MCH and the Data Processing units addressed to you using the same guidance for the LOI?

Response: The FOA does not specify to whom letters of support or commitment should be addressed. They can be addressed to the Scientific Program Official. The Letters of Intent should be on letterhead and uploaded into the Appendix as part of the application.

48. The Research Strategy component (Significance, Innovation, and Approach) of the Research Plan has a page limit of 25. Is there a page limit for the entire Research Plan?

Response: In the FOA Section IV.5.7 Page Limitations, it says 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. Additional information on page limits may be found in the SF424 R&R Application Guide, beginning on page I-130. Also on this page, is a link to a detailed Table of Page Limits that is available at http://grants.nih.gov/grants/forms_page_limits.htm Applicants should adhere to the number of pages given in this detailed Table of Page limits, unless the FOA directs otherwise.

The SF424 R&R Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

49. Page 16 of the FOA states that the award ceiling for Component A is \$175,000 and page 15 states that the average award will be \$140, 000. Are applicants advised to apply for the ceiling or the average?

Response: For Component A, Core Surveillance, the budget ceiling is \$175,000 and floor is \$0.00. If an applicant requests a funding amount greater than the ceiling for the first year (\$175,000), 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.

The average award amount is the anticipated funding each awardee will receive. The funding amount for an awardee may be higher or lower than the average award based on the availability of funds, and the scientific and technical merit of the application. Applicants should submit a budget that is necessary and consistent with their proposed project that does not exceed the ceiling.

50. Are word or character limits for the project summary/abstract?

Response: The SF424 R&R Application Guide, PART I. 2.6 Format Specifications for Text (PDF) Attachments, which begins on page I-26, provides guidance on the submission of documents, including guidance on font, format, page limits and other relevant information. The SF424 R&R Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

51. Is PRAMS considered "clinical research"? The FOA (pg. 25) states: "Clinical research is that which is conducted with human subjects... for which an investigator (or colleague) directly interacts with human subjects." Do the telephone interviews with sampled women constitute direct interaction and thus clinical research?

Response: In the FOA, Section 1.1. Background and Purpose, it states the purpose of DP16-001 is to collect state-specific, population-based data on maternal and child health indicators of high scientific quality that can inform programs and policies related to maternal and infant health. The overall goal of PRAMS is to reduce maternal and infant morbidity, and mortality by collecting information that can be used to inform maternal and infant health programs, health policies and maternal behaviors. This research is considered public health research because it will contribute to generalizable knowledge to improve public health practice.

52. Do I understand correctly that we should submit a budget for the first year in an amount not to exceed the award ceiling of \$175,000? Another portion of the FOA says the average award will be \$140,000 so I want to make sure that \$175,000 is the correct limit for the budget submission.

Response: For Component A, Core Surveillance, the budget ceiling is \$175,000 and floor is \$0.00. If an applicant requests a funding amount greater than the ceiling for the first year (\$175,000), 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.

The average award amount is the anticipated funding each awardee will receive. The funding amount for an awardee may be higher or lower than the average award based on the availability of funds, and the scientific and technical merit of the application.

53. How should we submit the estimated budgets for the 2nd to 5th year? Can these budget estimates be added to the first year budget justification or should we add budget periods for the 2nd through 5th year to

the budget application? If so, is a separate budget justification needed for each year, 2nd through 5th?

Response: The SF424 R&R Application Guide, PART I.2 Process for Application Submission via Grants.gov, provides guidance on submission of budgets. Consistent with the SF424 R&R Application Guide, Section 4.7 R&R Budget Form, beginning on page I-90, a budget and budget justification is required for first budget period. Estimated budgets for each subsequent year of the project period are also required. A budget justification is not required for years 2-5. The SF424 R&R Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

CDC guidance for completing a detailed budget is available at http://www.cdc.gov/grants/interested_inapplying/applicationresources.html

54. I just want to confirm that there will not be a meeting in the first year of the next grant cycle. If I don't budget anything for that line item, we wouldn't be able to use grant funding in the event that there was a national meeting we needed to attend.

Response: In Section IV.5 Research Plan, Components A, B, C, and D include a Budget category. For each Component, the Budget category instructs applicants to include at least one trip per year to Atlanta, GA.

55. I have a question related to the Management and Staffing Plan section for Component A of the PRAMS FOA. It states that it is strongly recommended that to full-time equivalents be committed to working on the daily operations. How should the time of staff at contracting agencies for phone operations be included in this time recommendation?

Response: In Section IV.5 Research Plan, Component A and B, the FOA states that it is strongly recommended that a minimum of two full-time equivalents (FTE) be committed to working on daily operations and coordination of PRAMS, and for Component C a minimum of .5 full-time equivalent. The FOA does not provide recommendations for contractor full-time equivalents. Applicants will need to determine FTE needs for contractors.

56. Given that we currently have an existing cooperative agreement that ends in April 2016, for following the instructions in the guidance are we a "new" application, or a "renewal" application?

Response: This funding opportunity announcement application type is new.

57. According the guidance, The Inclusion Enrollment Report is to be completed and submitted for "renewal and revision applications only," for "clinical research." Based on this, I'm not quite sure if PA PRAMS will need to complete and submit this particular report. Based on what I have read in the guidance and the instructions for the 424, I think we will not. Can you clarify?

Response: Applicants should follow 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. The Inclusion Enrollment Report should be completed for Renewal and Revision applications ONLY. This FOA is for new applications.

58. Would CDC be able to share a draft of the pilot stillbirth survey that was developed and will be piloted as part of the funding of Component C for PRAMS RFA-DP-16-001?

Response: For Component C: Stillbirth Surveillance Pilot, the protocol is currently under

development and will be provided at the beginning of the Project Period. Component C is a pilot study, which will allow CDC to collaborate with states to test survey questions and refine the methods.

59. Component D - Our state cancer registry is very interested in partnering with us because they were funded by the CDC to do the cancer genomics project. They are curious what the survey questions are and when those questions will go into the field? In addition to breast and ovarian cancer, our experts are asking if we can add questions about colorectal cancer.

Response: Component D: Family History of Breast and Ovarian Cancer survey questions are under development and will be shared at the beginning of the Project Period. CDC PRAMS will consider allowing grantees to incorporate additional questions at the end of the survey.

60. If the state chooses to use a Bona Fide Agent to do the application on the state's behalf is it possible/allowable to have someone from the state health department serve as a co-investigator on the application?

Response: 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.

States can use a Bona Fide agent. The research team can include state HD staff or other persons based on the applicant's determination. Applicants may include more than one PI, but the first PI will be identified as the "contact PI" for all CDC correspondence.

61. On page 15 for Evaluation it says Component C: Ensuring stable surveillance operations by following CDC's stillbirth surveillance protocol. Which leads me to believe that a stillbirth surveillance protocol has already been developed by CDC. Could you share this, please?

Response: For Component C: Stillbirth Surveillance Pilot, the protocol is currently under development and will be provided at the beginning of the Project Period. Component C is a pilot study, which will allow CDC to collaborate with states to test survey questions and refine the methods.

62. Can you tell me if the Component D questions would be included as a supplement to the survey or would it require modifying the Phase 8 survey to fit the questions in?

Response: Component D questions will supplement Core PRAMS questions. No modification of the Phase 8 survey will be necessary.

63. We have questions regarding Components B and D. We understand that we cannot apply for Component B. However, we have a tribal entity who may want to apply for Component B. Will you allow having a Component A grantee and a Component B grantee in the same state? If so, the tribal entity will probably want to contract with us to conduct survey operations. Is that allowed?

Response: The funding opportunity announcement does not prohibit more than one applicant or grantee per state, nor does it prohibit eligible applicants from contracting with each other.

64. Component D: We may be interested in applying for component D. However, without knowing what the proposed list of questions look like that states are to pilot, it is difficult to develop good costs estimates for workload. Will CDC share either the questions that are to be piloted or at least a description of the module (i.e. how many questions, types of questions, intent of questions, etc.)?

Response: Component D: Family History of Breast and Ovarian Cancer survey questions are under development and will be provided at the start of the project period. The funding opportunity announcement is being amended to say “it is anticipated that the list of questions will not exceed 15.”

65. In the guidance for Component A, it asks for CVs for key staff under the “Management and Staffing” section of the Research Plan and the grants.gov application package asks for a Biosketch in the “RESEARCH & RELATED Senior/Key Person Profile (Expanded)” form. Do we provide both a CV and a Biosketch for Key Persons mentioned in both sections?

Response: Applicants should complete the Biosketch, as described in the Application Guidance, available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf. The biosketch can take the place of the curriculum vitae that is referenced in the FOA.

66. Component C - Nowhere does it say HOW this survey should be implemented... the timing, number of mailings, etc. I’m not so concerned about seeing the instrument, but being able to address the expected methodology would be helpful in the write-up. Or are they not providing that because they’re leaving it open?

Response: Component C: Stillbirth Surveillance Pilot, will expand Core PRAMS methods and sampling to conduct a pilot survey among women who experienced a stillbirth. Component C is a pilot study, which will allow CDC to collaborate with states to refine the survey methods. The list of questions will be provided at the start of the project period. We are amending the funding opportunity announcement to include the following information. “The list of questions will be provided at the start of the project period. It is anticipated that they will be similar in length to the core PRAMS survey located at: <http://www.cdc.gov/prams/questionnaire.htm>”

67. Besides methods (and possibly the survey instrument) for Component C, how will the evaluation of the application be weighted: specifically will they be considering the number of stillbirths in the state or whether there is diversity to the population?

Response: In the FOA, Section V.1. Criteria, includes information about the review process. Only the review criteria described in this section 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 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).

b. Scored Review Criteria - Reviewers will consider each of the review criteria in the determination of scientific merit, and give a separate score for each. The review criteria include: Significance, Investigator(s), Innovation, Approach, Environment

Also in Section V.1. Criteria, are additional questions, by Component, the reviewers will consider.

An additional factor that may be considered in the decision for funding is the racial or ethnic diversity of the surveillance population.

68. Will applications have to be submitted via Grants.gov instead of through the mail as in the past?

Response: In the FOA, Section IV.9. Submission Dates & Times provides extensive information on the process for submitting an application. Organizations must submit applications via Grants.gov (<http://www.grants.gov>), the online portal to find and apply for grants across all Federal agencies. Paper applications will not be accepted.

69. Questions concerning Components C (stillbirth) and D (cancer history) of this grant. The announcement states that survey questions have already been developed for these components. Are these questions available on a website or other source? They would be very useful in preparing our grant application.

Response: The questions are not included in the PRAMS standard questions and are currently not available. The questions will be provided at the start of the Project Period.

70. I have not been able to find the Data-to-Action template in the PRAMS RFA. It is mentioned in the Evaluation/Performance Measurement section. Does this mean it's only a part of the annual report to grantees and not part of the competitive application?

Response: The Data-to-Action template is not required to submit an application. The template will be provided with the continuation application guidance.

71. There is a reference to a required project narrative and a required research strategy. There is also mention that the Research Strategy component of the Research Plan is limited to 25 pages. The guidance says that the research strategy should be organized under 3 headings: Significance, Innovation and Approach (Describe the proposed research plan, including staffing and timeline). The guidance for writing the project narrative (A: core) has multiple sections that do not match the three headings of Significance, Innovation and Approach. Can you explain the differences between these two documents – project narrative and research strategy? They are both required and it isn't clear if the project narrative has a page limit of 25 or the research strategy has a limit of 25 pages.

Response: In the FOA, Section IV. Research Plan, is an outline of the information that should be addressed in the application, by Component. The headings used in this section are recommended, but not required. The Research Strategy is the applicant's proposed research and should be organized under 3 headings: Significance, Innovation and Approach, as described in the FOA, under item 5. PHS 398 Research Plan Component on page 25. Also in the FOA on page 34, is information on page limits under item 5. Page Limits. In this section it says that Research Strategy component of the Research Plan narrative is limited to 25 pages. The Project Narrative is two or three sentences describing the relevance of the proposed research to public health. Information about the Project Narrative is located on page I-76 in the SF424 R&R Application Guide, available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf.

Information on Page Limits may be found in the SF424 R&R Application Guide, beginning on page I-130. Also on this page, is a link to a detailed Table of Page Limits that is available at http://grants.nih.gov/grants/forms_page_limits.htm. Applicants should adhere to the number of pages given in this detailed Table of Page limits, unless the FOA directs otherwise.

72. Are human subjects sections 5, 6, and 7 required? If so, does that count for the 25 page limit in the

research plan or not?

Response: In the SF424 R&R, on page I-129 is a table that includes information on the organization and content of the application. The Human Subjects sections 5, 6, 7 referenced on page I-129 must be completed and is not included in the 25 page limit.

Detailed information for completing the Human Subjects Sections of the FOA begins on page I-137 in the SF424 R&R Application Guide available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf.

73. It isn't clear which budget form should be used for the budget – both are in the optional forms category.

Response: Applicants should complete the R&R Budget Form, not the Modular Budget Form. Directions for completing the R&R Budget Form begin on page I-90, under item 4.7 R&R Budget Form, in the SF424 R&R Application Guide available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

74. Is a budget narrative required? If so, is there a form or template which can be used?

Response: In the FOA, Section V.3. Budget and Period of Support, a CDC website link is provided for applicants to obtain guidance for completing a detailed budget <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html>. A budget narrative is required.

75. Does the budget narrative include only the first year of the grant, or do you need a budget for each of the 5 years?

Response: Consistent with the SF424 R&R Application Guide, Section 4.7 R&R Budget Form, beginning on page I-90, a budget and budget justification is required for first budget period. Estimated budgets for each subsequent year of the project period are also required. The SF424 R&R Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf.

CDC guidance for completing a detailed budget is available at <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html>.

76. The biosketch form expired 8/31/15 in the link: <http://grants.nih.gov/grants/funding/424/index.htm#biosketch>. Do you have a new biosketch form and new instructions for biosketches or are these still acceptable to use?

Response: Applicants and grantees should use the forms included in the SF424 R&R Application Guide despite the expiration date of August 31, 2015. The Application Guide is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

77. Can you tell me if the family history of breast and ovarian cancer survey questions for Component D are included in the most recent PRAMS standard question document dated September 2015, or is there a separate set of survey questions for this component?

Response: For Component D, the questions are not included in the PRAMS standard questions. The survey questions will be provided at the start of the Project Period.

78. Is the FOA a Renewal application or Continuation application?

Response: This funding opportunity announcement application type is new.

79. Do we need to fill out the Inclusion Enrollment Report?

Response: Applicants should follow 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. The Inclusion Enrollment Report should only be completed for Renewal and Revision applications ONLY. This FOA is only for New applications.

80. If we apply for both Components A and C, do the two applications have to be entirely independent of one another? I understand that the narrative and research plan would be, but for the Letters of Intent, Commitment, Assurance, and Support, do they have to be separate and specific to each Component, or can we write and solicit letters that support both projects and include them with both applications?

Response:

- The FOA, in Section III.3 Special Eligibility and Section IV. 5 PHS 398, Research Plan, includes information on the submission of applications. These sections state that a separate application must be provided for each Component of funding, and each application will be peer-reviewed and evaluated separately. The specific components for each application are described in the Special Eligibility and the Research Plan sections. The FOA does not specify the relationship of the materials/requirements between Components, only for a specific Component; thus, the approach can be determined by the applicant.
- One letter of intent can be submitted that identifies multiple Components, as long as all required items are included for each Component
 - 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
 - Name of Component (i.e. A, B, C or D)

81. We also have a little confusion over the headings that are requested for the research strategy. In the guidance it says to follow the headings of impact, approach, and innovation, but we are also instructed to use the headings of “background and need,” “profile of state birth registration process,” “plan of operation,” “management and staffing plan,” etc. How should we organize these in combination with one another?

Response: The primary source of guidance on the content and organization of an application is the SF424 (R&R) application guide available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf. The FOA, in Section IV., the Research Plan outlines the topics that should be addressed in the application. The headings used in the Research Plan are recommended, but not required.

82. The FOA indicates that we need to complete many of the 16 sections of the PHS 398 Research Plan Component, but in the Application forms, just the Research Strategy section is highlighted and starred. Just to make sure that I am understanding the requirements correctly, the sections of the PHS 398 Research Plan

Component that we will be responsible for as a continuing/renewing PRAMS State are: Specific Aims, Research Strategy, Inclusion Enrollment Report, Progress Report Publication List, Protection of Human Subjects, Inclusion of Women and Minorities, Inclusion of Children, Vertebrate Animals (what do we include for this. Or is checking no earlier in the form sufficient?), Select Agent Research (what do we include for this..or is checking no earlier in the form sufficient?), Multiple PD/PI Leadership Plan, Consortium/Contractual Arrangements, Letters of Support, Resource Sharing Plan, and an Appendix. Please let me know if I missed anything or if I am incorrect in assuming that we need to include all the applicable bold subsections under section 5 (PHS 398 Research Plan Component) of the FOA.

Response: The primary source of guidance on the content and organization of an application is the SF424 (R&R) application guide available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

83. Will the due date for the application be extended if the government shuts down?

Response: The application due date is 11/20/2015. 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).

84. Am I missing it in the opportunity, or are there no actual DETAILS regarding component C and D, such as the survey instruments or methodology that they mention have already been tested by others? Especially for C since the target population is different.

Response: Part 2. Section 1.2 Approach, describes the each Component and the tools and methods. For Component C: Stillbirth Surveillance Pilot, grantees will expand Core PRAMS methods and sampling to conduct a pilot survey among women who experienced a stillbirth and provide essential data for monitoring stillbirth and related factors such as prenatal, obstetric and postpartum health care. CDC's Division of Reproductive Health, in collaboration with researchers from Emory University, subject matter experts, and women who experienced stillbirths, has developed a PRAMS-like survey for mothers with stillbirths. This stillbirth pilot questionnaire will be used for this Component.

85. I have a quick question about the Letter of Intent for the PRAMS FOA. Under Names of other key personnel, are we to list others who currently work on the project, or only provide this information if there's a co-PI?

Response: For the letter of intent, we would appreciate a list of the key personnel expected to be included in the application. These would include the program director/principal investigator (PD/PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

86. Do we need advance approval from CDC to contract most of the project work and all of the expenses to one of the Universities that we work with on other projects? If we do that, do we need to make the university a Bona Fide agent?

Response: In the FOA, Section VI. Cooperative Agreement Terms and Conditions of Award, the

FOA states on page 46 that 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. Please refer to the PI/PD and CDC Responsibilities, and Joint Responsibilities beginning on page 46. According to the CDC Budget Guidelines document, Cooperative Agreement recipients must obtain written approval from CDC prior to establishing a third-party contract to carry out of a portion of program activities. The Budget Guidelines document is available at <http://www.cdc.gov/grants/interestedinapplying/applicationresources>.

The decision to make the University a Bona Fide Agent resides with your organization. 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.