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-21-001
Application Due Date: 07/07/2020

Pregnancy Risk Assessment Monitoring System (PRAMS)
RFA-DP-21-001
TABLE OF CONTENTS

Part 1. Overview Information
- Key Dates
- Required Application Instructions
- Executive Summary

Part 2. Full Text
- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Pregnancy Risk Assessment Monitoring System (PRAMS)

Activity Code

U01

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-21-001

Assistance Listings (CFDA) Number(s)

93.946

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this NOFO is to support collection of population-based data on maternal and child health indicators (MCH) of high scientific quality from vital records jurisdictions that can be used to monitor the prevalence of maternal behaviors and experiences to inform programs, research, and systems changes that influence maternal and infant health.

This will be accomplished through three Components:

1) Component A: Core Surveillance - To implement population-based surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy, including emerging issues, among women with a recent live birth, in up to 53 vital records jurisdictions.

2) Component B: Point-in-time Tribal Surveillance - To implement point-in-time (one time, one birth year) surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy among women with a recent live birth in up to 2 federally recognized American Indian Tribes, Alaska Native Villages, or Urban Indian Organizations (UIOs) with at least 1,000 live births annually or tribal organizations that support American Indian Tribes, Alaska Native Villages or Urban Indian Organizations with a project area that covers at least 1,000 live births annually.

3) Component C: Stillbirth Surveillance - To implement population-based surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy among women who recently experienced a stillbirth, in up to 2 vital records jurisdictions.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-DP-21-001, 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:	**06/08/2020**
Application Due Date:	**07/07/2020**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time 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:	**09/07/2020**
Secondary Review:	**11/04/2020**
Estimated Start Date:	**05/01/2021**
Expiration Date:	**07/08/2020**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the

Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) 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.

Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

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

Applications should be submitted electronically.

Executive Summary

- **Purpose.** This NOFO solicits applications to: 1) implement standardized surveillance of postpartum women with a recent live birth or fetal death on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy; 2) implement surveillance on emerging issues related to maternal and child health that arise during the data collection cycle including post-disaster or emergency surveillance; and 3) ensure collection of timely, high quality data for ongoing monitoring of maternal and infant health to inform programs, research, and system changes.

  The activities will be conducted under three Components:

  Component A: Core Surveillance - To implement population-based surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy, including emerging issues, among women with a recent live birth in up to 53 vital records jurisdictions.

  Component B: Point-in-time Tribal Surveillance - To implement a point-in-time (one time, one birth year) surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy among women with a recent live birth in up to 2 federally recognized American Indian Tribes, Alaska Native Villages, or Urban Indian Organizations (UIOs) with at least 1,000 live births annually or tribal organizations that support American Indian Tribes, Alaska Native Villages or Urban Indian Organizations with a project area that covers at least 1,000 live births annually.

Component C: Stillbirth Surveillance - To implement population-based surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy among women who recently experienced a stillbirth in up to 2 vital records jurisdictions.

- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** The estimated total funding (direct and indirect) for entire period of performance is $41,200,000 to support up to 57 awards.

  Component A: Core Surveillance
  Estimated Funding (per year): $8,000,000
  Estimated Number of Awards: 53

  Component B: Point–in–Time Tribal Surveillance
  Estimated Funding (per year): $200,000
  Estimated Number of Awards: 2

  Component C: Stillbirth Surveillance
  Estimated Funding (per year): $200,000
  Estimated Number of Awards: 2

  Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may vary. The total amount awarded and the number of awards will depend upon the number, quality, duration, and cost of the applications received.

  Only one award within a defined vital records jurisdiction will be made for each Component of funding. Where there are multiple applicants within a jurisdiction, applicants are encouraged to coordinate on a single NOFO application per Component.

- **Budget and Period of Performance.** The estimated total funding (direct and indirect) for the first budget period, 05/01/2021 to 04/30/2022, is $8,400,000. The estimated total funding (direct and indirect) for the entire period of performance, 05/01/2021 to 04/30/2026, is $41,200,000. The anticipated average award amount for the first budget period (direct and indirect) for each component is as follows:

  Component A: Core Surveillance
  Period of Performance: 5 years (05/01/2021 to 04/30/2026)
  Estimated Funding (per year): $8,000,000
  Average amount of each award: $150,000

  Component B: Point–in–Time Tribal Surveillance
  Period of Performance: 3 years (05/01/2021 to 04/30/2024)
  Estimated Funding (per year): $200,000
  Average amount of each award: $100,000

  Component C: Stillbirth Surveillance

Period of Performance: 3 years (05/01/2021 to 04/30/2024)
Estimated Funding (per year): $200,000
Average amount of each award: $100,000

- **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 through their organization.
- **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. Any additional PIs are permitted, but would be referred to as Co-PIs.
- **Number of Applications.** One application per eligible institution (normally identified by having a unique DUNS number) is allowed for each Component of funding. Separate applications are required for each Component.
- **Application Type.** New
- **Special Date(s).** None
- **Application Materials**. See Section IV.1 for application materials. Please note that Form F is to be used when downloading the application package https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/research-forms-f.pdf

Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

A link to this NOFO on Grants.gov is available at https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.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, and Section 317 of the Public Health Service Act, 42 U.S.C. 247b.

1. Background and Purpose

Background

The Pregnancy Risk Assessment Monitoring System (PRAMS) was initiated in 1987 due to stagnant infant mortality rates [1]. PRAMS data are used to examine the associations between risk factors and outcomes, explore disparities by subpopulations, and compare health indicators

across jurisdictions. The CDC PRAMS Program provides population-based and jurisdiction-specific estimates on a variety of maternal and infant health indicators that may not be available from any other data source. For example, PRAMS data have been used to monitor progress over time for safe infant sleep position, unintended births, and patterns of health insurance coverage. PRAMS data are used to conduct research at the state and federal level.

PRAMS provides jurisdiction-specific and population-based data on women recently delivering a live birth or stillborn infant. Because less than 5% of the general population is pregnant at any time [2], there is a need for data that purposely samples from this population to provide stable estimates that can be stratified by population subgroup, as well as to provide jurisdiction-specific estimates of maternal experiences and behaviors that occur before, during, and shortly after pregnancy.

The data collection processes for PRAMS has been fine-tuned over time to achieve timely, high quality scientific data that meets the needs of various stakeholders by maximizing response rates, while minimizing respondent burden [3]. The CDC PRAMS Program continually assesses PRAMS methods and procedures through comparisons with industry standards, consultation with organizations funded to implement PRAMS, other experts in the field, and feedback from the PRAMS data collectors. A new version of the questionnaire, with potential adaptations to the existing PRAMS methodology (e.g., online data collection) will occur under this NOFO. Questions included on the PRAMS questionnaire are cognitively tested to ensure respondents understand survey questions as intended. The core PRAMS surveillance methodology, including study design, data collection procedures, questionnaires and sampling, is documented in the PRAMS protocol [1, 3, 4].

The CDC PRAMS Program regularly collaborates with other federal agencies to identify other sources of maternal and infant data that may be duplicative and identify opportunities to leverage and learn from other data collection systems. In recent years, PRAMS has also proven to be a versatile system to address emerging health issues through the use of questionnaire supplements [3]. Leveraging the PRAMS infrastructure has allowed survey supplements on emerging topics to be quickly implemented across impacted funded sites to provide timely data for analysis and dissemination. To date, survey supplements have been developed and implemented for a variety of topics, including the H1N1 flu pandemic, family history of breast and ovarian cancer, e-cigarette use, Zika virus, marijuana and prescription opioid drug use, maternal disability, and disaster preparedness. The PRAMS methodology has been adapted to conduct surveillance among women with a recent stillbirth, and to conduct a telephone call-back survey at 9 months postpartum in jurisdictions with high rates of opioid-related overdose deaths [5]. The PRAMS surveillance system has also been leveraged to inform efforts of the Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau by oversampling Healthy Start clients to allow comparisons with similar populations not participating in Healthy Start [6].

Purpose

The purpose of PRAMS is to collect vital records jurisdiction-specific and population-based data on maternal and child health indicators (MCH) of high scientific quality that can be used to monitor the prevalence of maternal behaviors and experiences to inform programs and systems changes that influence maternal and infant health, as well as conduct research.

The intent of this NOFO is to collect PRAMS data that can be used by federal agencies, states,

jurisdictions, clinical groups, policymakers, and researchers to monitor the prevalence of maternal behaviors and experiences and to assess progress on maternal and infant health indicators (e.g., Healthy People 2030 targets, Health Resources and Services Administration's (HRSA) Title V Maternal and Child Health Program performance measures) [7-9]; to investigate emerging issues in maternal and infant health; to support research; and to assess impacts of programs and system changes aimed at improving the health of mothers and infants.

Researchers have used PRAMS data to answer research and programmatic questions of interest to the field of maternal and child health using analytical techniques, such as econometric and epidemiological modeling. Findings from PRAMS data collection are also used to inform programs and policies that improve maternal and child health as described in CDC PRAMS Data to Action Success Stories [10] collected from exisiting and previous awardees. Results are translated into useable information for public health action, including fact sheets, presentations, and educational materials. The CDC PRAMS Program releases reports on surveillance topics and key indicators and highlight new publications on the CDC PRAMS website (https://www.cdc.gov/prams/) [1].

Healthy People 2020 and other National Strategic Priorities

PRAMS data will be used to monitor progress towards four HP2030 objectives related to Maternal, Infant, and Child Health (3 of which are developmental) [9]:

1. Increase the proportion of infants who are put to sleep on their backs.
2. (Developmental) Increase the proportion of infants who are put to sleep in a safe sleep environment.
3. (Developmental) Increase the percentage of women who are screened for postpartum depression at their postpartum checkup.
4. (Developmental) Decrease the proportion of pregnant women who use illicit opioid pain relievers during pregnancy.

Public Health Impact

PRAMS surveillance data will be used to establish an evidence base for data-driven public health decision making and program development. Data will be used to: 1) document estimates and trends in maternal and infant indicators; 2) identify subpopulations at greatest risk for the adverse birth outcomes and inform prevention strategies; 3) inform the HRSA Title V needs assessment process to help jurisdictions plan for and allocate MCH block grant funds; 4) develop programs and system changes that support improvement of maternal and infant health; 5) investigate emerging issues in maternal and infant health; and 6) support health professionals to incorporate the latest research findings into their standards of practice.

Relevant Work

Historically, the PRAMS surveillance project has been a collaboration between the Centers for Disease Control and Prevention (CDC) and health departments, which were funded to collect jurisdiction-specific, population-based data on maternal behaviors and experiences before, during, and shortly after pregnancy to provide information on a wide range of risk factors that influence maternal and infant health.

PRAMS has collected information from women with a recent live birth since inception of the

project, but there has been a data gap for women who have a pregnancy that results in a loss, such as a stillbirth, defined as a fetal death at 20 weeks of gestation or more. In 2016, CDC funded one site to adapt PRAMS methodology and data collection tools to assess maternal behaviors and experiences before, during and shortly after pregnancy among women with a recent stillbirth [5, 11]. Essential data for monitoring stillbirth and related factors such as periconceptional, antenatal, and postpartum health care after a pregnancy loss were obtained.

PRAMS data has been used in the assessment of CDC Winnable Battles (https://www.cdc.gov/winnablebattles/) [12] as they relate to maternal and infant health:

- Opioids
- HIV elimination
- Vaccine Preventable Disease

Other ongoing CDC activities in the National Center for Chronic Disease Prevention and Health Promotion's Division of Reproductive Health that complement this activity include the Maternal and Child Health Epidemiology Program (MCHEP), Enhancing Reviews and Surveillance to Eliminate Maternal Mortality Program (ERASE MM), Perinatal Quality Collaboratives (PQCs), CDC's Opioid Response Coordination Unit activities that encompass Rapid Assessment of Maternal Opioid Use and Overdose to Improve Outcomes and Save Lives. PRAMS data support these activities by providing population-based information on jurisdiction-level MCH priorities to help inform the initiatives and programs of the MCHEP, PQCs, and Maternal Mortality Review Committees (MMRCs) [13-16].

2. Approach

The Pregnancy Risk Assessment Monitoring System collects jurisdiction- and population-based information on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy. Awardees will implement major project components, including representative sampling, data collection operations, project staffing, convening of a steering committee, data analysis, and data translation according to the PRAMS protocol. The expected outcomes are to produce high quality data representative of the awardee's population that can be used to monitor prevalence of maternal behaviors and experiences to inform programs, research, and system changes that influence maternal and infant health.

This announcement includes 3 separate funding components:

Component A: Core Surveillance
Component B: Point-in-time Tribal Surveillance
Component C: Stillbirth Surveillance

Applicants may apply for Component A or B, but not both. To be funded for Component C, applicants must also apply for and receive funding for Component A. Separate applications are required for each Component.

Component A: Core Surveillance
5-year Period of Performance

Component A is to conduct standardized ongoing core PRAMS surveillance, using a core survey with approximately 55-questions, among women with a recent live birth. Sites

conducting PRAMS surveillance may adapt methods and implement survey supplements to respond to emerging issues that arise during the data collection cycle including response to post-disaster or emergency surveillance needs.

Requirements for Component A are listed below:

Data Collection

1. Collaborate with the Office of Vital Records, the official office to record all births within the jurisdiction to ensure availability of data for monthly sampling, data quality checks, an accurate sampling frame, and final year birth files.
2. Develop and implement a sampling stratification plan that addresses data collection among subpopulations that are disproportionately affected by adverse maternal and infant health outcomes (e.g., based on race, ethnicity, or geography).
3. Adhere to data collection procedures as documented in the current CDC PRAMS protocol or any future updates of the protocol, including closing and submitting of each monthly batch of data to CDC within the 95-day data collection period and maintaining telephone operations with maximum recommended calls to each sampled woman throughout the data collection process. All monthly batches for the entire year should be submitted to CDC by June 30 of the year following the data collection year.
4. Achieve the minimum annual response rate set by CDC, which is currently 55%
5. Use data collection software provided by CDC for PRAMS operations.
6. Maintain adequate staffing to conduct data collection activities and project operations, including a suggested minimum of 2 full-time equivalents, between CDC funded and in-kind support, committed to working on daily operations and project coordination, and a PD/PI dedicating at least 10% time to the project to support the PD/PI responsibilities outlined in Section VI.4. Cooperative Agreement Terms and Conditions of Award.
7. Submit final year birth files to CDC by September 1 of the year following the data collection year (i.e., 9/1/22 for 2021 data collection); the birth file must include all the elements required by CDC for data weighting.
8. Provide input into the development of a new version of the PRAMS questionnaire, and implement the new questionnaire within the specified timeline with potential adaptations to the existing PRAMS methodology (e.g., online data collection).

Data Analysis and Research

1. Form a Steering Committee as outlined in the PRAMS protocol to advise the jurisdiction's PRAMS project in the development and selection of questions for the survey and on the use, dissemination, and application of findings; steering committees are expected to meet annually beginning during the first year post-award.
2. Develop an analysis plan by the 8th month post award to be updated annually at the end of each calendar year that reflects the jurisdiction's priorities for PRAMS analyses.
3. Analyze and disseminate jurisdiction-specific PRAMS results annually, within 1 year of receiving a weighted dataset from CDC.
4. Sign a data sharing agreement that will be provided by CDC, to allow CDC to release a pre-determined, restricted set of birth certificate variables to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees for the duration of the period of performance.

CDC will provide one standard PRAMS Data Sharing Agreement at the time of award as opposed to separate agreements for resource purposes and to facilitate data sharing on behalf of awardees. Compliance with this data sharing agreement is required to ensure that the objectives of the NOFO are met.

Data Translation

1. Collaborate with the maternal and child health (MCH) unit of the applicant jurisdiction's approved Title V recipient to identify contact information for sampled women and to assist with the selection of questions for the survey and on the use, dissemination, and application of findings.
2. Document two data-to-action examples using the CDC-provided template annually and submit to CDC with the yearly continuation application.

Capacity Building

1. Participate in routine conference calls to discuss operational and analytic activities with CDC; participate in webinars and conference calls organized by CDC to discuss issues that affect all awardees; and attend in-person awardee meetings hosted by CDC.

Component B: Point-in-Time Surveillance Tribal Surveillance
3-year period of performance

Component B is to conduct point-in-time (one time, one birth year) PRAMS surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy among women with a recent live birth for federally-recognized American Indian Tribes, Alaska Native Villages, or Urban Indian Organizations (UIOs) with at least 1,000 live births annually or tribal organizations that support American Indian Tribes, Alaska Native Villages or Urban Indian Organizations. To provide reliable statistical estimates, the proposed project should cover an area with at least 1,000 live births annually to American Indian/Alaska Native women.

Requirements for Component B are listed below:

Data Collection

1. Collaborate with the Office of Vital Records, the official office to record all births within the jurisdiction to ensure availability of data for monthly sampling, data quality checks, and final year birth files.
2. Develop and implement a sampling stratification plan that addresses data collection among subpopulations that are disproportionately affected by adverse maternal and infant health outcomes (e.g., based on race, ethnicity, or geography).
3. Adhere to data collection procedures as documented in the CDC PRAMS protocol, including closing and submitting of each monthly batch of data to CDC within the 95-day data collection period and maintaining telephone operations with maximum recommended calls to each sampled woman throughout the data collection process. All monthly batches for the entire year should be submitted to CDC by June 30 of the year

following the data collection year.
4. Achieve the minimum annual response rate set by CDC, which is currently 55%
5. Use data collection software provided by CDC for PRAMS operations.
6. Maintain adequate staffing to conduct data collection activities and project operations, including a suggested minimum of 2 full-time equivalents, between CDC funded and in-kind support, committed to working on daily operations and project coordination, and a PD/PI dedicating at least 10% time to the project to support the PD/PI responsibilities outlined in Section VI.4. Cooperative Agreement Terms and Conditions of Award.
7. Submit final year birth files to CDC by September 1 of the year following the data collection year (i.e., 9/1/22 for 2021 data collection); the birth file must include all the elements required by CDC for data weighting.

Data Analysis and Research

1. Form a Steering Committee, as outlined in the PRAMS protocol, to advise the awardee's PRAMS project in the development and selection of questions for the survey and on the use, dissemination, and application of findings; steering committees are expected to meet annually beginning during the first year post-award.
2. Develop an analysis plan by the 8th month post award that reflects the jurisdiction's priorities for PRAMS analyses.
3. Analyze and disseminate jurisdiction-specific PRAMS results beginning within 1 year of receiving a weighted dataset from CDC.
4. Sign a data sharing agreement that will be provided by CDC, to allow CDC to release a pre-determined, restricted set of birth certificate variables to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees for the duration of the period of performance. CDC will provide one standard PRAMS Data Sharing Agreement at the time of award as opposed to separate agreements for resource purposes and to facilitate data sharing on behalf of awardees. Compliance with this data sharing agreement is required to ensure that the objectives of the NOFO are met.

Data Translation

1. Collaborate with the maternal and child health (MCH) unit of the applicant jurisdiction's approved Title V recipient to identify contact information for sampled women and to assist with the use, dissemination, and application of findings.
2. Document two data-to-action examples using the CDC-provided template within 1 year of receiving a weighted dataset from CDC.

Capacity Building

1. Participate in routine conference calls to discuss operational and analytic activities with CDC; participate in webinars and conference calls organized by CDC to discuss issues that affect all awardees; and attend in-person awardee meetings hosted by CDC.

Component C: Stillbirth Surveillance

3-year period of performance

Component C is to conduct standardized PRAMS surveillance among women who recently experienced a stillbirth. PRAMS stillbirth surveillance is a stand-alone project with a separate survey (approximately 60 questions) that will be used to gather data for monitoring stillbirth occurrence and related factors such as periconceptional, antenatal, and postpartum health care after a stillbirth. The information collected will fill data gaps and inform efforts to help prevent the occurrence of stillbirth and improve care and provide support to women who experience stillbirth.

Requirements for Component C are listed below:

Data Collection

1. Collaborate with the Office of Vital Records, the official office to record all fetal deaths within the jurisdiction to ensure availability of data for monthly sampling, data quality checks, and final year fetal death files.
2. Develop and implement a sampling stratification plan that addresses data collection among subpopulations that are disproportionately affected by stillbirth (e.g., based on race, ethnicity, or geography).
3. Adhere to data collection procedures as documented in the CDC PRAMS Stillbirth protocol, including closing and submitting of each monthly batch of data to CDC within the 95-day data collection period and maintaining telephone operations with maximum recommended calls to each sampled woman throughout the data collection process. All monthly batches for the entire year should be submitted to CDC by June 30 of the year following the data collection year.
4. Achieve the minimum annual response rate set by CDC, which is currently 55%.
5. Use data collection software provided by CDC for PRAMS operations.
6. Maintain adequate staffing to conduct data collection activities and project operations, including a suggested minimum of 2 full-time equivalents, between CDC funded and in-kind support, committed to working on daily operations and project coordination, and a PD/PI dedicating at least 10% time across components A and C to support the PD/PI responsibilities outlined in Section VI.4. Cooperative Agreement Terms and Conditions of Award.
7. Submit final year fetal death files to CDC by December 1 of the year following the data collection year (i.e.,12/1/22 for 2021 data collection); the fetal death file must include all the elements required by CDC for data weighting.

Data Analysis and Research

1. Form a Steering Committee, as outlined in the PRAMS protocol, to advise the jurisdiction's PRAMS project in the development and selection of questions for the survey and on the use, dissemination, and application of findings.
2. Develop an analysis plan by the 8th month post award to be updated annually at the end of each calendar year that reflects the jurisdiction's priorities for PRAMS analyses; steering committees are expected to meet annually beginning during the first year post-award.
3. Analyze and disseminate jurisdiction-specific PRAMS results within 1 year of receiving

a weighted dataset from CDC.

4. Sign a data sharing agreement that will be provided by CDC, to allow CDC to release a pre-determined, restricted set of birth certificate variables to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees for the duration of the period of performance. CDC will provide one standard PRAMS Data Sharing Agreement at the time of award as opposed to separate agreements for resource purposes and to facilitate data sharing on behalf of awardees. Compliance with this data sharing agreement is required to ensure that the objectives of the NOFO are met.

Data Translation

1. Collaborate with the maternal and child health (MCH) unit of the applicant jurisdiction's approved Title V recipient to identify contact information for sampled women and to assist with the selection of questions for the survey and on the use, dissemination, and application of findings.
2. Document two data-to-action examples using the CDC-provided template within 1 year of receiving a weighted dataset from CDC.

Capacity Building

1. Participate in routine conference calls to discuss operational and analytic activities with CDC; participate in webinars and conference calls organized by CDC to discuss issues that affect all awardees; and attend in-person awardee meetings hosted by CDC.

Objectives/Outcomes

Component A: Core Surveillance

Objectives:

1. To implement population-based surveillance within a defined vital records jurisdiction on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy among women with a recent live birth, including emerging issues and post-disaster surveillance needs, as they arise.
2. To ensure data is of high scientific quality and comparable to other jurisdictions by following the methodology documented in the CDC PRAMS protocol.
3. To conduct comprehensive analyses of PRAMS data based on a written jurisdiction-specific analysis plan designed to inform programmatic activities, research, 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 jurisdiction-level steering committee.

Expected outcomes:

1. Produce timely, high quality data representative of the jurisdiction's population to monitor risk factors for maternal and infant health.

2. Analyze and disseminate PRAMS data on a variety of MCH topics to inform public health programs, research and system changes, and health care system changes.
3. Document efforts to translate data into useable information for public health action.
4. Make PRAMS data available to stakeholders including public health agencies, clinical providers, health systems, and researchers for studies to inform knowledge gaps in maternal and infant health.

Component B: Point-in-Time Surveillance Tribal Surveillance

Objectives:

1. To implement point-in-time (one time, one birth year) PRAMS surveillance on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy among women with a recent live birth for federally-recognized American Indian Tribes, Alaska Native Villages, or Urban Indian Organizations (UIOs) with at least 1,000 live births annually or tribal organizations that support American Indian Tribes, Alaska Native Villages or Urban Indian Organizations with a project area that covers at least 1,000 live births annually.
2. To ensure data is of high scientific quality and comparable to other jurisdictions by following the methodology documented in the CDC PRAMS protocol.
3. To conduct comprehensive analyses of PRAMS data based on a written project-specific 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 project-level steering committee.

Expected outcomes:

1. Produce timely, high quality data representative of awardee's population to monitor risk factors for maternal and infant health.
2. Analyze and disseminate PRAMS data on a variety of MCH topics to inform public health programs, research and system changes, and health care system changes.
3. Document efforts to translate data into useable information for public health action.
4. Make PRAMS data available to stakeholders, including tribes, tribal organizations, public health agencies, clinical providers, health systems, and researchers for studies to inform knowledge gaps in maternal and infant health.

Component C: Stillbirth Surveillance

Objectives:

1. To implement population-based surveillance within a defined vital records jurisdiction on selected maternal behaviors and experiences that occur prior to, during, and shortly after pregnancy among women who recently experienced a stillbirth.
2. To ensure data is of high scientific quality by using the standardized CDC PRAMS

stillbirth protocol.
3. To conduct comprehensive analyses of PRAMS stillbirth data based on a written jurisdiction-specific analysis plan designed to inform programmatic activities, research, 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 jurisdiction-level steering committee.

Expected outcomes:

1. Produce timely, high quality data representative of the vital records jurisdiction population, to monitor risk factors for stillbirth occurrence.
2. Analyze and disseminate PRAMS data on a variety of MCH topics to inform prevention efforts and clinical practice to prevent stillbirths.
3. Document efforts to translate stillbirth data into useable information for public health action.
4. Make PRAMS data available to stakeholders including federal, state, and local public health agencies, clinical providers, health systems, and researchers for studies to inform knowledge gaps in stillbirth research.

Target Population

Component A: Core Surveillance - This NOFO component addresses the population of women with a recent live birth in a defined vital records jurisdiction. This group will benefit directly from implementation of programs, research, and system changes aimed at improving the health of mothers and infants jurisdiction-wide.

Components B: Point-in-Time Tribal Surveillance - This NOFO component addresses the population of American Indian or Alaska Native women with a recent live birth in a defined area with at least 1,000 live births to American Indian or Alaska Native women annually. This group will benefit directly from implementation of programs, research, and system changes aimed at improving the health of American Indian and Alaska Native mothers and infants.

Component C: Stillbirth Surveillance - This NOFO component addresses the population of women experiencing a recent stillbirth in a defined vital records jurisdiction. This group will benefit directly from implementation of programs, research, and system changes aimed at reducing fetal deaths at 20 weeks of gestation or more.

Collaboration/Partnerships

Component A: Core Surveillance

Awardees are required to collaborate with the Office of Vital Records, the official office to record all births within the jurisdiction. This collaboration is critical to conducting PRAMS. Implementation of the activities under this funding announcement requires ongoing timely access to vital records information for monthly sampling, as well as timely availability of final year birth files for data weighting. The final vital statistics birth files are needed for weighting the annual data set. The final birth file is to be available to CDC by September 1 of the year following data collection and must include all the elements required by CDC for data weighting.

Awardees are required to collaborate with the maternal and child health (MCH) unit of the jurisdiction's approved Title V recipient. This is necessary since PRAMS data will be used to monitor jurisdiction-specific and national performance objectives for the Title V Maternal and Child Health (MCH) Program, a federal block grant which serves as a key source of support for promoting and improving the health and well-being of the nation's mothers, children, including children with special needs, and their families. The PRAMS data will serve to benchmark select Title V performance measures and enable jurisdictions to demonstrate the impacts of Title V on selected health outcomes within the jurisdiction. This collaboration is critical to ensuring that the PRAMS project collects the data that are needed to support the jurisdiction's MCH Title V grant reporting requirements, emerging issues, and other jurisdictional priorities in MCH. In addition, implementation of PRAMS activities requires access to jurisdiction-level maternal and child health data sources, many of which are funded, maintained, or accessible through partnership with the jurisdiction's Title V recipient. These data sources, such as high-risk infant screening, newborn metabolic screening, Sudden Unexpected Infant Death (SUID), and birth defects programs, Medicaid, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) [17], or others are needed in order to locate participant contact information for the target population.

Awardees are required to form a Steering Committee to advise the jurisdiction's PRAMS project on the development and selection of questions for the survey and on the use, dissemination, and application of findings. The committee should include a multi-disciplinary mixture of individuals from the public and private sector, as well as from the academic community. Steering Committees should include a representative from the Vital Registrars, jurisdiction-level health department maternal and child health unit. Other members may include stakeholders in maternal and infant health such as family planning, substance abuse prevention, oral health, behavioral health, SUID, epidemiology units, state Medicaid programs, state Special Supplemental Program for Women, Infants, and Children (WIC) programs, hospital associations, state chapters of professional medical organizations, perinatal quality collaboratives, regional/local health departments, tribes or tribal organizations, foundations, and public health departments of state and/or local universities.

Awardees whose vital records jurisdiction includes tribal populations that are served by a Tribal Epidemiology Center (TEC) are encouraged, but not required, to work with the TEC on surveillance of their American Indian/Alaska Native (AI/AN) populations. The activities of TECs consist of surveillance to develop and evaluate MCH programmatic activities in coordination with tribes and urban AI/AN communities. In addition, they serve as liaisons with counties, states, the Indian Health Service (IHS), and other Federal public health authorities, in order to improve public health capacity for surveillance and research within AI/AN communities.

Awardees are expected to leverage funding or other in-kind resources to maximize project outcomes. Recipients should consider collaborating with relevant state and local agencies, community-based organizations, and national, non-governmental organizations external to CDC that have similar interests in the health and well-being of mothers and infants.

Awardees may volunteer to be part of the PRAMS Coordinating Committee. The PRAMS Coordinating Committee (CC) will be comprised of CDC Project Scientists and awardees. The PRAMS Coordinating Committee will help with project planning and to promote exchange of

information and best practices for program development and evaluation.

Component B: Point-in-Time Tribal Surveillance

Awardees are required to collaborate with the Office of Vital Records, the official office to record all births within the jurisdiction. This collaboration is critical to conducting PRAMS. Implementation of the activities under this funding announcement requires ongoing timely access to vital records information for monthly sampling, as well as timely availability of final year birth files for data weighting. The final vital statistics birth files are needed for weighting the annual data set. The final birth file is to be available to CDC by September 1 of the year following data collection and must include all the elements required by CDC for data weighting.

Awardees are required to collaborate with the maternal and child health (MCH) unit of the jurisdiction's approved Title V recipient. This is necessary since PRAMS data will be used to monitor jurisdiction-specific and national performance objectives for the Title V Maternal and Child Health (MCH) Program, a federal block grant which serves as a key source of support for promoting and improving the health and well-being of the nation's mothers, children, including children with special needs, and their families. The PRAMS data will serve to benchmark select Title V performance measures and enable jurisdictions to demonstrate the impacts of Title V on selected health outcomes within the jurisdiction. This collaboration is critical to ensuring that the PRAMS project collects the data that are needed to support the jurisdiction's MCH Title V grant reporting requirements, emerging issues, and other jurisdictional priorities in MCH. In addition, implementation of PRAMS activities requires access to jurisdiction-level maternal and child health data sources, many of which are funded, maintained, or accessible through partnership with the jurisdiction's Title V recipient. These data sources, such as high-risk infant screening, newborn metabolic screening, Sudden Unexpected Infant Death (SUID), and birth defects programs, Medicaid, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) [17], or others are needed in order to locate participant contact information for the target population.

Awardees are required to form a Steering Committee to advise the PRAMS project on the development and selection of questions for the survey and on the use, dissemination, and application of findings. The committee should include a multi-disciplinary mixture of individuals from the public and private sector, as well as from the academic community. Steering Committees should include tribal representatives, tribal organizations, and a representative from the Vital Registrars, jurisdiction-level health department maternal and child health unit. Other members may include stakeholders in maternal and infant health such as family planning, substance abuse prevention, oral health, behavioral health, SUID, epidemiology units, state Medicaid programs, state Special Supplemental Program for Women, Infants, and Children (WIC) programs, hospital associations, state chapters of professional medical organizations, perinatal quality collaboratives, regional/local health departments, foundations, tribal organizations, and public health departments of state and/or local universities.

Awardees whose project area includes tribal populations that are served by a Tribal Epidemiology Center (TEC) are encouraged, but not required, to work with the TEC on surveillance of their American Indian/Alaska Native (AI/AN) populations. The activities of

TECs consist of surveillance to develop and evaluate MCH programmatic activities in coordination with tribes and urban AI/AN communities. In addition, they serve as liaisons with counties, states, the Indian Health Service (IHS), and other Federal public health authorities, in order to improve public health infrastructure within AI/AN communities.

Awardees are expected to leverage funding or other in-kind resources to maximize project outcomes. Recipients should consider collaborating with relevant state and local agencies, community-based organizations, and national, non-governmental organizations external to CDC that have similar interests in the health and well-being of mothers and infants.

Awardees may volunteer to be part of the PRAMS Coordinating Committee. The PRAMS Coordinating Committee (CC) will be comprised of CDC Project Scientists and awardees. The PRAMS Coordinating Committee will help with project planning and to promote exchange of information and best practices for program development and evaluation.

Components C: Stillbirth Surveillance

Awardees are required to collaborate with the Office of Vital Records, the official office to record all fetal deaths within the jurisdiction. This collaboration is critical to conducting PRAMS. Implementation of the activities under this funding announcement requires ongoing timely access to vital records information for monthly sampling, as well as timely availability of final year fetal death files for data weighting. The final vital statistics fetal death files are needed for weighting the annual data set. The final fetal death file is to be available to CDC by December 1 of the year following data collection and must include all the elements required by CDC for data weighting.

Awardees are required to collaborate with the maternal and child health (MCH) unit of the jurisdiction's approved Title V recipient. This is necessary since PRAMS data will be used to monitor jurisdiction-specific and national performance objectives for the Title V Maternal and Child Health (MCH) Program, a federal block grant which serves as a key source of support for promoting and improving the health and well-being of the nation's mothers, children, including children with special needs, and their families. The PRAMS data will serve to benchmark select Title V performance measures and enable jurisdictions to demonstrate the impacts of Title V on selected health outcomes within the jurisdiction. This collaboration is critical to ensuring that the PRAMS project collects the data that are needed to support the jurisdiction's MCH Title V grant reporting requirements, emerging issues, and other jurisdictional priorities in MCH. In addition, implementation of PRAMS activities requires access to jurisdiction-level maternal and child health data sources, many of which are funded, maintained, or accessible through partnership with the jurisdiction's Title V recipient. These data sources, such as high-risk infant screening, newborn metabolic screening, Sudden Unexpected Infant Death (SUID), and birth defects programs, Medicaid, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) [17], or others are needed in order to locate participant contact information for the target population.

Awardees are required to form a Steering Committee to advise the jurisdiction's PRAMS project on the development and selection of questions for the survey and on the use, dissemination, and application of findings. The committee should include a multi-disciplinary mixture of individuals from the public and private sector, as well as from the academic community. Steering Committees should include a representative from the Vital Registrars,

jurisdiction-level health department maternal and child health unit. Other members may include stakeholders in maternal and infant health such as family planning, substance abuse prevention, oral health, behavioral health, SUID, epidemiology units, state Medicaid programs, state Special Supplemental Program for Women, Infants, and Children (WIC) programs, hospital associations, state chapters of professional medical organizations, perinatal quality collaboratives, regional/local health departments, tribes or tribal organizations, foundations, and public health departments of state and/or local universities.

Awardees whose vital records jurisdiction includes tribal populations that are served by a Tribal Epidemiology Center (TEC) are encouraged, but not required, to work with the TEC on surveillance of their American Indian/Alaska Native (AI/AN) populations. The activities of TECs consist of surveillance to develop and evaluate MCH programmatic activities in coordination with tribes and urban AI/AN communities. In addition, they serve as liaisons with counties, states, the Indian Health Service (IHS), and other Federal public health authorities, in order to improve public health infrastructure within AI/AN communities.

Awardees are expected to leverage funding or other in-kind resources to maximize project outcomes. Recipients should consider collaborating with relevant state and local agencies, community-based organizations, and national, non-governmental organizations external to CDC that have similar interests in the health and well-being of mothers and infants.

Awardees may volunteer to be part of the PRAMS Coordinating Committee. The PRAMS Coordinating Committee (CC) will be comprised of CDC Project Scientists and awardees. The PRAMS Coordinating Committee will help with project planning and to promote exchange of information and best practices for program development and evaluation.

Evaluation/Performance Measurement

The awardees are expected to create an evaluation plan by the 8th month post award that assesses fidelity to data collection protocols, examines key data collection operations indicators using reports generated from the CDC-provided software system, monitors data quality, assesses overall and subpopulation response rates, provides timely access to data for processing and weighting, analyzes data, and demonstrates use of these data in informing system changes, research, and programs. Evaluation plans will be refined in collaboration with CDC post-award.

Translation Plan

Components A, B and C

Awardees are expected to develop a research translation and dissemination plan by the 8th month post award, in collaboration with steering committee members to ensure surveillance findings are translated into system changes or programs that address maternal and infant health. Translation plans will be refined in collaboration with CDC post-award. The plans should:

1. Describe the data priority topics for PRAMS analyses.
2. Describe partnerships, existing or proposed, for dissemination and translation and how findings will be disseminated through various channels, including steering committee members, health policy makers, and health providers.
3. Describe how data will be translated into public health action.

4. Track and document examples of data to action translation.

Data Management Plan (DMP)
Awardees will implement a standard CDC PRAMS Data Management Plan (DMP). CDC PRAMS will provide the DMP following award.

OMB/PRA will apply.

References:

1. Centers for Disease Control and Prevention (CDC). PRAMS. Available at: www.cdc.gov /PRAMS. Accessed January 28, 2020.
2. Mosher, WD, Martinez, GM, Chandra, A, Abma, JC, & Willson, SJ. (2004). Use of contraception and use of family planning services in the United States: 1982-2002. Adv Data, (350), 1-36.
3. The Pregnancy Risk Assessment Monitoring System (PRAMS): Overview of Design and Methodology. H. B. Shulman, D. V. D'Angelo, L. Harrison, R. A. Smith, L. Warner. Am J Public Health. Published online ahead of print August 23, 2018: e1–e9. doi:10.2105/AJPH.2018. 304563).
4. Centers for Disease Control and Prevention (CDC). PRAMS Protocol. Available at: https://www.cdc.gov/prams/protocol-files/PRAMS-Model-Protocol-2018.zip. Accessed January 28, 2020.
5. Centers for Disease Control and Prevention (CDC). PRAMS Special Projects. Available at: https://www.cdc.gov/prams/special-projects/index.htm. Accessed January 28, 2020.
6. http://www.healthystartepic.org/wp-content/uploads/2017/01/Transformed-Healthy-Start-Program-Evaluation-Plan91916.pdf. Accessed January 29, 2020.
7. US Department of Health and Human Services. National Performance Measures. Available at: https://mchb.tvisdata.hrsa.gov/PrioritiesAndMeasures/NationalPerformanceMeasures. Accessed January 28, 2020.
8. Office of Disease Prevention and Health Prevention. Healthy People 2020: maternal, infant, and child health. Available at: https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health. Accessed January 28, 2020.
9. Office of Disease Prevention and Health Prevention. Healthy People 2030: Advisory Committee. Available at: https://www.healthypeople.gov/2020/About-Healthy-People/Development-Healthy-People-2030/Advisory-Committee. Accessed January 28, 2020.
10. Centers for Disease Control and Prevention (CDC). PRAMS Data to Action Success Stories. Available at: https://www.cdc.gov/prams/state-success-stories/data-to-action-success.html. Accessed January 28, 2020.
11. Christiansen-Lindquist L, Sahay K, Hogue C. Improving surveillance for the hidden half of fetal-infant mortality: a pilot study of the expansion of the Pregnancy Risk Assessment Monitoring System to include stillbirth. Ann Epidemiol. 2016;26(6):401–404.
12. Centers for Disease Control and Prevention (CDC). Winnable Battles. Available (https://www.cdc.gov/winnablebattles/). Accessed January 28, 2020.
13. Centers for Disease Control and Prevention (CDC). Maternal and Child Health Epidemiology Program. Available at:https://www.cdc.gov/reproductivehealth/mchepi/index.htm. Accessed January 29, 2020.

14. Centers for Disease Control and Prevention (CDC). ERASE Maternal Mortality. Available at: https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/. Accessed January 29, 2020.
15. Centers for Disease Control and Prevention (CDC). Perinatal Quality Collaboratives. Available at: https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm. Accessed January 29, 2020.
16. Centers for Disease Control and Prevention (CDC). Available at: https://www.cdc.gov/pregnancy/opioids/about.html. Accessed January 29, 2020.
17. US Department of Agriculture. Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Available at: https://www.fns.usda.gov/wic. Accessed January 29, 2020.

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: $41,200,000

Estimated total funding (direct and indirect costs) for the first budget period is $8,400,000 and the estimated total funding (direct and indirect) for the entire period of performance is $41,200,000.

Anticipated Number of Awards: 57

Award Ceiling and Floor by Component

Component A: Core Surveillance
Ceiling: $175,000 (total direct and indirect costs)
Floor: $125,000 (total direct and indirect costs)
These amounts are for the first 12-month period of performance.

Component B: Point-in-Time Tribal Surveillance
Ceiling: $125,000 (total direct and indirect costs)
Floor: $75,000 (total direct and indirect costs)
These amounts are for the first 12-month period of performance.

Component C: Stillbirth Surveillance
Ceiling: $125,000 (total direct and indirect costs)

Floor: $75,000 (total direct and indirect costs)
These amounts are for the first 12-month period of performance.

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

Award ceiling and floor are for the first 12-month budget period only.

Award Ceiling:	$175,000 Per Budget Period
Award Floor:	$75,000 Per Budget Period
Total Period of Performance Length:	5 year(s)

Throughout the Period of Performance, 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/ sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:	State governments County governments City or township governments Special district governments Independent school districts Public and State controlled institutions of higher education Native American tribal governments (Federally recognized) Public housing authorities/Indian housing authorities Native American tribal organizations (other than Federally recognized tribal governments) Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education Private institutions of higher education For profit organizations other than small businesses

Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)
Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Eligibility Category:

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

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

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

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

Other:

Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state

or local government as documentation of the status is required. Attach with "Other Attachment Forms."
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR

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. Additional Information on Eligibility

This NOFO is open competition

Special Eligibility

For an application to be considered, the application must be responsive to these Special Eligibility Requirements. If your application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

The special eligibility requirements address the key components of PRAMS that are integral to establishing and maintaining successful standardized surveillance of women with a recent live birth or stillbirth.

Component A: Core Surveillance

A. Access to Vital Records Data

1. Throughout the 5-year period of performance, applicants must have:
    a. timely (i.e. between two and four months after delivery) access to edited birth certification information from the Vital Records Office in the vital records jurisdiction for sampling on a monthly basis; and
    b. timely access to the final birth file for submission to CDC by September 1 of the year following the data collection year (i.e., 9/1/22 for 2021 data collection), and the file must include all the elements required by CDC for data weighting.
2. Applicants must be able to release a pre-determined, restricted set of birth certificate variables to CDC to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees. Note: CDC will provide the PRAMS Data Sharing Agreement at the time of award. Compliance with this data sharing agreement is required. The current data sharing agreement is located in the PRAMS protocol Appendix R, "Data Sharing."

B. Collaboration with Maternal and Child Health Unit

1. Applicants must have support from the maternal and child health (MCH) unit of the applicant vital records jurisdiction's approved Title V recipient (https://mchb.tvisdata.hrsa.gov/) to facilitate access to jurisdiction-level maternal and child health data sources throughout the 5-year period of performance.

C. CDC Access to PRAMS Questionnaire and Operational Data

1. Applicants must be able to provide CDC with unrestricted access to PRAMS operational and questionnaire data throughout the 5-year period of performance.
2. Applicants must be able to allow CDC to release a pre-determined set of questionnaire and operational variables to internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees. Note: CDC will provide the PRAMS Data Sharing Agreement at the time of award. Compliance with this data sharing agreement is required. The current data sharing agreement is located in the PRAMS protocol Appendix R, "Data Sharing."

Component B: Point-In-Time Tribal Surveillance

A. Access to Vital Records Data

1. Throughout the 3-year period of performance, applicants must have:
    a. timely (i.e. between two and four months after delivery) access to edited birth certification information from the Vital Records Office in the vital records jurisdiction for sampling on a monthly basis; and
    b. timely access to the final birth file for submission to CDC by September 1 of the year following the data collection year (i.e., 9/1/22 for 2021 data collection), and the file must include all the elements required by CDC for data weighting.
    c. If the project area will span across multiple vital records jurisdictions, applicants must have timely access from each jurisdiction's Vital Records Office.

2. Applicants must be able to release a pre-determined, restricted set of birth certificate variables to CDC to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees. Note: CDC will provide the PRAMS Data Sharing Agreement at the time of award. Compliance with this data sharing agreement is required. The current data sharing agreement is located in the PRAMS protocol Appendix R, "Data Sharing."

B. Collaboration with Maternal and Child Health Unit

1. Applicants must have support from the maternal and child health (MCH) unit of the approved Title V recipient (https://mchb.tvisdata.hrsa.gov/) of the jurisdictions within the project area to facilitate access to jurisdiction-level maternal and child health data sources throughout the 3-year period of performance.
2. If the project area will span across multiple jurisdictions, support from each jurisdiction's MCH unit is required.

C. CDC Access to PRAMS Questionnaire and Operational Data

1. Applicants must be able to provide CDC with unrestricted access to PRAMS operational and questionnaire data throughout the 3-year period of performance.
2. Applicants must be able to allow CDC to release a pre-determined set of questionnaire and operational variables to internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees. Note: CDC will provide the PRAMS Data Sharing Agreement at the time of award. Compliance with this data sharing agreement is required. The current data sharing agreement is located in the PRAMS protocol Appendix R, "Data Sharing."

D. Evidence of 1,000 live Births Annually

1. Applicants must provide documentation that there are at least 1,000 live annual births to American Indian/Alaska Native women in the applicant's proposed project area. The information on the number of births must be from official vital records data.

Component C: Stillbirth Surveillance

A. Access to Vital Records Data

1. Throughout the 3-year period of performance, applicants must have:
    a. timely (i.e. between two and six months after death) access to edited fetal death certificate information from the Vital Records Office in the vital records jurisdiction for sampling on a monthly basis; and
    b. timely access to the final fetal death file for submission to CDC by December 1 of the year following the data collection year (i.e., 12/1/22 for 2021 data collection), and the file must include all the elements required by CDC for data weighting.
2. Applicants must be able to release a pre-determined, restricted set of variables from the fetal death certificate to CDC to share with internal and external stakeholders and

researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees. Note: CDC will provide the PRAMS Data Sharing Agreement at the time of award. Compliance with this data sharing agreement is required. The current data sharing agreement is located in the PRAMS protocol Appendix R, "Data Sharing."

B. Collaboration with Maternal and Child Health Unit

1. Applicants must have support from the maternal and child health (MCH) unit of the applicant jurisdiction's approved Title V recipient (https://mchb.tvisdata.hrsa.gov/) to facilitate access to jurisdiction-level maternal and child health data sources throughout the 3-year period of performance.

C. CDC Access to PRAMS Questionnaire and Operational Data

1. Applicants must be able to provide CDC with unrestricted access to PRAMS operational and questionnaire data throughout the 3-year period of performance.
2. Applicants must be able to allow CDC to release a pre-determined set of questionnaire and operational variables to internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees. Note: CDC will provide the PRAMS Data Sharing Agreement at the time of award. Compliance with this data sharing agreement is required. The current data sharing agreement is located in the PRAMS protocol Appendix R, "Data Sharing."

D. Applicants must demonstrate they have applied for Component A: Core Surveillance.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

If the Responsiveness information requested below is incomplete or non-responsive to these requirements, the application will not enter into the review process.

Component A: Core Surveillance

A. Access to Vital Records Data - Applicants must provide a letter from the Vital Records Office in the jurisdiction. The letter should be on official letterhead and signed by an authority from Vital Records who can commit the efforts of their unit. The letter should indicate the following:

1. Throughout the 5-year period of performance, the applicant will have:
    a. timely (i.e. between two and four months after delivery) access to edited birth certificate information for sampling on a monthly basis to ensure fidelity to CDC PRAMS data collection protocol; and
    b. timely access to the final birth file for submission to CDC by September 1 of the year following the data collection year (i.e., 9/1/22 for 2021 data collection), and the file will include all the elements required by CDC for data weighting.
2. The Vital Records office will allow a pre-determined, restricted set of birth certificate variables be made available to CDC to share with internal and external stakeholders and

researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees.

This letter should be placed in Appendix A of the application and labeled "Core_Vitals_LOS."

B. Collaboration with Maternal and Child Health Unit - Applicants must provide a letter from maternal and child health (MCH) unit of the applicant jurisdiction's approved Title V recipient. The letter should be on official letterhead and signed by an authority from the MCH unit who can commit the efforts of their unit. The letter should indicate the following:

1. The MCH unit will support the project by facilitating access to jurisdiction-level maternal and child health data sources in order to locate contact information for sampled women including Medicaid, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), high-risk infant screening programs, newborn metabolic screening programs, or other data sources.

This letter should be placed in Appendix A of the application and labeled "Core_MCH_LOS."

C. CDC Access to PRAMS Questionnaire and Operational Data - Applicants must provide a letter from the applicant organization. The letter should be on official letterhead and signed by an authority who can commit the efforts of their organization. The letter should indicate the following:

1. PRAMS questionnaire and operational variables will be available to CDC without restriction throughout the 5-year period of performance.
2. The applicant organization will allow a pre-determined group of questionnaire and operational variables to be made available to CDC to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreements between CDC and awardees.

This letter should be placed in Appendix A of the application and labeled "Core_Data_LOS."

Component B: Point-in-Time Tribal Surveillance

If the project area will span across multiple jurisdictions, letters of support from each jurisdiction's Vital Records Office and MCH Unit are required.

A. Access to Vital Records - Applicants must provide a letter from the Vital Records Office in the jurisdiction. The letter should be on official letterhead and signed by an authority from Vital Records who can commit the efforts of their unit. The letter should indicate the following:

1. Throughout the 3-year period of performance, the applicant will have:
    a. timely (i.e. between two and four months after delivery) access to edited birth certificate information for sampling on a monthly basis to ensure fidelity to CDC PRAMS data collection protocol; and
    b. timely access to the final birth file for submission to CDC by September 1 of the

year following the data collection year (i.e., 9/1/22 for 2021 data collection), and the file will include all the elements required by CDC for data weighting.

2. The Vital Records office will allow a pre-determined, restricted set of birth certificate variables be made available to CDC to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees.

This letter should be placed in Appendix A of the application and labeled "Tribal_Vitals_LOS."

B. Collaboration with Maternal and Child Health Unit - Applicants must provide a letter from maternal and child health (MCH) unit of the applicant jurisdiction's approved Title V recipient. The letter should be on official letterhead and signed by an authority from the MCH unit who can commit the efforts of their unit. The letter should indicate the following:

1. The MCH unit will support the project by facilitating access to jurisdiction-level maternal and child health data sources in order to locate participant contact information including Medicaid, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), high-risk infant screening programs, newborn metabolic screening programs, or other data sources.

This letter should be placed in Appendix A of the application and labeled "Tribal_MCH_LOS."

C. CDC Access to PRAMS Questionnaire and Operational Data - Applicants must provide a letter from the applicant organization. The letter should be on official letterhead and signed by an authority who can commit the efforts of their organization. The letter should indicate the following:

1. PRAMS questionnaire and operational variables will be available to CDC without restriction throughout the 3-year period of performance.
2. The applicant organization will allow a pre-determined group of questionnaire and operational variables to be made available to CDC to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees.

This letter should be placed in Appendix A of the application and labeled "Tribal_Data_LOS."

D. Documentation of 1,000 Annual Live Births - Applicants must provide a letter or memo from the applicant organization. The letter or memo should be on official letterhead and signed by a member of the applicant organization that verifies the information. The letter should indicate the following:

1. The number of live births to American Indian/Alaska Native women in the applicants proposed project area.
2. The documentation references official vital records data as the source of the information on the number of live births.

This letter should be placed in Appendix A of the application and labeled "Tribal_Births_LOS."

Component C: Stillbirth Surveillance

A. Access to Vital Records - Applicants must provide a letter from the Vital Records Office in the jurisdiction. The letter should be on official letterhead and signed by an authority from Vital Records who can commit the efforts of their unit. The letter should indicate the following:

1. Throughout the 3-year period of performance, the applicant will have:
    a. timely (i.e. between two and six months after death) access to edited fetal death certificate information for sampling on a monthly basis to ensure fidelity to CDC PRAMS data collection protocol; and
    b. timely access to the final fetal death file for submission to CDC by December 1 of the year following the data collection year (i.e., 12/1/22 for 2021 data collection), and the file will include all the elements required by CDC for data weighting.
2. The Vital Records office will allow a pre-determined, restricted set of fetal death certificate variables be made available to CDC to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing agreement between CDC and awardees.

This letter should be placed in Appendix A of the application and labeled "Stillbirth_Vitals_LOS."

B. Collaboration with Maternal and Child Health Unit - Applicants must provide a letter from maternal and child health (MCH) unit of the applicant jurisdiction's approved Title V recipient. The letter should be on official letterhead and signed by an authority from the MCH unit who can commit the efforts of their unit. The letter should indicate the following:

1. The MCH unit will support the project by facilitating access to jurisdiction-level maternal and child health data sources in order to locate participant contact information including Medicaid, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), or other data sources.

This letter should be placed in Appendix A of the application and labeled "Stillbirth_MCH_LOS."

C. CDC Access to PRAMS Questionnaire and Operational Data -Applicants must provide a letter from the applicant organization. The letter should be on official letterhead and signed by an authority who can commit the efforts of their organization. The letter should indicate the following:

1. PRAMS questionnaire and operational variables will be available to CDC without restriction throughout the 3-year period of performance.
2. The applicant organization will allow a pre-determined group of questionnaire and operational variables to be made available to CDC to share with internal and external stakeholders and researchers for analytic purposes, per terms of the data sharing

agreement between CDC and awardees.

This letter should be placed in Appendix A of the application and labeled "Stillbirth_Data_LOS."

D. Applicants must include a copy of the face page of their Component A: Core Surveillance application in Appendix A .

6. Required Registrations

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

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

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

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principle Investigator (PD/PI) 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 eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

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 recipient 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 recipient 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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity 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 NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

One application per eligible institution (normally identified by having a unique DUNS number) is allowed for each **Component** of funding. Separate applications are required for each **Component**.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.
If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via:

- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf, except where instructed in this Notice of Funding Opportunity 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 package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.
When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

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** [Core Surveillance], **Component B** [Point-in-time Tribal Surveillance] or **Component C** [Stillbirth Surveillance], etc.).

3. Letter of Intent

Due Date for Letter of Intent: **06/08/2020**

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 July 8, 2020, 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
- Component(s) applicant intends to submit an application(s)

The letter of intent should be sent to:

Sue Shaw, MPH
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: 770.488.6142
Email: zgx7@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

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 components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf and http://grants.nih.gov/grants/how-to-apply-application-guide.htm for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, 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 NOFO.
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 time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan.**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**
10. **Resource Sharing Plan(s)**
11. **Authentication of Key Biological and/or Chemical Resources**
12. **Appendix**

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf and here: http://grants.nih.gov/grants/how-to-apply-application-guide.htm must be followed along with any additional instructions provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• A description of the data to be collected or generated in the proposed project;
• Standards to be used for the collected or generated data;
• Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of
provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights -
this section should address access to identifiable and de-identified data);
• Statement of the use of data standards that ensure all released data have appropriate documentation that
describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation
and access are not justified (this section should address archiving and preservation of identifiable and deidentified
data).
Examples of DMPs may be found here: USGS, http://www.usgs.gov/products/data-and-tools/data-management/data-management-plans

Applicants are not required to submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application.
Awardees will implement a standard CDC PRAMS Data Management Plan (DMP) for AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html. The standard CDC PRAMS

DMP will be provided to awardees post award.

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.

RESEARCH PLAN

- Applicants should clearly indicate the Component(s) 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: Core Surveillance, Component B: Point-in-Time Tribal Surveillance, or Component C: Stillbirth Surveillance**).
- Applicants may apply for Component A: Core Surveillance or Component B: Point-in-Time Tribal Surveillance, not both.
- To be funded for Component C: Stillbirth Surveillance, applicants must also apply for and receive Component A: Core Surveillance funding.
- A separate application must be submitted for each Component.

The applicant's research plan should address activities that will be conducted over the entire period of performance and should include the following items:

Component A: Core Surveillance
5-year period of performance

Background and Need

1. Describe the vital records jurisdiction. Describe the composition of the birth population, giving the numbers of overall live births and live births in each sub-population of interest within the vital records jurisdiction.
2. Describe how subpopulations in the jurisdiction that are disproportionately affected by adverse maternal and infant health outcomes (e.g., based on race, ethnicity, or geography) and strategies for using PRAMS data to address these disparities, such as implementing stratified sampling based on various characteristics to make inferences about subgroups of high public health interest. This may be assessed in relation to relevant national rates, jurisdiction program activities, HRSA Maternal and Child Health Bureau indicators, or the Healthy People 2030 Objectives.
3. Describe how the proposed research will improve or have an impact on population health.
4. Describe the maternal and child health priorities for the jurisdiction and how PRAMS data can be integrated into the jurisdiction's activities to address those priorities and evaluate jurisdiction programs.
5. Identify gaps in needed information concerning risk factors for adverse pregnancy and

infant outcomes and describe how PRAMS data can be used to fill these gaps and aid in program development.

6. Describe how data from PRAMS will complement the jurisdiction's use of vital records or other MCH data by increasing understanding of maternal and infant health issues, and evaluating programs designed to address them.

Profile of Jurisdiction Birth Registration and Sampling Process

1. Describe plans for obtaining monthly birth samples including:
    A. Describe the jurisdiction's process for registering births and drawing monthly samples. 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.
    B. Present a timeline for the cleaning of critical variables, such as name, address, and date of birth.
    C. Provide a timeline or flow chart documenting that the birth certificate information is available within two to four months after the date of birth for sampling.
    D. Describe the schedule on which birth certificate information will be available for monthly sampling.
2. Describe any jurisdiction laws or policies that place restrictions on the release of vital records data to outside organizations for surveillance purposes and indicate the impact of these laws or policies on core PRAMS operations.
3. Describe any jurisdiction laws or policies that place restrictions on the temporary secure upload of information to the CDC-provided software system for use by jurisdiction-level PRAMS staff to contact sampled women, and describe a plan for addressing any restrictions.
4. Describe plans for identifying a Vital Statistics representative to liaise with the PRAMS program to develop and maintain the sampling program and make any modifications needed throughout the life of the program.
5. Describe plans for ensuring 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 awardee PRAMS program in a timely fashion.

Management and Staffing Plan

1. Describe the proposed management and staffing plan for the study. Include a jurisdiction-level staffing plan (roles, percentage of time on project) that identifies and describes the jurisdiction staff, including those who will contribute to PRAMS throughout the period of performance.
2. Describe plans for maintaining Project Activities when staff vacancies occur.
3. Document (with curriculum vitae) and describe experience and expertise of proposed staff, including ability to conduct the proposed study. Describe the proposed team's experience collecting surveillance data, including, 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.
4. Document (with curriculum vitae) and describe the experience of project leadership

overseeing or conducting PRAMS, PRAMS-like, or other surveillance activities within the jurisdiction, and level of performance in achieving project aims. Include project and agency organizational charts with key personnel.

5. Describe plans for ensuring the program maintains local IRB approval and new key personnel or other significant contributors involved in the design or conduct of research involving human subjects meet educational program requirements in the protection of human subjects.

Analysis and Translation plan

1. 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.
2. 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.
3. Describe any jurisdiction laws or policies that place restrictions on the re-release of birth certificate variables to internal and external stakeholders or researchers for analytic purposes, and describe a plan for addressing them. If none, please indicate.
4. Describe the specific roles and responsibilities of staff responsible for identifying analytic priorities, developing analysis plans, and analyzing PRAMS data.
5. Describe a plan for data use that integrates the MCH priorities that can be addressed by PRAMS, addresses disparities, and will be used for program planning, program evaluation, policy development, and resource allocation.
6. 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.
7. 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 partners and stakeholders for the use and promotion of PRAMS data.
2. Describe the project-level steering committee consisting of a multi-disciplinary mixture of individuals from the public and private sector.
3. Describe willingness to collaborate on development and implementation of a new version of the questionnaire with potential adaptations to the existing PRAMS methodology (e.g., online data collection) in conjunction with CDC, other awardees, and stakeholders in maternal and infant health.

Plan of Operation

1. Describe how the major project components, such as mail and telephone operations, staffing plan, steering committee, and data analysis, will be developed and implemented within the first year of funding.
2. Describe the planned approach for establishing and maintaining the expected response rates throughout the period of performance (55% since 2015, but evaluated by CDC

annually). Include a plan and timeline for ensuring achievement of response rates meeting the CDC threshold in any population or sub-population within the first year of data collection, as well as plans for addressing lower than expected response rates.

3. Provide examples of previous data collection efforts, such as with PRAMS, PRAMS-like, or other surveillance systems. Describe any barriers that precluded complete and successful implementation of the project (e.g. sources of contact information, staffing patterns, and response rates).
4. Describe capacity to implement survey supplements on emerging issues (questions added to the end of the PRAMS survey in the middle of a questionnaire cycle) to explore and monitor issues of relevance to maternal and infant health that may arise during the data collection cycle including the response to post-disaster or emergency surveillance needs.
5. Describe plans to comply with the requirement to use CDC-provided software to collect and report PRAMS data.

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 and towards completing development of the analysis plan, evaluation plan, and translation and dissemination plan.
2. Identify key milestones for the remainder of the period of performance.

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.
2. Include one trip to Atlanta, GA for up to 2 FTEs to attend an orientation meeting.

Component B: Point-in-Time Tribal Surveillance
3-year period of performance

Background and Need

1. Describe the project area, including composition of the birth population, giving the numbers of overall live births to American Indian or Alaska Native women covered by the applicant's project area.
2. Describe how subpopulations within the applicant's project area are disproportionately affected by adverse maternal and infant health outcomes and related risk factors such as inadequate prenatal care or unintended pregnancy (e.g., based on race, ethnicity, or geography) and strategies for using PRAMS data to address these disparities, such as implementing stratified sampling based on various characteristics to make inferences about subgroups of high public health interest.
3. Describe how a point-in-time project will meet the needs of the tribal population.
4. Describe how the proposed research will improve or have an impact on population

health.

5. Describe the maternal and child health priorities for the jurisdiction and how PRAMS data can be integrated into the jurisdiction's activities to address those priorities and evaluate jurisdiction programs.
6. Identify gaps in needed information concerning risk factors for adverse pregnancy and infant outcomes and describe how PRAMS data can be used to fill these gaps and aid in program development.
7. Describe how data from PRAMS will complement the use of vital records or other MCH data by increasing understanding of maternal and infant health issues, and evaluating programs designed to address them.

Profile of Jurisdiction Birth Registration and Sampling Process

1. Describe plans for obtaining monthly birth samples including:
    A. Describe the jurisdiction's process for registering births and drawing monthly samples. 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.
    B. Present a timeline for the cleaning of critical variables, such as name, address, and date of birth.
    C. Document that the birth certificate information is available within two to four months after the date of birth for sampling.
    D. Describe the schedule on which birth certificate information will be available for monthly sampling.
2. Describe any jurisdiction laws or policies that place restrictions on the release of vital records data to outside organizations for surveillance purposes and indicate the impact of these laws or policies on core PRAMS operations.
3. Describe any jurisdiction laws or policies that place restrictions on the temporary secure upload of information to the CDC certified software system for use by internal jurisdiction PRAMS staff to contact sampled women, and describe a plan for addressing any restrictions.
4. Describe plans for identifying a Vital Statistics representative to liaise with the PRAMS program to develop and maintain the sampling program and make any modifications needed throughout the life of the program.
5. Describe plans for ensuring 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 awardee PRAMS program in a timely fashion.

Management and Staffing Plan

1. Describe project-level staffing plan (roles, percentage of time on project) that identifies and describes the project staff, including those who contribute to PRAMS throughout the period of performance.
2. Describe plans for maintaining project activities when staff vacancies occur.
3. Document (with curriculum vitae) and describe experience and expertise of proposed staff, including ability to conduct the proposed study. Describe the proposed team's experience collecting surveillance data, including, 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.

4. Document (with curriculum vitae) and describe the experience of project leadership overseeing or conducting PRAMS, PRAMS-like, or other surveillance activities and level of performance in achieving project aims. Include project and agency organizational charts with key personnel.
5. Describe plans for ensuring program maintains local IRB approval and new key personnel or other significant contributors involved in the design or conduct of research involving human subjects meet educational program requirements in the protection of human subjects.

Analysis and Translation plan

1. 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.
2. If applicable, describe any laws or policies that place restrictions on the re-release of birth certificate variables to internal and external stakeholders or researchers for analytic purposes, and describe a plan for addressing them.
3. Describe the specific roles and responsibilities of staff responsible for identifying analytic priorities, developing analysis plans, and analyzing PRAMS data.
4. Describe a plan for data use that integrates the MCH priorities that can be addressed by PRAMS, addresses disparities, and will be used for program planning, program evaluation, policy development, and resource allocation.
5. 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.
6. 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.
2. Include plans to assure active cooperation and collaboration among participating organizational units, specifically with the Vital Records Unit. Collaborations with other relevant units, such as state and local MCH programs, tribes, tribal organizations, and Tribal Epidemiology Centers should also be described.
3. Describe the project-level steering committee consisting of a multi-disciplinary mixture of individuals from the public and private sector.
4. Describe plans for using a new version of the questionnaire with potential adaptions to the existing PRAMS methodology (e.g., online data collection) in conjunction with other awardees and stakeholders in maternal and infant health.

Plan of Operation

1. Describe how the major project components, such as mail and telephone operations, staffing plan, steering committee, and data analysis, will be developed and implemented within the first year of funding.
2. Describe the planned approach for establishing and maintaining, the expected response rates throughout the period of performance (55% since 2015, but evaluated by CDC annually). Include a plan and timeline for ensuring achievement of response rates meeting the CDC threshold in any population or sub-population within the first year of data collection, as well as plans for addressing lower than expected response rates.
3. Provide examples of previous data collection efforts such as 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).
4. Describe plans to comply with the requirement to use CDC-provided software to collect and report PRAMS data.

Timetable

1. Identify key milestones for the remainder of the period of performance.
2. 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 and towards completing development of the analysis plan, evaluation plan, and translation and dissemination plan.

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.
2. Include at least one trip to Atlanta, GA for up to 2 FTEs to attend an orientation meeting.

Component C: Stillbirth Surveillance
3-year period of performance

Background and Need

1. Describe the vital records jurisdiction. Describe the scope and burden of stillbirth within the vital records jurisdiction. Identify gaps in needed information concerning stillbirth and describe how PRAMS data may be used to fill these gaps and address disparities.
2. Describe how subpopulations are disproportionately affected by stillbirth.
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 experience with conducting surveillance of stillbirths or an active stillbirth

registry.

Profile of Jurisdiction Birth Registration and Sampling Process

1. Describe, in detail, the jurisdiction's process for registering fetal deaths:
    A. 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.
    B. Document that the fetal death certificate information is available for sampling within six months after the date of death.
    C. Describe the schedule on which death certificate information will be available for monthly sampling.
2. Describe any jurisdiction laws or policies that place restrictions on the release of vital records data to outside organizations for surveillance purposes and indicate the impact of these laws or policies on PRAMS Stillbirth operations.
3. Describe plans for identifying a Vital Statistics representative to liaise with the PRAMS program to develop and maintain the sampling program and make any modifications needed throughout the life of the program.
4. Describe plans for ensuring any changes in the vital statistics system, such as with file layouts or adoption of any new death certificate format, will be communicated in writing to the awardee PRAMS program in a timely fashion.

Management and Staffing Plan

1. Describe the proposed management and staffing plan for the study. Include a jurisdiction-level staffing plan (roles, percentage of time on project) that identifies and describes the jurisdiction staff, including those who contribute to PRAMS throughout the period of performance.
2. 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.
3. Describe plans for maintaining project activities when staff vacancies occur.
4. Describe how all units involved with the core PRAMS activities and the stillbirth surveillance will cooperate and collaborate.
5. Describe how the vital records office staff, birth defects registry, and other surveillance program or epidemiology staff will be involved with the project.
6. Describe plans for ensuring the program maintains local IRB approval and new key personnel or other significant contributors involved in the design or conduct of research involving human subjects meet educational program requirements in the protection of human subjects.

Analysis and Translation plan

1. If applicable, describe any jurisdiction laws or policies that place restrictions on the re-release of fetal death certificate variables to internal and external stakeholders or researchers for analytic purposes, and describe a plan for addressing them.
2. Describe a plan for data analysis related to stillbirth surveillance.

3. Describe the specific roles and responsibilities of staff responsible for identifying analysis priorities, developing analysis plans and strategies to address disparities, and analyzing PRAMS data.
4. 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.
2. Include plans to assure active cooperation and collaboration among participating organizational units to conduct stillbirth surveillance, specifically with the Vital Records Unit. Collaborations with other relevant units, such as MCH, and birth defects should also be described.
3. Describe the project-level steering committee consisting of a multi-disciplinary mixture of individuals from the public and private sector.
4. Describe any prior collaborations with Vital Records, the Birth Defects Registry, or other entities that will be providing support to the project.

Plan of Operation

1. Describe the plan for obtaining resources (including staff and analytic expertise) and expertise to carry out the stillbirth surveillance activities.
2. Describe how existing and new resources will be used to ensure sufficient staffing time and content area expertise for the project.
3. Describe how the major project components, such as mail and telephone operations, staffing plan, steering committee, and data analysis, will be developed and implemented within the first year of funding.
4. Describe the planned approach for establishing and maintaining the expected response rates throughout the period of performance (55% since 2015, but evaluated by CDC annually). Include a plan and timeline for ensuring achievement of response rates meeting the CDC threshold in any population or sub-population within the first year of data collection, as well as plans for addressing lower than expected response rates.
5. Describe how the jurisdiction's planned PRAMS structure will be adjusted to accommodate the additional workload related to adding a stillbirth sample. 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.
6. Indicate willingness of jurisdiction to collect and report surveillance using agreed upon software to be specified by CDC.

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 and towards completing development of the analysis plan, evaluation plan, and translation and dissemination plan.
2. Identify key milestones for the remainder of the period of performance.

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.
2. Include at least one trip to Atlanta, GA for up to 2 FTEs to attend an orientation meeting.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes.
Organizations must submit applications using the ASSIST web-based application preparation and submission process.
ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.

Applicants are able to access, view, and track the status of their applications in the eRA Commons.
Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.
Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time 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).
Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

It is important that applicants complete the application submission process well in advance of the due date time.
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. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

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

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

    a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.
    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **07/07/2020**

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

listed application due date.

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions, 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.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained. IRB approval letters must be dated and should specify the name of the NOFO or title of the project covered and the expiration date or lack of need for continuation review. If and when new supplements are added to the protocol, dated IRB approval letters for protocol amendments are required. If the amendment approval letter does not specify the content of the amendment, a summary of the amendment request that was submitted to the IRB is

required.

Awardee organizations that rely on other institutions for their IRB review responsibilities shall provide documentation of the reliance and the IRB approval. A sample written agreement is available at https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. Upload the questionnaire and supporting documents as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding

consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

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
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- http://era.nih.gov/erahelp/ASSIST/

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

Section V. Application Review Information

1. Criteria

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

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

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

Significance

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

Component A: Core Surveillance and Component B: Point-in-Time Tribal Surveillance

- To what extent does the applicant justify the need for the Core Surveillance or Point-in-time surveillance of tribal populations based on the burden of adverse pregnancy and infant outcomes?
- To what extent do disparities exist, within sub-populations, or defined geographical areas?
- How do outcomes compare to relevant national rates, the HRSA Maternal and Child

Health Bureau indicators, and the Healthy People 2030 Objectives?

- 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, or address disparities?
- To what extent does the applicant describe how new information from PRAMS will compliment vital records data and address the jurisdiction's or project's maternal and child health priorities?

Component C: Stillbirth Surveillance

- To what extent does the applicant justify the need for this program?
- Does the applicant adequately 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 and services for women with recent stillbirths?

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?

Component A: Core Surveillance and Component B: Point-in-Time Tribal Surveillance

- Does the applicant adequately document the experience of project leadership and their ability to achieve project aims related to PRAMS or other surveillance activities?
- To what extent do the roles and responsibilities for organizational units supporting PRAMS appear reasonable and appropriate, particularly for coordination with the jurisdiction's vital records agency, as well as other relevant partners such as state or jurisdiction-level MCH and other organizational units?
- To what extent are the roles and responsibilities for key personnel and their expertise and experience documented and appear reasonable and appropriate? Does their placement within the organization appear to be appropriate?
- Is the PD/PI time on to the project sufficient to support the PD/PI responsibility outlined in Section VI.4. Cooperative Agreement Terms and Conditions of Award?
- To what extent does the applicant provide a reasonable and appropriate staffing plan including a description of staff contributions, roles, time to PRAMS surveillance activities?
- Does the applicant adequately describe the composition and function of the steering committee?

Component C: Stillbirth Surveillance

- Does the applicant adequately document the experience of project leadership and their ability to achieve project aims related to PRAMS or other surveillance activities?
- To what extent do the roles and responsibilities for organizational units supporting PRAMS documented appear reasonable and appropriate, particularly for coordination with the jurisdiction's vital records agency, as well as other relevant partners such as state or jurisdiction-level MCH and other organizational units?
- To what extent are the roles and responsibilities for key personnel and their expertise and experience documented and appear reasonable and appropriate? Does their placement within the organization appear to be appropriate?
- Is the PD/PI time on to the project sufficient to support the PD/PI responsibility outlined in Section VI.4. Cooperative Agreement Terms and Conditions of Award?
- To what extent does the applicant provide a reasonable and appropriate staffing plan including a description of staff contributions, roles, time to PRAMS surveillance activities?
- Does the applicant adequately describe the composition and function of the steering committee?
- Does the applicant have experience with conducting surveillance of stillbirths or operating an active stillbirth registry?

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: Core Surveillance

- To what extent does the applicant propose methods or approaches for data collection, analysis, or translation that are likely to produce timely, high quality surveillance data?
- Does the applicant's plan adequately demonstrate capacity and willingness to carry out data collection in the future? To what extent does the applicant address planned procedures for implementing a survey supplement?
- To what extent do applicants describe plans to form a Steering Committee to advise the jurisdiction's PRAMS project in the development and selection of questions for the survey and on the use, dissemination, and application of findings?
- To what extent does the applicant plans ensure that the committee include a multi-disciplinary mixture of individuals from the public and private sector, as well as from the academic community?
- Do applicants whose vital records jurisdiction includes tribal populations that are served by a Tribal Epidemiology Center (TEC) describe plans to work with the TEC on surveillance of their American Indian/Alaska Native (AI/AN) populations?
- To want extent does the applicant describe plans to assure active cooperation and collaboration among participating organizational units, specifically with the

jurisdictions' Vital Records and Maternal and Child Health units?

Components B Point-in-Time Tribal Surveillance and C: Stillbirth Surveillance

- To what extent does the applicant propose methods or approaches for data collection, analysis, or translation that are likely to produce timely, high quality surveillance data?
- To what extent do applicants describe plans to form a Steering Committee to advise the jurisdiction's PRAMS project in the development and selection of questions for the survey and on the use, dissemination, and application of findings?
- To what extent does the applicant plans ensure that the committee include a multi-disciplinary mixture of individuals from the public and private sector, as well as from the academic community?
- Do applicants whose vital records jurisdiction includes tribal populations that are served by a Tribal Epidemiology Center (TEC) describe plans to work with the TEC on surveillance of their American Indian/Alaska Native (AI/AN) populations?
- To want extent does the applicant describe plans to assure active cooperation and collaboration among participating organizational units, specifically with the jurisdictions' Vital Records and Maternal and Child Health units?

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?

Component A: Core Surveillance and Component B: Point-in-Time Tribal Surveillance

- Is the operational plan adequate to carry out major project components (i.e., sampling, data collection operations, staffing plan, steering committee, research, data analysis, and data translation)?
- Does the proposed approach to accomplishing methods appear to be appropriate and is it likely to produce adequate response (i.e. 55% since 2015), from the target population, including high-risk subpopulations?
- Has the applicant provided evidence of experience administering surveillance systems?
- Does the plan for data analysis assure attention to MCH priorities and disparities?
- Does the plan for data analysis assure dissemination of findings through multiple channels, to include steering committee members, health policy makers, and health providers?
- Is the timetable specific, measurable, and realistic?
- To what extent does the timetable incorporate major PRAMS activities and key milestones?

Component C: Stillbirth Surveillance

- Is the operational plan adequate to carry out major project components (i.e., sampling, data collection operations, staffing plan, steering committee, data analysis, and data translation)?
- Has the applicant provided evidence of experience administering surveillance systems?
- 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 key 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, B, and C

- If restrictions are identified related to uploading data to CDC-provided 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?
- To what extent 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 provide documentation supporting sharing of birth certificate data for surveillance and analytic purposes?
- Does the applicant's Vital Records Unit have a plan for dealing with revisions of the birth certificate?
- Does applicant adequately address plans to ensure IRB approval and human subjects protections in accordance with the project timeline to meet project goals?

Component A: Core Surveillance

- How timely and thorough is the jurisdiction's vital records 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?
- If restrictions are identified related to the release of minimal personal identifier information for use by jurisdiction-level PRAMS staff to contact sampled women, is there a description of how PRAMS data collection operations can successfully be conducted considering the restrictions?
- To what extent has the applicant presented a plan likely to achieve or maintain minimal levels of participant response (55% since 2015) overall and by sub-populations for the duration of the period of performance?
- Has the applicant provided 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?
- To what extent has PRAMS, PRAMS–like or other surveillance data been used for health program planning, program evaluation, policy development, and research and resource allocation?
- Have specific examples of dissemination and translation been shared and partners in these activities identified?

Component B: Point-in-Time Tribal Surveillance

- Does the applicant thoroughly document the jurisdiction's vital records birth registration process?
- Is the birth certificate information cleaned, 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?
- If restrictions are identified related to the release of minimal personal identifier information for use by jurisdiction-level PRAMS staff to contact sampled women, is there a description of how PRAMS data collection operations can successfully be conducted considering the restrictions?
- To what extent has the applicant presented a plan likely to achieve or maintain minimal levels of participant response (55% since 2015) overall and by sub-populations for the duration of the period of performance?

Component C: Stillbirth Surveillance

- 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 support the sharing of fetal death data for surveillance and analytic purposes?
- Does the applicant's Vital Records Unit have a plan for dealing with revisions of the fetal death certificate?
- Does applicant adequately address plans to ensure IRB approval and human subjects

protections are met?

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 (https://www.cdc.gov/grants/additionalrequirements/ar-1.html).

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 (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://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 four 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) 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 4) 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 (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

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.

Applicants are not required to submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. Awardees will implement a standard CDC PRAMS Data Management Plan (DMP) for AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html. The standard CDC PRAMS DMP will be provided to awardees post award.

Resource Sharing Plan(s)
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: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The

submitted DMP will be evaluated for completeness and quality at the time of submission.

The DMP should include, at a minimum, a description of the following:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

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

The budget can include both direct costs and indirect costs as allowed.

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

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 NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding recommendations:

- 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.

One organization per vital records jurisdiction will be funded for Components A and C.

Additionally for Component A, the following will be considered:

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

Additionally for Components C, the following will be considered:

- Number of annual fetal deaths
- Racial or ethnic diversity of surveillance population

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or

procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

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 NOFO 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
(https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/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.

Recipient 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

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www.access.gpo.gov/nara/cfr/cfr-table- search.html.

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements ;

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

AR-7: Executive Order 12372 Review

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: Data Management and Access

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: Research Definition

AR-32: Appropriations Act, General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-34: Language Access for Persons with Limited English Proficiency

AR-36: ; Certificates of Confidentiality

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 NOFO:
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: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, 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 website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 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.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will

be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.
The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–
Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).

The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at:
https://www.cdc.gov/grants/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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 75, 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 Officer 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:

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

Additionally for **Components A and B**:

1. Assuring and maintaining confidentiality of all relevant data and documents containing private identifiable information of survey participants.
2. Ensuring adherence to the surveillance protocol; adapting the jurisdiction-specific portions of the written procedures to meet state needs; and promptly (within 5 business days) responding to CDC if discrepancies in operational procedures are identified. Processing of data for weighted data sets by CDC is subject to awardees' adherence to protocol and meeting a minimum response rate target.
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-provided software system for data collection and operational components of the project.
7. Ensuring staff conduct monitoring of the data collection and management efforts.
8. Establishing and maintaining communication with key research partners.

9. Initiating or maintaining PRAMS program collaboration with vital records department that assures timely access to needed vital records information for sampling and weighting.
10. Assuring active cooperation and collaboration among the participating organizational units such as MCH, Vital Records, and other units.
11. Assuring that the vital records data required for linkage to the PRAMS analytic dataset are made available to CDC in a timely fashion, by September 1 of the year following the data collection year (i.e., 9/1/22 for 2021 data collection), for creation of data set released external researchers and stakeholders per terms of the data sharing agreement between CDC and sites.
12. Providing assurance that PRAMS questionnaire and operational variables are available to CDC in accordance with the project timeline, and CDC may distribute these variables to internal and external researchers and stakeholders per terms of the data sharing agreement between CDC and sites.
13. Using a new version of the questionnaire (Phase 9) with potential adaptations to the existing PRAMS methodology (e.g. online data collection) in conjunction with awardees and stakeholders in maternal and infant health.
14. Forming or maintaining a jurisdiction-level or project-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.
15. 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.
16. Developing strategies to interact and share findings with health departments, professional societies, voluntary agencies, universities, Tribal Epidemiology Centers (TECs), other PRAMS states, and other interested individuals and organizations.
17. Documenting and sharing examples of dissemination products and examples of how data have been translated into useable information for public health action.
18. Attending project review meetings or site visits, national meetings and any additional working meetings with CDC.
19. Complying with the CDC PRAMS Standard Data Management Plan (DMP) for AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Additionally for Component C:

1. Assuring and maintaining confidentiality of all relevant data and documents containing private identifiable information of survey participants.
2. Ensuring adherence to the stillbirth surveillance protocol; adapting the jurisdiction-specific portions of the written procedures to meet state needs; and promptly (within 5 business days) responding to CDC if discrepancies in operational procedures are identified. Processing of data for weighted data sets by CDC is subject to awardees' adherence to protocol and meeting a minimum response rate target.
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-provided software system for data collection and operational components of the project.
7. Ensuring interviewers are trained to conduct telephone interviewing using standard PRAMS procedures. For the stillbirth survey it is recommended that grief counseling or other specialized training be provided to telephone interviewers.
8. Ensuring staff conduct monitoring of the data collection and management efforts.
9. Establishing and maintaining communication with key research partners.
10. Initiating or maintaining PRAMS program collaboration with vital records department that assures timely access to needed vital records information for sampling and weighting.
11. Assuring active cooperation and collaboration among the participating organizational units such as MCH, Vital Records, and other units.
12. Assuring that the vital records data required for linkage to the PRAMS analytic dataset are made available to CDC in a timely fashion, by December 1 of the year following the data collection year (i.e., 12/1/22 for 2021 data collection), for creation of data set released external researchers and stakeholders per terms of the data sharing agreement between CDC and sites.
13. Providing assurance that PRAMS questionnaire and operational variables are available to CDC in accordance with the project timeline, and CDC may distribute these variables to internal and external researchers and stakeholders per terms of the data sharing agreement between CDC and sites.
14. Forming a jurisdiction-level steering committee related to stillbirth surveillance activities consisting of representatives from organizational units housing collaborating on PRAMS, other public and private health community representatives, and subject matter experts.
15. 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.
16. Developing strategies to interact and share findings with health departments, professional societies, voluntary agencies, universities, Tribal Epidemiology Centers (TECs), other PRAMS states, and other interested individuals and organizations.
17. Documenting and sharing examples of dissemination products and examples of how data have been translated into useable information for public health action.
18. Attending project review meetings or site visits, national meetings and any additional working meetings with CDC.
19. Complying with the CDC PRAMS Standard Data Management Plan (DMP) for AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Awardees will retain custody of and have primary rights to the data 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 and C:

1. Maintain CDC Institutional Review Board approvals as required when engaged in research involving human subjects.
2. Obtain Office of Management and Budget (OMB) approval in accordance with the Paperwork Reduction Act (PRA), as required.
3. Provide model procedures and assist with development of jurisdiction-specific written procedures. Conduct periodic review of written procedures and provide recommendations for improvement if needed.
4. Provide CDC-provided 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.
10. Conduct regular operational evaluations and provide recommendations for improvements if needed.
11. Provide technical assistance for data editing.
12. Provide technical assistance on implementation of survey supplements to address emerging issues that may arise during the project.
13. Assist with implementation of a new version of the questionnaire (Phase 9) with potential adaptions to the existing PRAMS methodology (e.g. online data collection) in conjunction with awardees and stakeholders in maternal and infant health.
14. Provide awardees with epidemiologic technical assistance including identifying relevant data sources, developing descriptive analyses and preparing reports on a range of topics.
15. Conduct the statistical weighting and create annual data sets for awardees. Processing of data for weighted data sets by CDC is subject to awardees' adherence to protocol and meeting a minimum response rate target.
16. Assist awardee staff in obtaining training in software to analyze PRAMS data.
17. Facilitate the dissemination of weighted analytic datasets to researchers per data sharing agreement.
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 awardees in workshops, trainings, meetings, and coordinating committees to exchange information among awardees.
21. Coordinate and participate in PRAMS National Awardee Meetings.
22. Participate in the voluntary PRAMS Coordinating Committee comprised of CDC Project

Scientists and awardees to promote exchange of information and best practices for program development and evaluation.

23. Assist awardee with complying with the CDC PRAMS Standard Data Management Plan for AR25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Additionally for Component C:

1. Provide awardees 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.
3. Organize on-going opportunities for exchange of information on challenges and best practices in establishing stillbirth surveillance or other enhanced activities.
4. Assist awardee with complying with the CDC PRAMS Standard Data Management Plan for AR25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Additionally, an HHS/CDC Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above.

Additionally, an HHS/CDC agency Program Official will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will be:

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

Areas of Joint Responsibility include: Participation in the PRAMS Coordinating Committee:

- The PRAMS Coordinating Committee (CC) is comprised of CDC Project Scientists and the Awardee Working Group (AWG). This work group 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 awardees 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 AWG consists of a primary and secondary representative from 7 defined regions.
- Primary representatives actively participate in calls and serve as the liaison between the AWG and the awardee in their assigned region as needed (i.e. take the lead in conveying or gathering information). Secondary representatives participate in calls and back up the primary representatives as needed. Representation rotates each year so that secondary representatives become primary representatives and each jurisdiction in the region has an opportunity to participate during the grant cycle. The AWG meets quarterly by

phone. The frequency of the meetings is subject to change depending on the operational and methodologic issues underway.

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

1. Routine conference calls to discuss operational and analytic activities at the jurisdiction-level;
2. All awardee calls to discuss emerging issues that affect all awardees; and
3. In-person awardee meetings.

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) 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 recipients 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 recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. 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** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) 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 period of performance**.

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.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.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

In addition to the reporting requirements outlined above, awardees should include the following with their **Yearly Non-Competing Grant Progress Report**:

- Documentation, using the CDC-provided PRAMS Data to Action form, of 2 or more examples of PRAMS data use to inform maternal and child health policies or programs, starting within 1 year of receiving a weighted dataset from CDC.
- Certification that any new key personnel or other significant contributors involved in the design or conduct of research involving human subjects have completed an educational program in the protection of human subjects.

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.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients 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 recipients are now available

at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.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: https://grants.nih.gov/support/index.html

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

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons 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: https://era.nih.gov/docs/Commons_UserGuide.pdf.

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 period of performance. 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.

- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

Section VII. Agency Contacts

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

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

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

Scientific/Research Contact(s)

Sue Shaw, MPH
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: 770.488.6142
Email: zgx7@cdc.gov

Peer Review Contact(s)

Jaya Raman, Ph.D.
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: 770.488.6511
Email: kva@cdc.gov

Financial/Grants Management Contact(s)

Dwayne R. Cooper, Sr.
Grants Management Specialist
Centers for Disease Control and Prevention
Office of Financial Resources (OFR)
Atlanta, Georgia 30341
Telephone: 770.488.2874
Email: DCooper1@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities 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, and Section 317 of the Public Health Service Act, 42 U.S.C. 247b.