Centers for Disease Control and Prevention

NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS)

RFA-DD-23-001

01/17/2023

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:

National Center on Birth Defects and Developmental Disabilities

Notice of Funding Opportunity (NOFO) Title

Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS)

Activity Code

U01

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DD-23-001

Assistance Listings Number(s)

93.073

Category of Funding Activity

HL - Health

NOFO Purpose

The National Center on Birth Defects and Developmental Disabilities (NCBDDD), Division of Birth Defects and Infant Disorders (DBDID), seeks to fund a multi-site, case-control study of selected major birth defects and of stillbirths.

The purpose of this announcement is to identify novel epidemiologic and genetic risk factors for major structural birth defects and for stillbirths, and to advance research that can be translated into birth defects and stillbirth prevention strategies. The focus will be on studying these

exposures during pregnancy: (1) chronic diseases and their treatments; (2) infectious diseases; and (3) medications.

This NOFO has two funding components:

Component A (Core): Support the exploration of epidemiological and genetic risk factors for birth defects.

Component B (Stillbirth): Support the exploration of epidemiological risk factors for stillbirths. Component B is optional, however, applicants must apply for and receive concurrent Component A funding.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DD-23-001, 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:

12/06/2022
12/6/2022

Application Due Date:

01/17/2023
1/17/2023

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 11:59 PM U.S. Eastern Time.

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

For more information on 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 http://grants.nih.gov/support/index.html.

- E-mail: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552
- Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays

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:

03/21/2023

Secondary Review:
05/09/2023

Estimated Start Date:
09/01/2023

Expiration Date:
01/18/2023

Required Application Instructions

It is critical that applicants follow the instructions in the How to Apply - 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.

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

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

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

Executive Summary

Birth defects affect about three percent of all births in the United States and are a leading cause of infant mortality, morbidity, and healthcare costs. Although some causes of birth defects have been identified (e.g., genetics, medications, and environmental exposures), the causes of two-thirds of birth defects remain unknown. It is important to study specific birth defects individually because the etiology may differ substantially. Stillbirths are an understudied pregnancy outcome and there is little information on the causes of stillbirths.

In 1996 Congress appropriated funds to develop the Centers for Birth Defects Research and Prevention. Since then, CDC has awarded cooperative agreements to nine different centers. The two major collaborative activities of the centers have been case-control studies called the **N**ational **B**irth **D**efects **P**revention **S**tudy, which collected data for deliveries between 1997 and 2011, and the **B**irth **D**efects **S**tudy **T**o **E**valuate **P**regnancy exposure**S** (BD-STEPS), which began collecting data for deliveries in 2014 and is ongoing through 2023. To support research assessing risk factors for stillbirths (fetal deaths at 20 or more weeks gestation), a case-control study of risk factors for stillbirth was added to BD-STEPS in 2014, and data collection began in 2015.

The purpose of this funding opportunity is to support the capacity of BD-STEPS to identify novel epidemiologic and genetic risk factors for major, structural birth defects and for stillbirths, and to provide research findings that are intended to be translated into public health prevention messages, as warranted. The focus will be on studying these exposures during pregnancy: (1) chronic diseases and their treatments; (2) infectious diseases; and (3) medications.

Component A (BD-STEPS Core): Support the exploration of epidemiological and genetic risk factors for birth defects.

Component B (BD-STEPS Stillbirth): Support the exploration of epidemiological risk factors for stillbirths. Component B is optional, however, recipients must apply for and receive concurrent Component A funding.

Applicants should clearly identify the component(s) for which they are applying at the beginning of the title (i.e., Component A or Component B). For example, Comp A: BD-STEPS Core; Comp B: BD-STEPS Stillbirth. Separate applications are required for each component.

Mechanism of Support. Cooperative Agreement

- **Funds Available and Anticipated Number of Awards.** CDC anticipates up to 9 awards being made for Component A and up to 9 awards for Component B. The estimated total level of funding for Components A and B (total direct and indirect for entire project period) is $20,650,000. 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 also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration, and cost of the applications received.

- **Budget and Project Period.**

    1. **Component A. BD-STEPS Core**: The estimated total funding (direct and indirect) for the first budget period, 9/1/2023 - 8/31/2024, is $5,300,000. The estimated total funding (direct and indirect) to support up to 9 awards for the entire project period of 3.5 years, 9/1/2023 - 2/28/2027, is $18,550,000. Average annual amount of each award is $700,000.
    2. **Component B. BD-STEPS Stillbirth**: The estimated total funding (direct and indirect) for the first budget period, 9/1/2023 - 8/31/2024, is $600,000. The estimated total funding (direct and indirect) to support up to 9 awards for the entire project period of 3.5 years, 9/1/2023 - 2/28/2027, is $2,100,000. Average annual amount of each award is $300,000.

- **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.

- **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.** Only one application per component may be submitted by an eligible institution; institution as identified by unique UEI number.
- **Application Type**. New.
- **Special Date(s).** Not Applicable.
- **Application Materials**. See Section IV.1 for application materials. Please note that Form D is to be used when downloading the application package. http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf%20
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

Section I. Funding Opportunity Description

Statutory Authority

This program is authorized under Sections 301 and 317C of the Public Health Service Act [42 U.S.C. 241, and 247b-4 as amended].

1. Background and Purpose

Birth defects affect about three percent of all births in the United States and are a leading cause of infant mortality, morbidity, and healthcare costs [1]. Birth defects account for one in five infant deaths and contribute substantially to long-term disability [2]. Although some causes of birth defects have been identified (e.g., genetics, medications, and environmental exposures), the causes of two-thirds of birth defects remain unknown [3]. It is important to study specific birth defects individually because the etiology of specific birth defects may differ substantially. Because individual types of birth defects are relatively rare, it has been difficult in the past to conduct a study large enough to provide the necessary power to assess risk factors for specific defects [4]. Additionally, significant racial disparities exist. For instance, infant deaths related to birth defects were found to be 34 percent and 26 percent higher for infants born to non-Hispanic Black and Hispanic women, respectively, than for infants born to non-Hispanic White women [5].

More than 20,000 pregnancies in the U.S. ended in a stillbirth (pregnancy loss at 20 or more weeks of gestation) [6] in 2020. Stillbirths are an under-evaluated public health issue and there is little information on the causes of stillbirths [7]. Significant racial disparities exist, with non-Hispanic black women at much higher risk of having a stillbirth than non-Hispanic white women [8].

Overview

In 1996 Congress appropriated funds to initiate some of the activities described in the Birth Defects Prevention Act of 1998, including funding the **C**enters for **B**irth **D**efects **R**esearch and **P**revention (CBDRP). Beginning that fiscal year, CDC awarded cooperative agreements to nine different sites overall, referred to as "centers" [8]. CDC also launched a center at its Atlanta headquarters. The two major collaborative activities of the CBDRP have been multi-site, case-control studies called the **N**ational **B**irth **D**efects **P**revention **S**tudy (NBDPS) and the **B**irth

Defects **S**tudy **T**o **E**valuate **P**regnancy exposure**S** (BD-STEPS). Both rely on data from existing state- or jurisdiction-based birth defects surveillance systems (e.g., the Metropolitan Atlanta Congenital Defects Program).

CBDRP Study Designs for NBDPS and BD-STEPS

NBDPS included deliveries on or after October 1, 1997 and ended with deliveries on December 31, 2011; the last interview was conducted in March 2013 [10, 11]. Nine centers were funded during the study period and CDC was included as an additional study site. Pregnancies affected by 1 of more than 30 major structural birth defects ("cases") and those unaffected by a major structural birth defect ("controls") were ascertained using birth hospital medical records and state vital records, respectively. Clinicians used standard definitions to review cases for eligibility [12, 13]. If the birth defect was known or strongly suspected to be caused by a syndrome or other known genetic or teratogenic factor, the case was excluded. Computer-assisted telephone interviews were conducted with more than 40,000 women, who were asked about exposures from one month before through the end of pregnancy. At the end of the maternal interview, participants were sent buccal (cheek) cell collection kits to collect cells from themselves, the biological father, and the infant (if living) [14, 15].

In September 2013 and again in September 2018, NCBDDD funded six centers (with CDC serving as the seventh center) to conduct BD-STEPS, which extended and focused the efforts of the NBDPS. For example, only a subset of NBDPS birth defects were included which were most reliably ascertained and likely to have the greatest public health importance. In addition, the maternal interview was modified to better capture certain exposures, particularly those related to maternal chronic diseases and their treatments; infectious disease in pregnancy; and medications used during pregnancy. The exposure period for many exposures was limited to the month before through the first three months of pregnancy. Methodologically, BD-STEPS incorporated reportable infectious disease information from participants, residual newborn bloodspots for use in genetic research, and an online questionnaire about occupational exposures.

Beginning in 2014, CDC funded two BD-STEPS centers to adapt BD-STEPS methodology and data collection tools to assess risk factors specific to stillbirths to enable research of this understudied birth outcome. In addition to the core BD-STEPS activities noted above, these centers collected information on stillbirths without birth defects as a separate case group. (Stillbirths with birth defects not meeting BD-STEPS inclusion criteria were not included.). Control infants from the core BD-STEPS case-control study also served as controls for the stillbirth study. Both groups were asked to complete a longer interview that includes the BD-STEPS core interview and collected additional information on exposures later in pregnancy, and exposures most relevant to elucidating causes of stillbirths.

The CBDRP has been a collaborative effort between CDC's NCBDDD and the funded applicants. Together, they have fine-tuned the study methods and data collection processes to achieve timely, high-quality scientific data. For the past 25 years, the CBDRP case-control studies have provided a unique and unprecedented opportunity to assess a variety of exposures for their potential association with specific birth defects and/or stillbirths. Over 350 articles in peer-reviewed journals have reported results from analyses (http://www.nbdps.org/research/keyfindings.html), which have also been disseminated through

conference proceedings and coverage by the popular press.

The CBDRP research collaboration demonstrates several areas in which public health could benefit from further birth defects and stillbirth research. For example, although the association between diabetes, obesity, and specific birth defects has been observed in analyses [16-18], further study is needed to indicate if improved glycemic control might mitigate some of the negative impact of obesity and diabetes on birth defects. Evaluating this relationship is an important next step for targeted and appropriate public health recommendations. This collaborative research has also demonstrated the importance of documenting the indication for which a medication was taken (e.g., fever vs. pain for acetaminophen) and the dose that was consumed (e.g., 25 to 200 mg/day for sertraline). With the additional information collected via this NOFO, CDC anticipates sufficient sample sizes to examine the impact of indication and dose on certain common medication exposures (e.g., antibiotics). Focusing on medication use in this NOFO provides the opportunity to look at newly released medications and provide much needed evidence about the prevalence of prescription and over-the-counter medication use during pregnancy.

Although previous CBDRP research has identified associations between infections and birth defects (e.g., gastroschisis and genito-urinary infections [19]), this NOFO crucially continues these avenues of research to include new exposures such as COVID-19. Continuing to ascertain the maternal status of reportable infectious diseases from the state health department sustains a focus on studying infectious causes of birth defects, and ascertaining infection status from all women who experienced a stillbirth, will provide opportunities to focus on infectious causes of stillbirths. The increased total sample size will allow for continued improvement in the ascertainment of potential risk factors for stillbirth. Ascertaining all stillbirths with and without birth defects in the catchment areas will allow for the calculation of prevalence estimates. Currently, only participants who experienced a stillbirth with an eligible birth defect for BD-STEPS were asked for access to reportable infectious disease information and for additional information using an online survey. In this NOFO, all women who experienced a stillbirth will be eligible for both study activities.

The additional data collected via this NOFO will add diversity among the study population with regard to geography, racial/ethnic composition, socioeconomic status, and acculturation, and will allow continued evaluation of social determinants of health and their effect on disparities in occurrence of birth defects and stillbirths. Of particular interest for improving health equity are analyses of key social determinants of health, such as socioeconomic status; health insurance coverage; education; language and acculturation; employment and conditions in the workplace, neighborhood, and environment, including air and water quality.

This notice of funding opportunity will start with deliveries in late 2023. Increasing the total BD-STEPS pooled sample size is especially important for some rarer exposures (e.g., medications, infections, genetic variants) and less common reproductive outcomes such as stillbirth and specific birth defects. By including multiple centers, BD-STEPS aims for a study population that is representative of the racial/ethnic composition of the study regions.

This NOFO has two funding components:

- Component A is an open competition to identify applicants with the capability to conduct epidemiological and genetic risk factor research for birth defects.
- Component B (optional) provides an opportunity for successful Component A applicants to explore epidemiological risk factors for stillbirths.

Healthy People 2030 and other National Strategic Priorities

The BD-STEPS program addresses several Healthy People 2030 objectives in the Maternal, Infant, and Child Health focus area, including to reduce the rate of fetal deaths (MICH-01), infant deaths (MICH-02), and child deaths (MICH-03).

Measurable outcomes of the program align with the goal of the NCBDDD Division of Birth Defects and Infant Disorders to accelerate identification of trends, risk factors, and prevention opportunities for birth defects, other adverse pregnancy outcomes, infant disorders, and related conditions.

Public Health Impact

This NOFO contributes substantially to the scientific understanding of the causes of birth defects, which account for one in five infant deaths and contribute substantially to childhood morbidity and long-term disability, as well as that of stillbirths. Currently, the causes of two-thirds of birth defects are unknown and the causes of stillbirth are unexplained in up to half of all cases. The increased sample size for BD-STEPS and continued investigation of high-priority hypotheses enhances the potential to successfully investigate birth defect and stillbirth risk factors and to explore disparities by subpopulations, so that public health guidance and education can reduce prevalence.

Of key importance is the ascertainment of exposure information for newly released medications, as new drugs are released every year. This is especially important because pregnant women are usually not included in clinical trials. The Zika and COVID-19 outbreaks highlight the devastating effect infectious diseases can have on the developing fetus. Linking with reportable infectious disease surveillance systems is anticipated to further elucidate the role of infectious diseases as a cause of birth defects and stillbirth.

Analyzing social determinants of health, along with other determinants of health (genetics, behavior, and physical influences) will improve understanding of disparities, with the ultimate goal of translating findings into improved health equity.

Relevant Work

NCBDDD supports activities that complement BD-STEPS, including local and national birth defects surveillance; Surveillance for Emerging Threats to Mothers and Babies Network (SET-NET), including Zika virus and COVID-19 infections; surveillance and research on substance use in pregnancy; surveillance and research on congenital heart defects and spina bifida through the lifespan; and surveillance and prevention of neural tube defects.

2. Approach

BD-STEPS is a multi-site, population-based case control study of risk factors for birth defects and stillbirths. Each site, referred to as a "center," should encompass a birth population and geographic study area that has between 30,000 - 80,000 births annually. The intended source population across all study sites is diverse with regard to geography, racial/ethnic composition,

socioeconomic status, and acculturation, so applicants are encouraged to describe their source population with regard to these characteristics.

The BD-STEPS coordinating council, composed of the principal investigators from each center, will establish public health priorities each year, and the centers will be expected to prioritize their research accordingly. Key study committees will provide guidance to BD-STEPS centers. Committees include the data sharing committee, clinicians' committees, project management committee, epi-analyst committee, questionnaire and methods committee, biologics-related committees, and the coordinating council. These committees will have representatives from each center and will discuss and assist each other in their processes, but will not provide consensus advice on CDC operations and activities. Applicants will be expected to analyze data and publish findings from BD-STEPS, as well as have the opportunity to analyze data previously collected for the NBDPS.

Component A focuses on birth defects and Component B focuses on stillbirth. All activities outlined below, except where noted in section II below, apply to both Component A and, if awarded, Component B**.** Component B applicants must apply for and receive concurrent funding under Component A.

I. Activities for both Components A and B

Data collection

Case and control ascertainment: Briefly, applicants will identify all pregnancies affected by a birth defect and/or stillbirth (cases) in their source population, as well as a sample comparison group of liveborn infants without a birth defect (controls), as described in more detail in section II.

Core interviews: Women who experienced a pregnancy affected by a birth defect and/or stillbirth and mothers of controls will be asked questions during the "core" interview regarding chronic diseases and their treatments, infectious disease, and medications as well as demographics, environmental exposures, and other exposures, predominantly during early pregnancy. CDC, via a central interviewing contractor, is responsible for contacting women about their interest in participating and for conducting the interviews.

Linkage to National Electronic Disease Surveillance System: Women who experienced a pregnancy affected by a birth defect and/or stillbirth and mothers of controls will be asked for consent to allow applicants to request their reportable disease records from their state health departments. The applicants are expected to work with their state health department to obtain available information from the state National Electronic Disease Surveillance System (NEDSS) to ascertain any of the following tentative list of reportable conditions (Chickungunya, Chlamydia, COVID-19, Dengue fever, Gonorrhea, Hepatitis A B or C, HIV, Lyme disease, Malaria, Novel Influenza A virus, West Nile virus, Zika virus) that affected the participants in the two years before or during pregnancy. Applicants will be expected to obtain hard copy consents or e-consents, if it is allowed, for the infectious disease linkage.

Online survey: Women who experienced a pregnancy affected by a birth defect and/or stillbirth and mothers of controls will be queried about occupational exposures before and during

pregnancy via online surveys. The applicants (or interviewing contractor) will send links to electronic surveys via email to interviewed participants requesting additional information via online surveys.

Novel data collection efforts: Applicants will be expected to assist with the development, beta-testing, and evaluation of novel methods of information collection for BD-STEPS (e.g., electronic consents and hard copy surveys).

Data reporting
Applicants are expected to collect, store, and transmit data in a standardized and secure manner with common elements mutually agreed upon by CDC and all recipients. On at least a weekly basis, applicants will transfer identifiable, individual-level data (including contact information) to the contract interviewer using the CDC-provided Secure Access Management Service (SAMS) or other secure transfer mechanism. On at least a monthly basis, applicants will be expected to transfer identifiable, individual-level clinical and demographic data (without contact information) from potentially eligible cases and controls to CDC using SAMS. This clinical and demographic data should conform to the structure and format of the CDC clinical database. Applicants are required, to the fullest extent possible, to also share these clinical and demographic data from potentially eligible cases with CDC and other applicants for review to determine eligibility, for standardized birth defect and/or stillbirth classification, and for the creation of a pooled analytic database. Applicants are expected to respond to additional clinical and classification-related data requests in a timely manner (e.g., within 2 months).

Applicants should be able to utilize MS Access and REDCap in conjunction with their existing birth defects and/or stillbirth surveillance infrastructure. During this funding period of BD-STEPS, beta testing of cloud-based systems for sharing these data will be required. Applicants should have flexible and scalable systems so they can adopt changing technologies for data collection (e.g., be able to utilize and/or integrate with a cloud-based system in conjunction with their existing birth defects and/or stillbirth surveillance infrastructure).

Any information on the reportable diseases will be transferred by the applicant to a central database at CDC. Online questionnaire data will be collected via a REDCap database hosted at CDC or a similar system. Applicants may be asked to enter hard copy responses into the REDCap database. CDC will manage the shared databases (tracking, analysis, biologic, data sharing) and interviewing, and provide any needed software applications.

Once data is in CDC's custody and control, it is subject to applicable federal law. As research, these data are also governed by a certificate of confidentiality under Section 301(d) of the Public Health Service Act. Availability of CBDRP data for public access is documented at NBDPS Public Access Procedures via http://www.cdc.gov/ncbddd/birthdefects/nbdps-public-access-procedures.html.

Data analysis, research, and training
Applicants are expected to work together and with CDC to compile data repositories and to conduct analyses to assess risk factors for birth defects and/or stillbirths. Centers will be required to assist with cleaning and processing of core and/or stillbirth interview data that were collected

by the contract interviewer and the pooled clinical datasets. All applicants will be provided access to the pooled BD-STEPS analytic data upon IRB approval and for use within the context of data sharing policies. Applicants may also have the opportunity to analyze NBDPS data. Data will be publicly available in accordance with applicable federal law. Applicants are expected to produce a number of manuscripts and presentations, as described in section II; these must conform to BD-STEPS data sharing policies and CDC policies. See Section VI.3. Copyright Interests Provision.

To further the birth defects and stillbirth prevention and research knowledge base among researchers, applicants will be expected to establish a training plan and employ junior researchers for training and mentoring such as Masters- and PhD-level students, post-doctoral fellows, medical students and residents, and other junior public health professionals. The training plan should address how junior researchers, through this mentoring, will gain skills in dysmorphology, birth defects epidemiology, stillbirth epidemiology, public health research, and/or other study-related skills. Senior scientists and mentors should limit their number of direct trainees (e.g., no more than four per primary mentor at a given time) to provide more effective training. Quality of training is more important than the quantity of trainees. Each center will be required to provide project/writing groups to assist junior researchers in learning about CBDRP-specific and more general birth defect and stillbirth research study design and methodologies. The training plan should also address how junior researchers can help the center meet the publication and presentation goals.

Project management
Unless prohibited, any participant mailings and standardized participant incentives as agreed upon by CDC and the other recipients are the responsibility of CDC. The applicants are expected to provide evidence of legal authority to access data needed to accomplish the activities required by this NOFO, including HIPAA and IRB requirements. The applicants should also provide evidence of legal authority to share identifiable, individual-level contact information with the interviewing contractor and individual-level data without names and addresses with CDC and the other NOFO recipients to create a pooled analytic database. For joint academic/state applications, applicants are expected to provide documentation of a planned meaningful collaboration between the state health department and the academic institution.

This NOFO utilizes a single IRB. The updated Common Rule requires single IRB approval of cooperative (i.e., multi-institutional) research conducted in the United States (https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf). The single IRB model is expected to be more efficient and require less personnel time and fewer resources than the previous model requiring review and approval from each institution's IRB. Compliance with this requirement started January 20, 2020. Each recipient's local IRB will be expected to defer to the CDC IRB unless 1) CDC determines and documents that use of a single IRB is not appropriate, or 2) the recipient is an institution that requires more than single IRB review by law (including tribal law). This policy does not relieve local study sites of their obligations to protect human subjects. If a center cannot defer to a single IRB, uniform study protocols and materials will need to be submitted to the local IRB without modification. If modifications are required by the local IRB, documentation needs to be provided to CDC to consider implementation study wide.

II. Activities Specific to Each Component

Component A (BD-STEPS Core): Component A supports the epidemiological and genetic **birth defect-related** research capabilities of BD-STEPS.

Data collection

Case ascertainment: Applicants are expected to use data from existing, funded, population-based, birth defects surveillance systems with active case ascertainment (defined at https://www.cdc.gov/ncbddd/birthdefects/surveillancemanual/facilitators-guide/module-3/mod3-3.html#Active) to timely identify all cases (either live born, stillborn, or induced abortions) diagnosed with any of the proposed eligible birth defects (Table 1) within one year of delivery. The applicant should be able to send 80% of the cases to the contract interviewer within 10 months after delivery. Funds from this NOFO cannot be used to support the core birth defects surveillance system but can be used to enhance the system (e.g., inclusion of prenatally diagnosed cases, improved timeliness). Applicants are expected to describe the existing active birth defects surveillance system, its attributes, its funding, and the geographical area the source population will encompass. This description should also include processes for quality control, including how multiple abstractions on the same case are synthesized and in what timeframe.

Additional information needed to determine case eligibility or classification will be abstracted from hospital records or vital records by the applicant. Applicants are to conduct clinical review for case confirmation.

Control ascertainment: The applicants will select a random sample of live births without major birth defects using hospital records or vital records from the same source population as the cases to serve as the comparison group (controls). These random samples are expected to include approximately 75-100 births for each study year at each study site. The applicant should be able to send 80% of the controls to the interviewer within 10 months after birth.

Consenting for Release of Newborn Bloodspots: Women who deliver a liveborn infant in BD-STEPS will be asked to consent for use of residual newborn bloodspots, if blood spots are retained in the state. Women with multiple gestation pregnancies (i.e., twins or higher order) will be asked to consent for use of residual newborn bloodspots for all their liveborn infants. The applicants will be expected to track consents (if required by state law) and, when applicable, request residual newborn bloodspots from the state health department for any liveborn infant that was part of the pregnancy, if the applicant is able to retrieve and store bloodspots linked to the study participant. Applicants will be expected to implement hard copy consents or e-consents, if it is allowed, for the newborn bloodspots.

Data reporting

Any residual newborn bloodspots that participants consent to release will be stored by the applicants at a local facility. Any genetic data will be transferred to a central database at CDC. CDC will manage the central lab, centralized biorepository, and shared biologic databases.

Data analysis, research, and training

Analytic projects can include epidemiologic analyses as well as genetic analyses performed at

local or external laboratories and funded through alternative funding sources.

Recipients should produce at least seven center-led manuscripts using pooled data during the funding period, with a goal of two per year. Recipients should produce at least seven center-led presentations using pooled data during the funding period, with a goal of two per year.

Project management
Staffing should include the following key personnel with sufficient time dedicated to the study: Principal Investigator, Project Manager, Data Manager (15% FTE minimum), Epidemiologist(s), Clinical Geneticist and Pediatric Cardiologist (each 5% FTE minimum). The initial eligibility reviews for congenital heart defects (CHDs) should be conducted by the Pediatric Cardiologist and for non-CHD birth defects by the Clinical Geneticist.

Table 1. Birth Defects included in BD-STEPS Core

Spina bifida without anencephaly
Microcephaly if combined with brain anomaly
Holoprosencephaly
Anophthalmia/microphthalmia
Cataracts, glaucoma
Posterior eye defects
Anotia/microtia
Transposition of the great arteries (TGA)
Tetralogy of Fallot
Truncus arteriosus
Pulmonary atresia
Tricuspid atresia
Coarctation of aorta
Hypoplastic left heart syndrome
Anomalous pulmonary venous return
Cleft lip +/- cleft palate
Cleft palate
Esophageal atresia
Arthrogryposis in 2 or more joints
Transverse limb deficiency
Diaphragmatic hernia
Gastroschisis

Component B (BD-STEPS Stillbirth): Component B supports the exploration of epidemiological risk factors for **stillbirths**. Component B applicants must apply for and receive concurrent Component A funding.

Data collection
Case ascertainment: Applicants are expected to use data from surveillance systems, fetal death records, and/or delivery records to timely identify pregnancies that ended in a stillbirth not ascertained as part of component A in their BD-STEPS catchment area -- either those with birth defects other than those ascertained in BD-STEPS or those without a birth defect. The applicant should be able to send 80% of the stillbirth cases to the contract interviewer within 10 months of delivery. Applicants are expected to use the same region that is being covered for Component A, BD-STEPS Core. A subset of funds (up to 25%) from this NOFO can be used to support the implementation and enhancement (e.g., improved timeliness) of population-based surveillance for stillbirths in the region covered in Component A.

Applicants are expected to describe the existing stillbirth surveillance system or plans to implement stillbirth surveillance, its attributes, its funding, and the geographical area the source population will encompass. This description should include processes for quality control, including how multiple abstractions on the same case are synthesized and in what timeframe, and the availability of and access to autopsy and placental pathology records.

Additional information needed to determine case eligibility or classification will be abstracted from hospital records or vital records by the applicant. Applicants are to conduct clinical review for case confirmation.

Control ascertainment: The controls selected for Component A, BD-STEPS Core, will also serve as controls for Component B.

Stillbirth-specific interviews: Women who experienced a stillbirth and mothers of controls will be invited to answer additional questions in a supplemental interview related to risk factors for stillbirth, such as sleeping position, and maternal disease and medication use throughout pregnancy. CDC, via a CDC interviewing contractor, is responsible for contacting women about their interest in participating and for conducting the interviews.

Data analysis, research, and training
Recipients should produce at least three center-led manuscripts using pooled data during the funding period, with a goal of one per year. Recipients should produce at least three center-led presentations using pooled data during the funding period, with a goal of one per year.

Project management
Staffing should include the following key personnel with sufficient time dedicated to the study: Principal Investigator, Project Manager, Epidemiologist(s), Clinical Specialist (e.g., OB/GYN, MFM, Perinatal Pathologist) for 5% FTE minimum.

Objectives/Outcomes
1. To identify and characterize pregnancies affected by specific birth defects (including live births, stillbirths, and, to the fullest extent possible, induced abortions) and/or stillbirth, and live births without major birth defects, in a timely manner.

2. To identify epidemiologic risk factors (e.g., medications, chronic and infectious diseases) for specific birth defects and stillbirths.

3. To identify genetic risk factors for birth defects through the use of residual newborn bloodspots from liveborn infants.

4. To characterize the impact of infections on birth defects and stillbirth through the use of state National Electronic Disease Surveillance System data on infectious diseases before and during pregnancy.

5. To better understand occupational factors associated with birth defects and stillbirths.

6. To evaluate existing, and develop and evaluate novel modes of information collection for BD-STEPS (e.g., e-consents, online questionnaires, hard copy questionnaires)

7. To improve health equity by increasing the understanding of the role of social determinants of health, along with other determinants of health (genetics, behavior, and physical influences) on the risk for birth defects and stillbirths.

8. To disseminate birth defect and stillbirth research findings via presentations and publications in order to facilitate translation into prevention messages.

9. To train the future generation of birth defects and stillbirth researchers.

OMB will apply; the current OMB (#0920-0010) approval will expire on 2/29/2023.

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Target Population

Component A: BD-STEPS Core - The target population is families with pregnancies recently affected by selected major birth defects in a defined geographic study area. There is no restriction on maternal age, except as required by any state laws.

Component B: BD-STEPS Stillbirth - The target population is families recently affected by stillbirths in a defined geographic study area. There is no restriction on maternal age, except as required by any state laws.

Research findings from both components are likely also to have broader impacts on women of childbearing potential, families contemplating pregnancy, public health care professionals, health care providers, and pregnant women. The goal for both components is to include a source population across all study sites that is diverse with regard to geography, racial/ethnic composition, socioeconomic status, and acculturation.

Collaboration/Partnerships

Applicants are expected to establish collaborations between state health departments, educational institutions, other recipients under this NOFO, and with the CDC. Ideally, BD-STEPS centers should be a meaningful collaboration between state health departments and academic institutions. When appropriate, centers should collaborate and coordinate across state agencies and clinical settings for data collection not only for the ascertainment of cases, but also for the ascertainment of reportable infectious diseases. Recipients should work with CDC, other

recipients, and a central interviewer to adhere to and implement standardized processes, methods, data collection, and other project activities.

Evaluation/Performance Measurement

Award recipients are expected to create an evaluation plan within six months after award start date that assesses fidelity to data collection protocols, examines key data collection operations indicators (e.g., timeliness), monitors data quality, assesses overall response rates, monitors timely access to data for processing, monitors progress on presentation and publication goals, and describe how the use of these data can inform system changes and research. A plan should also include how applicants can remediate any data problems or poor performance, and make improvements over time.

Evaluation plans will be refined in collaboration with CDC post-award.

Translation Plan

Applicants are expected to analyze data and publish findings from BD-STEPS and/or NBDPS. Study results are expected to be presented at national scientific conferences and published in the peer-reviewed literature for dissemination to key stakeholders in order to facilitate translation into prevention messages.

Component A recipients will be expected to provide a plan that includes analyses of BD-STEPS and/or NBDPS data:

a. Lead at least seven manuscripts using pooled data by the end of the 3.5-year project period, with the goal of two manuscripts using pooled data submitted for publication per year.
b. Give at least seven presentations (e.g., oral, poster) using pooled data by the end of the 3.5-year project period, with the goal of two presentations using pooled data per year.

Component B recipients will be expected to provide a plan that includes analyses of BD-STEPS and/or NBDPS data:

a. Lead at least three manuscripts using pooled data by the end of the 3.5-year project period, with the goal of one manuscript using pooled data submitted for publication per year.
b. Give at least three presentations (e.g., oral, poster) using pooled data by the end of the 3.5-year project period, with the goal of one presentation using pooled data per year.

A confidential abstract draft should be provided to CDC for each manuscript developed that was supported in part or whole by this NOFO. The draft should be submitted to CDC at the time the manuscript is accepted for publication.

3. Funding Strategy

Not Applicable.

Section II. Award Information

Funding Instrument Type:

CA (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:
$20,650,000
Component A: BD-STEPS Core estimated total funding per year is $5,300,000 with the average annual amount of $700,000 per award. Award Floor amount is $600,000 and Award Ceiling amount is $800,000. All cited amounts are the inclusive total of direct and indirect costs.

Component B: BD-STEPS Stillbirth estimated total funding per year is $600,000 with the average annual amount of $300,000 per award. Award Floor amount is $200,000 and Award Ceiling amount is $350,000. All cited amounts are the inclusive total of direct and indirect costs.

Anticipated Number of Awards:
9
Component A: BD-STEPS Core: CDC anticipates funding up to 9 awards with an average annual amount of $700,000 per award. Award Floor amount is $600,000 and Award Ceiling amount is $800,000. All cited amounts are the inclusive total of direct and indirect costs.

Component B: BD-STEPS Stillbirth: CDC anticipates funding up to 9 awards with an average annual amount of $300,000 per award. Award Floor amount is $200,000 and Award Ceiling amount is $350,000. All cited amounts are the inclusive total of direct and indirect costs.

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

Award Ceiling:
$800,000
Per Budget Period

Award Floor:
$200,000
Per Budget Period

Total Period of Performance Length:
3.5 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 (https://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.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

99 (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:

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 include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Additional Information on Eligibility

For an application to be considered, it must be responsive to the following information. If it is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirement.

Both Components A and B should have:

- A selected birth population and geographic study area that includes between 30,000 - 80,000 births annually.

- Access to state National Electronic Disease Surveillance Systems (NEDSS) for ascertainment of reportable infections is required.
- Legal authority to share identifiable, individual-level data with CDC and other recipients.

Component A Core should also have:

i. Legal access to a pre-existing, population-based, active birth defects surveillance system.
ii. Legal access to data sources to ascertain liveborn control infants.
iii. A funding amount request that is less than the ceiling of $800,000 (for Component A) as indicated in Section II. Award Information.

Component B Stillbirths should also have:

i. Legal access to data sources to ascertain stillbirths.
ii. Documentation of component A application (copy of face page).
iii. A funding amount request that is less than the ceiling of $350,000 (for Component B) as indicated in Section II. Award Information.

4. Justification for Less than Maximum Competition

Not Applicable.

5. Responsiveness

Both Components A and B should have evidence for these criteria presented in Appendix A of the application:

- **Documented evidence of a selected geographic study area with between 30,000 and 80,000 birth annually.** Applicants must provide evidence in the form of a letter from the applicant organization that includes:

1. The number of live births annually in the applicant's proposed BD-STEPS catchment area.
2. Documentation as to the source of the information on the number of live births.

The evidence should be placed in Appendix A of the application and labeled "Birth_Pop_Evidence."

- **Documented evidence of access to the state's NEDSS for ascertainment of reportable infections.** Applicants must provide evidence in the form of a letter from the appropriate unit(s) of the state health department. The letter should be on official letterhead and signed by an authority from the state health department that verifies the information. The letter should indicate that:

1. The applicant will be provided information from the state NEDSS to ascertain any of the tentative list of reportable conditions that affected the participants in the two years before or during pregnancy.
2. The applicant will have access to the system for purposes and duration of the activities in this NOFO.

The evidence should be placed in Appendix A of the application and labeled "NEDSS_Evidence."

Component A. BD-STEPS Core.
Evidence must also be presented that the applicant will have:

- **Documented evidence of access to and legal authority to share information from a birth defects surveillance system.** Applicants must provide evidence in the form of a letter from the state health department, other state organization, or private organization. The letter should be on official letterhead and signed by an authority that verifies the information. The letter should indicate that:

1. The applicant has access to the pre-existing, funded, population-based birth defects surveillance system with active case ascertainment (defined at https://www.cdc.gov/ncbddd/birthdefects/surveillancemanual/facilitators-guide/module-3/mod3-3.html#Active) that can provide data on all birth defects listed in Table 1 within one year of delivery.
2. The applicant will have the legal authority to share identifiable, individual-level contact information with the central interviewer and individual-level data without names and addresses with CDC and other applicants to create a pooled analytic database.
3. The applicant will have access to the system for purposes and duration of the activities in this NOFO.

The evidence should be placed in Appendix A of the application and labeled "BD_Surv_Evidence."

- **Documented evidence of access to and legal authority to share data on control infants.** The applicant must demonstrate access with a letter or other type of evidence from the state health department, other state organization, and/or private organization ensuring access. The evidence must indicate that:

1. The applicant has access to data source(s) necessary to ascertain liveborn control infants (i.e., vital records or birth hospital records) within one year of birth.
2. The applicant will have the legal authority to share identifiable, individual-level contact information with the central interviewer and individual-level data without names and addresses with CDC and other applicants to create a pooled analytic database.
3. The applicant will have access to the system for purposes and duration of the activities in this NOFO.

The evidence should be placed in Appendix A of the application and labeled "BD_Control_Evidence."

Component B. BD-STEPS Stillbirth.
Evidence must also be presented that the applicant will have:

- **Documented evidence of access to and legal authority to share data on stillbirths.** The applicant must demonstrate legal access, in the form of a letter, or other evidence from the state health department, other state organization, and/or private organization. The evidence must indicate that:

1. The applicant has access to data source(s) necessary to ascertain all pregnancies that end in stillbirth (from a surveillance system, vital records, and/or birth hospital records) within one year of delivery.
2. The applicant will have the legal authority to share identifiable, individual-level contact information with the central interviewer and individual-level data without names and addresses with CDC and other applicants to create a pooled analytic database.
3. The applicant will have access to the system for purposes and duration of the activities in this NOFO.

The evidence should be placed in Appendix A of the application and labeled "Stillbirth_Surv_Evidence."

If your application is incomplete or non-responsive to the special eligibility requirements, HHS/CDC will consider the application non-responsive, and it will not enter into the review process.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI replaced the Data Universal Numbering System (DUNS) and is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US Instructions for NSPA NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.
- 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 Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal 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 an 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 Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, 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.gov 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 SAM.gov and the SAM.gov Knowledge Base.

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 UEI 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 NOFO 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.

Only one application per institution (normally identified by having a unique UEI number) is allowed for each component for a potential of two applications per applicant. One application for Component A: BD-STEPS Core; and one optional additional application for Component B: BD-STEPS Stillbirths. Component B is optional. Component B recipients must apply for and receive concurrent Component A funding.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

To use ASSIST, applicants must visit https://public.era.nih.gov 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: http://grants.nih.gov/support/index.html

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages.

Application guides for FORMS-G application packages are posted to the How to Apply - Application Guide page.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide How to Apply - Application Guide 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.

Please use the form and instructions for SF424 (R&R) Form G.

3. Letter of Intent

Due Date for Letter Of Intent 12/06/2022

12/06/2022
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information it contains allows CDC staff to plan the review.

The letter should be sent to: Scientific Program Official, Alison Amoroso, researchnofo@cdc.gov. Please include the NOFO number in the subject line of the email.
Submit by the date listed above and in Part 1. Overview Information.

Prospective applicants are asked to submit a letter of intent for each component that includes the following information:

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

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 at How to Apply - Application Guide 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 at How to Apply - Application Guide 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).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

Other examples of DMPs may be found here: USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

Applicants must use FORMS-G application packages.

Application guides for FORMS-G application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) Form G.

RESEARCH PLAN NARRATIVE:

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: BD-STEPS Core, Component B: BD-STEPS Stillbirth). To be funded for Component B: BD-STEPS Stillbirth, applicants must also apply for and receive Component A: BD-STEPS Core 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, at a minimum, include the following items.

Component A: BD-STEPS Core

Background and significance

- Describe how the proposed birth defects research will improve or have an impact on population health.
- Describe the existing active birth defects surveillance system, its attributes, its funding, and the geographical area the source population will encompass.
- Provide the number of births and data source used to identify the proposed BD-STEPS catchment area, which should be between 30,000 and 80,000 births annually.
- Describe the diversity of the catchment area population with regard to racial/ethnic composition and other factors (e.g., socioeconomic status, acculturation).
- Describe ability of the birth defects surveillance program to actively ascertain the defects listed in Table 1 in a timely manner (within 1 year of birth), types of pregnancy outcomes ascertained (live birth, stillbirth, and/or terminations), and method of processes for quality control (including how multiple abstractions on the same case are synthesized and in what timeframe).

Methods

- Describe how a random sample of live births (between 75-100 per year) without major birth defects to serve as the comparison group (controls) will be identified from the same source population as the cases using hospital records or vital records.
- Describe plans to obtain available information from the National Electronic Disease Surveillance System (NEDSS) to ascertain reportable conditions that affected BD-STEPS participants in the two years before or during pregnancy.
- Describe plans to track consents (if required by state law) and, when feasible, request residual newborn bloodspots from the state health department for any liveborn infant that was part of the pregnancy (including multiple gestation pregnancies).
- Describe the planned process for the initial eligibility review for congenital heart defect (CHD) cases to be conducted by a Pediatric Cardiologist and for non-CHD birth defect cases by a Clinical Geneticist.
- Describe plans to improve the understanding of the role of social determinants on the risk for birth defects.

Data analysis and research

- Describe plans to monitor and address additional clinical and classification-related data requests in a timely manner.
- Provide a list of abstracts, presentations, publications, and specific examples of dissemination and translation of NBDPS or BD-STEPS data, or other birth defects-related research, within the past 3 years.
- Describe a training plan that at least: (i) prioritizes quality over quantity; (ii) encompasses plans to identify and mentor junior birth defects researchers; (iii) includes a description of plans for the project/writing group used to assist junior researchers in learning about CBDRP-specific and more general birth defect study design and methodologies, including the frequency of meetings, topics addressed, etc.; and (iv) addresses how junior researchers can help the center meet the publication and presentation goals.

Project management

- Provide a staffing and management plan that includes at least the following: Principal Investigator, Project Manager, Data Manager (15% FTE minimum), Epidemiologist(s), Clinical Geneticist and Pediatric Cardiologist (each 5% FTE minimum).
- Describe plans for maintaining project activities when staff vacancies occur.
- Document (with curriculum vitae) and describe experience and expertise of proposed staff, including ability to conduct the proposed study.
- Describe ability to implement e-consents for the requests for infectious disease data from state NEDSS and, if consent is required by state law, residual newborn bloodspots.
- Describe ability to send links to electronic surveys via email to interviewed participants requesting additional information via online surveys and ability to enter data from hardcopy versions of the online questionnaire from participants into the online database, if necessary.
- Describe ability to share identifiable, individual-level contact information with the central interviewer and individual-level data without names and addresses with CDC and other recipients of this cooperative agreement.

- Describe plans to ensure that data submitted will conform to the structure and format of the CDC database.
- Describe capacity and ability to assist with beta testing of cloud-based systems for sharing of data.
- Describe the timeline with specific activities and expected accomplishments for each year.

Component B: BD-STEPS Stillbirth

Background and significance

- Describe how the proposed stillbirth research will improve or have an impact on population health.
- Describe the stillbirth surveillance system, its attributes, its funding, and the geographical area it encompasses. Describe any plans to use funding from this NOFO to augment the current system. Describe availability of and access to autopsy and placental pathology records.
- Briefly describe the BD-STEPS stillbirth catchment area and indicate that it is the same as the Component A catchment.
- Describe ability of the stillbirth surveillance program to timely identify pregnancies that ended in a stillbirth not ascertained as part of component A (i.e., either those with birth defects other than those ascertained in BD-STEPS or those without a birth defect), and method of processes for quality control (including how multiple abstractions on the same case are synthesized and in what timeframe).

Methods

- Describe plans to obtain available information from the National Electronic Disease Surveillance System (NEDSS) to ascertain reportable conditions that affected BD-STEPS Component B participants in the two years before or during pregnancy.
- Describe plans to improve the understanding of the role of social determinants on the risk for stillbirth.

Data analysis and research

- Describe plans to monitor and address clinical and classification-related data requests in a timely manner.
- Provide a list of abstracts, presentations, publications, and specific examples of dissemination of stillbirth-related research (NBDPS, BD-STEPS, or other) within the past 3 years.
- Describe a training plan that at least: (i) prioritizes quality over quantity; (ii) encompasses plans to identify and mentor junior stillbirth researchers; (iii) includes a description of plans for the project/writing group used to assist junior researchers in learning about CBDRP-specific and more general stillbirth epidemiology and study design/methodology, including the frequency of meetings, topics addressed, etc.; and (iv) addresses how junior researchers can help the center meet the publication and presentation goals.

Project management

- Provide a staffing and management plan that includes at least the following: Principal Investigator, project manager (can be the same staff for both Component A and B), data manager at 15% effort (can be the same staff for both Component A and B), clinical specialist (e.g., obstetrician, maternal fetal medicine specialist, perinatal pathologist) at 5% effort (specific to Component B), and an epidemiologist (for Component A and B).
- Describe plans for maintaining project activities when staff vacancies occur.
- Document (with curriculum vitae) and describe experience and expertise of proposed staff, including ability to conduct the proposed study.
- Describe ability to implement e-consents from Component B participants for the requests for infectious disease data from state NEDSS.
- Describe ability to send links to electronic surveys via email to interviewed Component B participants requesting additional information via online surveys and ability to enter data from hardcopy versions of the online questionnaire from Component B participants into the online database, if necessary.
- Describe ability to share identifiable, individual-level contact information with the central interviewer and individual-level data without names and addresses with CDC and other recipients of this cooperative agreement.
- Describe plans to ensure that data submitted to the central interviewer and/or CDC will conform to the structure and format of the CDC database.
- Describe capacity and ability to assist with beta testing of cloud-based systems for sharing of data.
- Describe the timeline with specific activities and expected accomplishments for each year.

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 publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

As applicable, applicants can provide links to publications and other information in lieu of attaching PDF documents as required in the Eligibility and Responsiveness sections of this NOFO.

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 30 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 at .How to Apply - Application Guide.

Applicants must use FORMS-G application packages.

Application guides for FORMS-G application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) Form G.

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. Applicants will use a platform or system to submit applications.

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications 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 must be 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 01/17/2023

01/17/2023
Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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 and speak to your GMS.

All HHS/CDC awards are subject to the federal regulations, in 45 CFR Part 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.

Public Health Data:

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.

Data Management Plan:

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/additional-requirements/ar-25.html

Human Subjects:

Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

Reimbursement of pre-award cost is not allowed.

11. 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. 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 UEI.

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 Senior/Key Personnel (including any Program Directors/Principal Investigators (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.

It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.

The applicant organization must ensure that the UEI 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. BD-STEPS Core

- To what extent does the work address a scientific problem of importance to public health research and/or practice?
- To what extent will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?
- To what extent do disparities exist, within sub-populations, or defined geographical areas?

Component B. BD-STEPS Stillbirth

- To what extent does the work address a scientific problem of importance to public health research and/or practice?
- To what extent will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?
- To what extent do disparities exist, within sub-populations, or defined geographical areas?

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. BD-STEPS Core

- Is the PD/PI time on the project sufficient to support the PD/PI responsibility outlined in Section VI.4. Cooperative Agreement Terms and Conditions of Award?
- Is there evidence of past collaborations among key members of the proposed research team?
- Has previous research focused on birth defects resulted in high-quality outputs (as evidence by publications in high-impact journals) and contributed to improvements in public health practice and population health?
- Do the investigators adequately describe their collaborative working relationships with: (i) the team responsible for birth defects surveillance in their state health department; (ii) their vital records agency; and (iii) the team(s) responsible for reportable disease surveillance and newborn bloodspots, when available, in their state health department?

Component B. BD-STEPS Stillbirth

- Is the PD/PI time on the project sufficient to support the PD/PI responsibility outlined in Section VI.4. Cooperative Agreement Terms and Conditions of Award?
- Is there evidence of past collaborations among key members of the proposed research team?
- Have previous research focused on stillbirth resulted in high quality outputs (as evidence by publications in high impact journals) and contributed to improvements in public health practice and population health?
- Do the investigators adequately describe their collaborative working relationships with: (i) the team responsible for stillbirth surveillance; (ii) their vital records agency; and (iii) the team(s) responsible for reportable disease surveillance in their state health department?

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. BD-STEPS Core

- To what extent does the research plan address gaps in knowledge related to birth defects in the state?
- Does the applicant's plan adequately describe feasibility and/or address barriers to implementation of e-consents for the requests for infectious disease linkage and residual newborn bloodspots (if consent is required by state law)?

- Does the applicant's plan adequately demonstrate capacity and ability to beta test cloud-based systems, and the flexibility and scalability needed so they can adopt changing technologies for data collection?

Component B. BD-STEPS Stillbirth

- To what extent does the research plan address gaps in knowledge related to stillbirths in the state?
- Does the applicant's plan adequately describe feasibility and/or address barriers to implementation of e-consents for the requests for infectious disease linkage?
- Does the applicant's plan adequately demonstrate capacity and ability to beta test cloud-based systems, and the flexibility and scalability needed so they can adopt changing technologies for data collection?

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. BD-STEPS Core

- To what extent do the proposed methods build on previous experience with birth defects research and do they provide a high likelihood of success in identifying new risk factors? Is the timeline reasonable to complete the objectives of the project?
- To what extent does the applicant propose an operational plan or approach for case and control ascertainment, data collection (e.g., case and control demographic, clinical and contact information; state infectious disease data; residual newborn bloodspots; online questionnaire data), storage, sharing (with CDC, central interviewer, and/or other recipients), and linkage, and analysis that are likely to produce timely, high-quality results that also meet the case ascertainment and timeliness requirements of the project?
- To what extent are the roles and responsibilities for key personnel and their expertise and experience documented and do they appear reasonable and appropriate? Do the proposed staff include at least a project manager, data manager at 15% effort, clinical geneticist at 5% effort, pediatric cardiologist at 5% effort and epidemiologist?
- Is the applicant able to defer to a single IRB?
- Does the training plan include mentoring Masters- and PhD-level students, post-doctoral fellows, medical students and residents, and/or other junior public health professionals, and address how junior researchers can help the center meet the publication and presentation goals? How likely is the training plan to result in quality training as opposed to quantity of trainees, and improve skills in dysmorphology, birth defects epidemiology, and other study-related activities through this mentoring?

Component B. BD-STEPS Stillbirth

- To what extent do the proposed methods build on previous experience with stillbirth research and do they provide a high likelihood of success in identifying new modifiable risk factors? Is the timeline reasonable to complete the objectives of the project?
- To what extent does the applicant propose an operational plan or approach for stillbirth case ascertainment, data collection (e.g., case demographic, clinical and contact information; state infectious disease data; online questionnaire data), storage, sharing (with CDC, central interviewer, and/or other recipients), and linkage, and analysis that are likely to produce timely, high-quality results that also meet the case ascertainment and timeliness requirements of the project?
- To what extent does the applicant provide a reasonable and appropriate staffing plan including a description of staff contributions, roles, and time to BD-STEPS activities? Do the proposed staff include at least a project manager (can be the same staff for both Component A and B), data manager at 15% effort (can be the same staff for both Component A and B), clinical specialist (e.g., obstetrician, maternal fetal medicine specialist, perinatal pathologist) at 5% effort (specific to Component B), and an epidemiologist (for Component A and B)?
- To what extent do the BD-STEPS stillbirth activities appear to interface smoothly with the BD-STEPS Core activities?
- Does the training plan include mentoring Masters- and PhD-level students, post-doctoral fellows, medical students and residents, and/or other junior public health professionals, and address how junior researchers can help the center meet the publication and presentation goals? How likely is the training plan to result in quality training as opposed to quantity of trainees, and improve skills in stillbirth epidemiology, and other study-related activities through this mentoring?

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?

Component A. BD-STEPS Core

- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements such as a collaboration between an academic center and a health department?
- Is there evidence of sufficient existing support for the birth defects surveillance system and evidence from the state health department, other state organization, or private organization ensuring access for the purposes and duration of the activities in this NOFO to warrant timely and complete ascertainment of cases?
- Is there documented meaningful collaboration between the state health department and the applicant (if other than state health department)?

Component B. BD-STEPS Stillbirth

- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements such as a collaboration between an academic center and a health department?
- To what extent does the applicant document system capacity and readiness to support timely and complete ascertainment of stillbirth cases from the vital records system, including the availability of and access to autopsy and placental pathology records?
- Is there documented collaboration between the state health department and the applicant (if other than state health department)?

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/additional-requirements/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.

Not Applicable.

Applications from Foreign Organizations
N/A

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/additional-requirements/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.

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

Other examples of DMPs may be found here USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

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/application-resources.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.
- Racial/ethnic diversity of the proposed population for study.
- Higher annual number of live births.

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 with 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 45 CFR Part 75, subpart F, 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 UEI, 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).

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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: https://www.archives.gov/

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-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

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-36: Certificates of Confidentiality

AR-37: Prohibition on certain telecommunications and surveillance services or equipment for all awards issued on or after August 13, 2020.

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

To view brief descriptions of relevant CDC requirements visit: https://www.cdc.gov/grants/additionalrequirements/index.html

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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 applies 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 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/additional-requirements/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/additional-requirements/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 Part 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 recipients is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with

the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and HHS/CDC as defined below.

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

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access.
- Maintaining an adequate management and staffing plan and implementation to support all project activities.
- Assuring that the contact and clinical data are complete and submitted to CDC in a timely manner as indicated.
- Participating in the CBDRP Coordinating Council.
- Ensuring that all staff members are aware of the responsibilities associated with using data from NBDPS and BD-STEPS, and follow the data sharing guidelines.
- Assist in developing the research protocol.
- If not able to use a single IRB, submit the protocol for human subjects review.
- To the extent applicable, maintaining data consistent with Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d), as amended.

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

In this cooperative agreement, a NCBDDD Scientific Collaborator (SC) is a partner with scientific and programmatic involvement during the conduct of the project through technical assistance, advice, and coordination. For both Component A. BD-STEPS Core and Component B. BD-STEPS Stillbirth, the SC will:

- Use their experience in studies of this nature to advise the project on specific questions regarding the project.
- Provide scientific consultation and technical assistance in the development, implementation, and conduct of the evaluation.
- Assist in the development of the research protocol for CDC Institutional Review Board review and other required reviews and approvals, as needed.
- OMB/PRA requirements apply and CDC will obtain OMB approvals as required.
- Provide assistance on and participate in data analysis, interpretation, and reporting of findings in the literature.
- Participate in monthly, or more frequent, conference calls with recipient.

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

Component A. BD-STEPS Core

- Specifically, for this program, CDC will collaborate as a full center (e.g., providing cases and controls from Metropolitan Atlanta to the centralized tracking and clinical databases).
- Participate in all committees and work groups.
- Analyze data and prepare manuscripts.
- CDC will also provide technical assistance on clinical, epidemiological, and biological questions.
- Provide technical assistance and guidance on analysis, interpretation, and reporting of findings in the literature that can serve a broad range of scientific interests.
- Serve on the CBDRP Coordinating Council.
- Participate in designing, developing, and evaluating methodologies and approaches used for population-based birth defects surveillance and research.
- Participate in the collection, management, and analysis of data related to birth defects.
- Provide training and quality control exercises for use of the data from NBDPS and BD-STEPS, as well as guidance for potentially combining data from the two studies.
- For those centers that will be analyzing the DNA samples, CDC will coordinate the quality assurance/quality control exercises.
- Participate in the development, implementation, and conduct of the study protocol.
- Participate in the sharing of information between the participating CBDRPs (e.g., data sharing document formats, clinical, and biologic databases, potential research issues, etc.).
- Serve as a resource for sharing state, regional and national data and information pertinent to the surveillance, research, and prevention of birth defects.
- Manage the following activities: central lab and centralized biorepository; shared databases (tracking, analysis, biologic, data sharing); centralized interviewing; provide any needed software applications.

Component B. BD-STEPS Stillbirth

- CDC will provide technical assistance on clinical, epidemiological, and biological questions for stillbirth research.
- Provide technical assistance and guidance on analysis, interpretation, and reporting of findings in the literature that can serve a broad range of scientific interests.
- Participate in designing, developing, and evaluating methodologies and approaches used for population-based birth defects surveillance and research.
- Participate in the development, implementation, and conduct of the study protocol.
- Participate in the sharing of information between the participating CBDRPs (e.g., data sharing document formats, clinical databases, potential research issues, etc.).
- Serve as a resource for sharing state, regional and national data and information pertinent to the surveillance, research, and prevention of birth defects.
- Manage the following activities: shared databases (tracking, analysis, biologic, data sharing); and centralized interviewing and provide any needed software applications.

Areas of joint responsibility include:

- Finalizing the protocol and interview instrument.

- Membership of data sharing committee, clinician committee, and coordinating council.
- Participate fully in conference calls and other communication between CDC and other recipients.
- Use all of the agreed-upon methods and protocols including the clinical, tracking, biologic, and other database formats to input, maintain, and backup all data.
- Use generally accepted epidemiological methods to evaluate results.
- Publish the results in peer-reviewed journals.

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, and an HHS/CDC agency Scientific Program Official (SPO) will be responsible for the normal scientific and programmatic stewardship of the award. For Component A. BD-STEPS Core and Component B. BD-STEPS Stillbirth, 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.
- Assure assessment of the public health impact of the research conducted under this Notice Of Funding Opportunity and promote translation of promising practices, programs, interventions, and other results from the research.

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 submit:

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 (**Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after 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 contribute 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:

Not Applicable.

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the budget period. 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.

Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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 period of performance. 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).

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.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

7. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or

more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

“Foreign taxes” means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

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
Alison Amoroso
NCCDPHP/NCBDDD
Telephone: 770.488.1750

Inquiries: *Email all inquiries to*: **researchnofo@cdc.gov.** Please include the NOFO number (RFA-DD23-001) in the subject line.

Peer Review Contact
Katie Barrett
NCCDPHP/NCBDDD
Telephone: 404.718.7664
Email: ohi8@cdc.gov

Financial/Grants Management Contact(s)
TBD
CDC Office of Grants Services
Telephone: NNN-NNN-NNNN
Email: xxxx@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 of Federal Regulations.

This program is authorized under Sections 301 and 317C of the Public Health Service Act [42 U.S.C. 241, and 247b-4 as amended].