

Centers for Disease Control

National Center on Birth Defects and Developmental Disabilities Extramural Research Program Office

Coordinating Center for Research to Promote the Health of Children with Birth Defects and People with Developmental and Other Disabilities

RFA-DD-17-001

Application Due Date: 02/22/2017

Coordinating Center for Research to Promote the Health of Children with Birth Defects and People with Developmental and Other Disabilities

RFA-DD-17-001

TABLE OF CONTENTS

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

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

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

National Center on Birth Defects and Developmental Disabilities Extramural Research Program Office (NCBDDD ERPO)
National Center on Birth Defects and Developmental Disabilities (NCBDDD)

Funding Opportunity Announcement (FOA) Title

Coordinating Center for Research to Promote the Health of Children with Birth Defects and People with Developmental and Other Disabilities

Activity Code

Amendment 1. February 9, 2017.

- Appendix 2 "Questions from Potential Applicants and CDC Responses" added to Section VIII. "Other Information".

U19

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DD-17-001

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

93.073

Category of Funding Activity:

Health

FOA Purpose

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) seeks to develop an external coordinating center for research and dissemination of information that supports the Center's mission and advances scientific and research agenda by conducting research across a network of universities and other institutions of higher learning that specialize in birth defects, blood disorders, and developmental and other types of disability research.

Key Dates

Publication Date: **To receive notification of any changes to RFA-DD-17-001, 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: **01/20/2017**

Application Due Date: **02/22/2017**

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

Scientific Merit Review: **04/07/2017**

Secondary Review: **05/05/2017**

Estimated Start Date: **09/30/2017**

Expiration Date: **02/23/2017**

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

Required Application Instructions

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

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

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

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

Executive Summary

- **Purpose.** The National Center on Birth Defects and Developmental Disabilities (NCBDDD) seeks to develop an external coordinating center for research and dissemination of information that supports the Center's mission and advances its scientific and research agenda by conducting research across a network of universities and other institutions of higher learning that specialize in birth defects, blood disorders, developmental and other types of disability research.
- **Mechanism of Support. Cooperative Agreement**
- **Funds Available and Anticipated Number of Awards.** The estimated total level of funding (direct and indirect for entire project period in dollars) that is available for the FOA is $15,025,000. An Award issued under this FOA is contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. One award will be made.
- **Budget and Project Period.** The estimated total funding (direct and indirect) for the first budget period, 09/30/2017 through 09/29/2018, is $675,000 for one award. The estimated total funding (direct and indirect) for the entire project period, 09/30/2017 through 09/29/2022, is $15,025,000.
- **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 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 institution (normally identified by having a unique DUNS number) is allowed.
- **Application Type.** New.
- **Special Date(s).** N/A
- **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/funding/424/index.htm #inst
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

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

1. Background and Purpose

Created by the Children's Health Act of 2000, CDC's National Center on Birth Defects and Developmental Disabilities (NDBDDD) seeks to promote the health and well-being of babies, children, and adults by studying and addressing the causes of birth defects; helping children reach their potential by understanding developmental disabilities; reducing complications of blood disorders; and improving the health of people living with disabilities. In collaboration with our many national, state, local and professional organization partners, NCBDDD strives to identify the risk factors and causes of these conditions to enhance the potential for healthy and productive living for all. NCBDDD envisions a future where babies are born healthy. Children reach their potential. And everyone thrives.

Saving Babies through Birth Defects Prevention and Research

Major birth defects (BD) are conditions that cause structural changes in one or more parts of the body; are present at birth; and have a serious adverse effect on health, development, or functional ability. About 1:33 babies are born with a birth defect. Birth defects are a leading cause of infant death, accounting for more than one of every five infant deaths. In addition, babies born with birth defects have a greater chance of illness and long term disability than babies without birth defects.

Helping Children Reach Their Potentional by Understatnding Developmental Disabilities

Developmental disabilities are a diverse group of conditions that include mental and/or physical impairments. People with developmental disabilities have problems with major life activities such as communication, mobility, learning, and independent living. Developmental disabilities begin prior to 22 years of age and usually last throughout a person's lifetime. Autism Spectrum Disorders (ASDs), are a group of developmental disabilities that can cause significant social, communication, and behavioral challenges. CDC estimates that an average of 1:68 children in the United States (U.S.) have an ASD.

Additionally NCBDDD focuses on protecting people who are especially vulnerable to health risks, in particular young children. The early years of life (birth to 5 years of age) are critical to a child's cognitive, social, and emotional development. CDC works with partners to develop public health tools and interventions that give all children the opportunity to reach their full potential

Protecting People and Preventing Complications of Blood Disorders

Blood disorders, including bleeding and clotting disorders and hemoglobinpathies, such as sickle cell disease affects millions of people each year in the United States, cutting across the boundaries of age, race, sex, and socioeconomic status. Men, women, and children of all backgrounds live with the complications associated with these conditions, many of which are painful and potentially life-threatening. With proper preventive actions and early intervention, many of these disorders and their complications could, to a large extent, be eliminated. We are dedicated to reducing the public health burden resulting from these conditions by contributing to a better understanding of blood disorders and their complications; ensuring that prevention programs are developed, implemented, and evaluated; ensuring that information is accessible to consumers and health care providers; and encouraging action to improve the quality of life for people living with or affected by these conditions.

Improving the Health of People with Disabilities

People can acquire disabilities at any point throughout their life through injury, illness, chronic conditions and later-onset conditions. As a group, the 54 million adults in the U.S. living with disabilities experience worse health outcomes and quality of life than those without disabilities. Since the beginning, NCBDDD has provided sound science and program support for disability as a public health priority, striving for a balanced approach between primary prevention of disabilities and the prevention of secondary conditions. NCBDDD is committed to identifying and addressing the unique challenges to health experienced by people with disabilities across the lifespan.

Purpose

The purpose of this cooperative agreement award is to develop a central NCBDDD Coordinating Center to actively outreach and establish innovative partnerships with academic and other researchers to expand upon the scientific knowledge to promote the health and well-being of babies, children, and adults by studying and addressing the causes of birth defects; helping children reach their potential by understanding developmental disabilities; reducing complications of blood disorders; and improving the health of people living with disabilities.

Healthy People 2020 and other National Strategic Priorities

The applicable Healthy People 2020 goals and objectives:

Access to Health Services goal: Improve access to comprehensive, quality health care services.

Blood Disorders goal: Prevent illness and disability related to blood disorders and the use of blood products.

Disability and Health goal: Maximize health, prevent chronic disease, improve social and environmental living conditions, and promote full community participation, choice, health equity, and quality of life among individuals with disabilities of all ages.

Early and Middle Childhood goal: Document and track population-based measures of health and well-being for early and middle childhood populations over time in the United States.

Health Related Quality of Life and Well Being goal: Improve health-related quality of life and well-being for all individuals.

Hearing and Other Sensory or Communication Disorders goal: Reduce the prevalence and severity of disorders of hearing and balance; smell and taste; and voice, speech, and language.

Maternal, Infant, Child Health (MICH) objectives:

- Increase abstinence from alcohol, cigarettes, and illicit drugs among pregnant women
- Increase the proportion of women delivering a live birth who received preconception care services and practiced key recommended preconception health behaviors
- MICH Disability and Other Impairments: MICH objectives 25 through-29.5

- MICH Health Services: MICH objective 30.2, MICH objective 31, and MICH objective 32.

Social Determinants of Health goal: Create social and physical environments that promote good health for all.

Substance Abuse goal: Reduce substance abuse to protect the health, safety, and quality of life for all, especially children.

Tobacco Use goal: Reduce illness, disability, and death related to tobacco use and secondhand smoke exposure.

For further information on Health People 2020 please vist: https://www.healthypeople.gov/2020/topics-objectives

Public Health Impact

Accomplishing the objectives of this cooperative agreement will:

1. Enhance the conduct and coordination of important research by developing an organizational platform that can improve administrative efficiencies and focus research and programmatic efforts on critical NCBDDD priorities and populations;
2. Expand the use of scientifically valid health intervention and promotion strategies aimed at improving the well-being of children, youth, and adults with disabilities and their families; and
3. Improve communication and dissemination of scientific data aimed at improving the health of populations served by NCBDDD through the use of experts to stakeholders and other audiences.

Relevant Work

This cooperative agreement will build on the previous cooperative agreements, DD07-003 and DD12-006, by supporting the Center's mission and advancing it's scientific and research agenda.

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) through this Funding Opportunity Announcement (FOA) seeks to develop an external coordinating center for research, research translation and dissemination of information that supports the Center's mission and advances its scientific and research agenda. This mechanism has been very successful in advancing the research agenda of NCBDDD under previous cooperative agreements. Using the coordinating center strategy gives NCBDDD the flexibility, efficiency, and reach to conduct important research across a broad network of universities and other institutions of higher learning that specialize in birth defects, hereditary blood disorders, developmental and other types of disability research.

2. Approach

The purpose of this program is to strengthen the nation's capacity to carry out public health research in the areas of birth defects; complication of blood disorders; developmental disabilities; and improving the health of people living with disabilities across the lifespan. The activities will vary over the years of the award depending on funding, but the overall objectives are for one awardee to:

1. Establish a coordinating center for research;
2. Advance evidence-based practices and policies that promote the health and well-being of the populations served by NCBDDD;
3. Conduct research in support of NCBDDD priorities;
4. Communicate and disseminate information with and for stakeholders and other audiences; and
5. Evaluate and report on progress and findings.

During **Year One** of the award - the grant recipient will be expected to establish an organizational infrastructure, recruit and hire scientific and professional staffs and set processes and procedures in place to develop and conduct research activities. Given the focus on developing organizational capacities, the grantee

and its subrecipients will be expected to conduct a limited number of research projects. Projects proposed may begin in year one and can have a duration of no more than five years, based on the scope of the cooperative agreement. The project period of subsequent projects may not exceed the project period for the overall award.

During **Years Two through Five** of the award the grant recipient will be expected to have the infrastructure in place to accommodate the potential for additional research, translation and dissemination activities. In years two through five, the CDC will specify research project areas in the continuing application guidance and the grant recipient will forward all research proposals to the CDC to review, consider and select. In **Year Five,** new research projects will be limited to those that can be completed at the end of 12-months. At the conclusion of the 12-month period, the awardee will have up to 6-months to complete the analysis and submit the research findings.

Funding may vary dramatically from year to year, whether increasing or decreasing, based on the number, timeframe and scope of CDC activities to be funded as well as funding availability. CDC estimates between three to six new research projects per year, starting in Year Two. In years two through five new proposed research projects may be submitted as part of the non-competing continuation application using **(Appendix I)-Research Proposal Template.** CDC will use an external review process to assess the scientific merit of each new research proposal.

Objectives/Outcomes

Under this cooperative agreement, the funded coordinating center and its network of researchers will develop research proposals and projects in support of the initiatives and mandates of NCBDDD. Knowledge achieved through this FOA will be related to:

1) Improving surveillance and tracking systems that monitor incidence, prevalence and clinically meaningful information on birth defects, blood disorders, and developmental and other disabilities;

2) Expanding understanding of birth defects risk factors and causal pathways for birth defects, blood disorders, and developmental and other of disabilities.

3) Developing or improving methods of prevention or interventions to promote health and quality of life associated with disability or conditions resulting in disability; and

4) Improving dissemination that increases awareness and translational policy development in areas related to birth defects, blood disorders, and developmental or other disabilities, and improving health impact.

Objective 1: Establish a coordinating center for research, research translation and dissemination.

a) Identify and implement methods, guidance and infrastructure necessary to support public health research, research translation and dissemination of scientific information;

b) Develop and manage the process for evaluating research applications, including a rigorous review process to identify the most meritorious proposals aimed at accomplishing FOA objectives;

c) Oversee component projects conducted directly by the recipient organization and by sub-recipient organizations;

d) Develop and manage the process for tracking, reporting, and evaluating the progress of each research project at least quarterly; and

e) Assure that the coordinating center infrastructure supports all evaluation and monitoring activities.

Objective 2: Conduct and facilitate research in support of NCBDDD strategic priorities related to birth defects, blood disorders, and developmental and other types of disability research.

Through the development and support of a broad network of experts, address NCBDDD strategic priorities. The intent of the cooperative agreement is to have a disseminated network of researchers across the nation; therefore not more than 10% of the research project proposals can originate from the Coordinating

Center's organization. The research may include applied and public health research that develops and evaluates disability-related health promotion and disease intervention and control strategies that are community and population based. It can involve testing interventions for efficacy, effectiveness, or translational power; may focus on primary and secondary or tertiary risk factor research; or may provide insight and test strategies to improve health and prevent disease through approaches that involve changes to individual behavior, policy, or environmental structure, health systems, or socio-economic factors. Research may provide initial evidence of the efficacy or effectiveness of a health promotion or prevention strategy, raise current evidence to a higher level, or provide evidence of the effectiveness of a practice base strategy. It may also include etiological research if there is a clear gap in the knowledge about main determinants of birth defects, blood disorders, and developmental or other types of disability, or disease or conditions related to the disability. It may use the principles of community-based participatory research.

Year One research: The grantee and its sub-recipients will be expected to conduct not more than three research projects. Projects proposed may begin in year one and can have a duration of no more than five years, based on the scope of the cooperative agreement. Proposed projects for Year One should be submitted in the application using the Research Proposal Template in Appendix I. Project proposals should be included in Appendix B with a brief overview included for each in Research Strategy section.

Objective 3: Communicate and disseminate research opportunities and findings for stakeholders and other audiences.

a) Using a broad network of experts, stakeholders, and other partners, communicate and disseminate opportunities to conduct research and share research findings.

b) Identify data and information from the funded projects that supports potential policy that can be disseminated to inform and educate stakeholders.

c) Develop platforms to share research findings with stakeholders and other audiences, including in peer-reviewed journals.

Objective 4: Evaluate Coordinating Center and supported project activities

a) Develop a focused evaluation plan for the Coordinating Center and its supported project activities. That includes:

1. A logic model
2. Goals, objectives and activities that are specific, measurable, achievable, realistic and time-limited (SMART);
3. A description of mechanisms for engaging project researchers in evaluation activities;
4. Coordinating Center and supported project specific evaluation questions;
5. Evaluation methods; and
6. A description of how the evaluation results are intended to be used.

b) Track progress, outcome and the impact of funded projects, focusing on outcomes and stated goals; and

c) Report progress and outcome as part of regular communication with NCBDDD. Should the agency, consistent with grants regulations, wish to obtin copies or access to materials, data, or other research materials, the recipient or subrecipients should be able to readily produce said materials for the agency in a reasonable timeframe.

Target Population

1. Women of reproductive age and pregnant women;
2. Infants, children, youths and adults with birth defects, blood disorders, and developmental and other disabilities, including mobility impairments and intellectual and/or sensory disabilities;
3. Persons affiliated with organizations serving NCBDDD priority populations; and
4. Health care and public health practitioners.

Where appropriate, researchers within the coordinating center's network, selected to conduct research on behalf of NCBDDD programs, will be encouraged to include non-English speaking populations; lesbian, gay, bisexual, and transgender (LGBT) populations; people with limited health literacy, and/or other hard to reach traditionally underserved populations.

Collaboration/Partnerships

Applicants are expected to form or expand innovative partnerships between researchers to accomplish FOA objectives, including implementing and disseminating research findings resulting from this cooperative agreement. Where possible, applicants should provide letters of support from the proposed researchers as well as any other affiliated partners to indicate their full cooperation as members of the proposed research team. When applicable, this should include support for access to the data required for the evaluation or access to other data sources or populations needed to accomplish study objectives.y

Evaluation/Performance Measurement

Applicants are expected to develop a general use logic model clearly specifying domains of inputs, activities, outputs, and outcomes for activities related to this project; and develop and describe a realistic and focused evaluation plan that is aligned with the logic model for each proposed project. Applicants are expected to develop a plan to ensure that individual research projects selected for funding through the Coordinating Center develop individual evaluation plans and tracking methods that will measure process, outcome, and where feasible the impact of supported projects focusing on stated goals and objectives. These evaluation plans should describe the purpose of the evaluation, to include the objectives and activities, description of mechanism for engaging stakeholders in evaluation activities, evaluation methods, and a description of how evaluation results are intended to be used.

Translation Plan

Applicants are expected to develop a plan for research translation. This plan should include an approach to ensure that all research proposals submitted to the coordinating center include a proposed translation plan to communicate research findings to stakeholders and other appropriate audiences. The translation plan should address submission of draft manuscripts, research abstracts, key findings summary documents, data, and other relevant documents or products produced to communicate the research findings from each funded project.

The Coordinating Center is expected to work with its network of researchers to identify and use effective health communication and policy translation strategies that will raise awareness of public health practices that may lead to promising interventions, improved health outcomes, and reduced disparities amongst the populations served by NCBDDD.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

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

Application Types Allowed:

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

Estimated Total Funding: $15,025,000

Each year the awardee and CDC will establish a coordinated work plan that details the length and scope of each funded project with milestones that will serve as a guide for identifying and tracking projects and progress.

Budget Year	Infrastructure Budget	Approximate Number of Projects	Estimated Research Budget	Estimated Total Budget Ceiling
1	$225,000	3	$450,000	$675,000
2	$275,000	6-9	$1,650,000	$1,925,000
3	$275,000	9-12	$3,150,000	$3,425,000
4	$300,000	12-15	$4,650,000	$4,950,000
5	$300,000	12-15	$3,750,000	$4,050,000
			TOTAL	$15,025,000

Anticipated Number of Awards: 1

The estimated total funding (direct and indirect costs) for the first budget period is approximately $675,000 and the estimated total funding (direct and indirect) for the entire project period is $15,025,000**.**

It is anticipated that one award(s) will be made under this FOA DD17-001.

Funding may vary dramatically from year to year, whether increasing or decreasing; based on the number, timeframe and scope of CDC activities to be funded as well as funding availability.

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

Award Ceiling: $675,000 Per Budget Period

Award Floor: $225,000 Per Budget Period

Total Project Period Length: 5 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category: State governments
County governments
City or township governments

Special district governments
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses

Additional Eligibility Category:

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

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

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

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

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
Faith-based or Community-based Organizations
Regional Organizations
Foreign Organizations: a Foreign Organization is a public or private organization, whether non-profit or for-profit, located in a country other than the United States (U.S.) and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance.
Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

For this announcement, applicants may include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

- Applicant must have demonstrated public health research capacity.
- Applicant must have or establish a partner network to conduct public health research.
- Applicant must have the financial capability to rapidly award funding to sub-recipients with approved research projects.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

- To demonstrate existing public health research capacity, use the Research & Related Senior/Key Person Section of the SF424 (R&R) to describe the expertise of the PI and/or co-PI in conducting or managing the conduct of public health research projects within the last 5 years.
- To demonstrate access to the proposed partner network, the applicant must provide letters of support from existing or potential research partners.
- To demonstrate financial capability to rapidly award funding to sub-recipients, applicant must provide a letter from their finance officer assuring the applicant's ability to award sub-recipient funds within 30 days of approving a proposal.
- An application that exceeds the upper value of the specified dollar range will be considered non-responsive and will not receive further review.
- If your application is incomplete or non-responsive to the special eligibility requirement listed in this section, it will not enter into the review process.
- Applications with budgets exceeding the ceiling will not enter into the review process.

6. Required Registrations

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

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

annually, https://www.sam.gov/portal/SAM/#1.
- Grants.gov
- eRA Commons

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.
All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date**. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

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

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.
Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

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

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

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

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

the pending application.

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

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

2. Content and Form of Application Submission

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

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

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled "PHS398." Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from http://grants.nih.gov/grants/forms.htm

3. Letter of Intent

Due Date for Letter of Intent: **01/20/2017**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the potential review workload and plan the review.

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

Name of the Applicant

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Descriptive title of each proposed Year 1 research project (up to 3)

Name, address and telephone number of the PI for each research project

Names of other key personnel

Participating institutions

Number and title of this funding opportunity

The letter of intent should be sent to:

Natalie Darling

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-5740

Email: ndh6@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

1. Introduction to Application (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.

2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.

3. Research Strategy – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.

4. Inclusion Enrollment Report (Renewal and Revision applications ONLY)

5. Progress Report Publication List (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects

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

Other Research Plan Sections

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

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 (R&R) Application Guide unless otherwise specified in the FOA. All instructions in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf must be followed along with any additional instructions provided in the FOA.

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:

• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• 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
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified

Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Research Plan Applicant's research plan should address activities that will be conducted over the entire project period and should include the following items:

Year One research: The applicant will be expected to conduct not more than three research projects. Projects proposed may begin in year one and can have a duration of no more than five years, based on the scope of the cooperative agreement. Proposed projects for Year One should be submitted in the application using the Research Proposal Template in Appendix I. Project proposals should be included in appendix B with a brief overview included for each in Research Strategy section.

1. List research topics (title and PI) in the Research Strategy (the standard 25 pages) and

2. Provide research topic narratives in Appendix B, using a 6 page limit for each. Address specific requirements outlined in the FOA.

1) Establish a Coordinating Center for conducting research. Provide a description of how the coordination body of the network of research will operate, including a plan for reviewing and recommending potential research and programs in collaboration with NCBDDD. The plan should include:

a) Development of a process and mechanism to conduct effective and timely public health research review and model demonstrations in birth defects, developmental disabilities, blood disorders, and the prevention of secondary conditions among people who have a disability;

b) Describe the methods, guidance, and infrastructure necessary to support public health research. This may include office space, personnel, equipment, and other resources;

c) Describe the process for developing and managing the process for identification, solicitation, and evaluation of proposals, including a rigorous review process to identify the most meritorious proposals to accomplish FOA objectives;

d) Describe component projects conducted directly by the recipient organization, or by a sub-recipient as special projects;

e) Describe the process for tracking, reporting, and evaluation the progress of each research project at least annually;

f) Describe the approach for ensuring that all supported component projects are responsive to the public health mission of NCBDDD as it relates to birth defects, developmental disabilities, blood disorders, and reducing health disparities among people with disabilities across the life course;

g) Provide an organizational chart illustrating the applicant's internal structure, including reporting lines, and relationship with other partners or organizational members;

h) PD/PI and the planned percentage of time that will be devoted to the award. The PD/PI should be established expert in disabilities or birth defects with the leadership and institutional authority to direct the activities of the award. The qualification of the PD/PI should be documented in the form of previous experience developing and/or directing research and training, funding history, and publication in peer-reviewed journals or other reports;

i) Provide evidence of demonstrated partnerships and collaborations, to address the goals, objectives, and intent of the FOA. Examples of these partnerships or organizational memberships include partners with (1) state/territories/ or tribal authority; (2) professional organizations; (3) local public health agencies; (4) academic institutions (5) consumer organizations; (6) or other entities that can demonstrate public health research capacity that aligns with the objective of the FOA.

2) Conduct research in support of NCBDDD priorities related to birth defects, developmental disabilities, blood disorders, and improving health and reducing disparities in people living withith disabilities.

a) For each research project proposal, provide detailed and consistent instructions. Include:

i. Specific aims, including a description of the relationship of the research project to NCBDDD's mission and health priorities, Healthy People 2020 focus areas, CDC public health research agenda, and the needs of the community. Include a specific description of the research community if it differs from the partner community;

ii. Evidence of community and partner input and a description of how they will be engaged throughout the research process;

iii. A timeline for delivery; Information on the project team's experience in conducting research with the community in which the project will be implemented and experience in the research topics and methods;

iv. Provide a description of the qualifications of the PD/PI and the planned percentage of time they will devote to the award. The PD/PI should be an established researcher with the leadership and institutional authority to direct the activities of the award. The qualifications of the PD/PI should be

documented in the form of previous experience developing and/or directing research;

v. Provide a listing of key staff exclusive of the PD/PI who will be devoted to this activity. For each key personnel, describe their demonstrated knowledge, experience, and ability in the relevent area (e.g. population level surveillance, data management, analytical techniques) and subject matter expertise related to birth defects, developmental disabilities, blood disorders, and the prevention of secondary conditions among people who have a disability;

vi. Include the percentage of the time each person will devote to the research.

vii. Description of the study participants, including recruitment and retention strategies;

viii. Power calculations;

ix. Implementation timeline; and

x. Plans to report and disseminate research results and a description of community and partner involvement in planned dissemination.

b) For research related to identification, diagnosing, surveillance and tracking, additional information for each research plan should include:

i. A general description of possible approaches to be employed for identifying and assessing data sources related to the area;

ii. Describe how data sources and data elements may be selected. Include a rationale for selection of identification or tracking criteria;

iii. Describe the roles of key partners associate in the oversight and guidance of these surveillance related research activities, their qualifications, and evidence of their commitment and cooperation with areas of research (e.g., letters of collaboration, memoranda of understanding, and documentation of prior collaborations);

iv. Describe potential data success requirements for possible data sources (e.g., data use agreements (DUAs) or other data sharing mechanisms employed); evidence of existing partnerships or previous work with population-based data related to birth defects, developmental disabilities and blood disorders, or disparities associated with disabilities;

v. Evidence of sufficient instructional support (e.g., space, equipment, etc.) and a staffing plan and other resources that will enable the achievement of this objective with the project period;

vi. Describe the template for the overall analytic plan:

a. Specific measurable, time-framed sub-objectives for the funding period;

b. Benchmarks of adequate and timely progress;

vii. Provide a description of relationship(s) with the disability communities and also local and state health department agencies and other partners that may be relevant to the surveillance research.

c) For research related to increasing knowledge in areas of risk factors and causal pathways, additional information for each research plan should include:

i. A determinant (for hypothesis testing research on risk or causality of disease and conditions) or interventions (testing efficacy and effectiveness) approach that uses appropriate research designs such as:

a. Quantitative (e.g., observation, quasi-experimental, or experimental);

b. Qualitative (e.g., ethnographic, focus groups, in-depth interviews);

c . Mixed methods (e.g., combination of quantitative and qualitative);

ii. Documentation that any intervention research projects identify or modify an existing

evidence-based intervention for the implementation within a different setting (e.g., community-based rather than clinic-based) or population:

iii. The proposed intervention must be evidence-based in that it has undergone sufficient scientific evaluation to be proven efficacious or effective;

iv. Evidence of efficacy or effectiveness of the intervention and justify the intervention's relevance to the study population. Evidence of effectiveness can be found in a variety of of places, including;

a. Scientific evaluation in peer reviewed publication or quantitative or qualitative research.

b. Evaluation reports; Systematic reviews of literature; and description or survey research;

d) For an intervention research project that may identify or modify an existing practice-based intervention for implementation within or dissemination to a different setting (e.g., community-based rather than clinic- based) or population;

i. The proposed intervention must be a practice-based strategy that has undergone sufficient implementation to be proven acceptable by the community.

ii. Be sustainable due to evidence of appropriate partnerships and available resources; and

iii. Likely be effective (i.e., intervention initiation precedes minimal positive effect and change over time);

e) For a newly proposed intervention, provide a rationale for doing so and demonstrate that no applicable intervention exists;

i. Demonstrate that there is both a gap in the literature and a need for the intervention in the partner community; and

ii. Describe the design of the intervention and demonstrate that adoption of the intervention will be feasible for state or local agencies or community-based organizations in terms of cost and other practical limitations.

f) For research related to increasing knowledge in areas of health communication, policy translation and dissemination, additional information for each research plan should include:

i) Documentation that demonstrates expertise in communication and dissemination that includes:

a. An infrastructure/ inventory of resources and personnel to support communication and dissemination activities and a demonstrated ability to translate research activates and findings to different audiences.

b. Ability to develop and maintain a dedicated Website description of a focused and realistic coordinating center- wide communication plan that includes multi-year goals, objectives, and activities that integrates communication activities into research, training, evaluation, and community activities.

c. Demonstrated capacity and experience developing and disseminating materials to all stakeholders including communities, states, partners, professional organizations, and the scientific community; and

d. Evidence of experience communicating activities related to research projects through marketing materials and the media.

ii) Documentation that demonstrates evidence behind the intervention and that the results will include information and guidance for implementation of the intervention by other agencies,

organizations, or communities.

g) For investigator/ field initiated research, provide additional information, following appropriate guidelines for including additional information as needed from items a-d above:

i) Identification, diagnosing, surveillance and tracking;

ii) Increasing knowledge in areas of risk factors and causal pathways;

iii) Increasing knowledge in area of health commination, policy translation, and dissemination.

3) Communicate and disseminate intervention and other information with and for stakeholders and other audiences:

a) Describe an approach to convening research, policy, and programmatic issues:

i) Describe plans to convene annual meetings to share findings from research in progress among Coordinating Center researchers and NCBDDD;

ii) Describe processes for convening meetings with NCBDDD and national and state-level representatives of public health, medical, education, and other stakeholder organization to address policy issues, and describe the process for sharing results of policy meetings with participants and the broader range of stakeholders and others in the related field.

b) Describe how information about public health policy and legislation will be gathered for distribution to and use by stakeholders:

i) Describe plans for tracking and sharing information about federal and state legislation related to NCBDDD priorities, including birth defects, developmental disabilities, blood disorders, and the prevention of secondary conditions among people who have a disability.

ii) Identify potential stakeholder organizations that could be included in above.

4) Evaluate and report on findings.

a) Describe evaluation tracking methods that will measure process, outcome, and where feasible impact of supported programs focusing on stated goals and objectives.

i) Describe plans for collecting process and outcome data related to each major activity.

ii) Describe plans for reporting data and results related to each major activity.

b) Develop a general use logic model clearly specifying domains of inputs, activities, outputs, and outcomes for activities related to this project. Include a brief (two page maximum) narrative description of the logic model.

c) Develop and describe a realistic and focused evaluation plan that is aligned with the logic model for each proposed project that also describes the purpose of the evaluation. The evaluation plan should include:

i) Broad goals, objectives and activities.

ii) A description of mechanisms for engaging stakeholders in evaluation activities.

iii) Key local-level or activity-specific evaluation questions,

iv) Evaluation method

v) A description of how evaluation results are intended to be used.

Overall:

a) Provide current history and experience in addressing the major activities under this research

announcement. The application should incorporate an analysis of specific tasks performed; denote research conducted by the organization and/or by partners or organizational members; outline indication of oversight competencies; describe experience working with partner or organizational member to coordinate activities, conduct processes to solicit and review research proposals; and convey evidence of effective performance based on published reports of research and outcomes with cited broad public health applications. Describe experience conducting and coordinating research with (1) states and territories, (2) professionals working with state public health agencies and academic communities in the areas of birth defects, developmental disabilities, blood disorders, and the prevention of secondary conditions and health disparities among people who have a disability; and (3) consumers of these services.

b) Provide evidence of capacity to conduct research, identify and solicit strong competitive basic and applied research proposals from partners or organizational members, to implement efficient review, and to effectively manage and track the progress of the research.

c) Provide evidence of established processes and mechanisms to develop and conduct effective and timely public health research, review and model demonstrations in relation to birth defects, developmental disabilities, blood disorders, and the prevention of secondary conditions and health disparities among people who have a disability.

d) Describe the type of staffing required including the capacity to provide review of research proposals, conduct research, manage and track outcomes, support the Coordinating Center infrastructure, and provide core research capacity. There must be at least one full time person with scientific capacity and responsibility to plan, conduct, and coordinate research projects, review research proposals, and manage project activities.

e) Identify and describe qualifications and experience of key partners required in order to perform the research. Their roles should be clearly delineated within the context of each project. Partners should have demonstrated experience working with each other as well as NCBDDD's target populations and, where relevant, large data sets. In addition, for those projects involving interventions, partners should have experience in implementation and evaluation of interventions in community or population-based settings;

f) Describe timelines for accomplishing various activities proposed;

g) Describe infrastructure and work environment needed to accomplish proposed activities; and

h) Include travel to Atlanta, GA to conduct 2 site visits/reverse site visits.

6. Appendix

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

Year One research: The applicant will be expected to conduct not more than three research projects. Projects proposed may begin in year one and can have a duration of no more than five years, based on the scope of the cooperative agreement. Proposed projects for Year One should be submitted with the application using the Research Proposal Template in Appendix I. Project proposals should be included in appendix B with a brief overview included for each in Research Strategy section.

1) Provide research topic narratives in Appendix B using a 6 page limit for each. Address specific requirements outlined in FOA.

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

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 40 pages for all appendices.

8. Format for Attachments

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

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf.

9. Submission Dates & Times

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

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

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

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

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

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

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

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

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date.

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

application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, ***the applicant*** must:
1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
    a. If the status states "***rejected***," do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed. b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/22/2017**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions,and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
For more information on expanded authority and pre-award costs, go to:
http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf .
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants,cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.
Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Awardees 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: http://www.cdc.gov/grants/additionalrequirements/index.html for revised AR-25.

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained. Applicants are advised that any activities involving information collection (i.e., surveys, questionnaires, etc.) from 10 or more non-Federal individuals/entities are subject to OMB/PRA requirements and may require the CDC to coordinate an OMB Information Collection Clearance.
- Human Subjects Education Requirement documentation is provided for any new key personnel or other significant contributors involved in the design or conduct of research involving human subjects.
- Reimbursement of pre-award costs is not allowed.

12. Other Submission Requirements and Information

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**
Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.
For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_redirect.htm? id=11144).

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

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

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.
See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding_errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit_app.htm
Upon receipt, applications will be evaluated for completeness by the CDC 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?

- How will the research network be selected and established?
- How will the collaborators ensure that proposed research is addressing gaps in the science?

Investigator(s)

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

- Does the applicant show core research and program capacity and identify at least one full time person with scientific capacity and responsibility to plan and coordinate research projects, review of project proposals, and project activities.
- Does the staffing plan demonstrate the capacity to provide technical assistance, review proposals, conduct research, manage fellowships, track outcomes, support the center infrastructure, and provide core research capacity?
- Does the applicant demonstrate experience in professional training related to the field of health and disability?
- Does the applicant staffing plan demonstrate capacity to provide sufficient training capacity?

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?

- Will the application serve to advance evidence-based practice and policies that promote the health and well-being of children, youth, and adults with birth defects, developmental disabilities, blood disorders and those living with other disabilities and their families?
- Is the proposed research innovative and does it offer reasonable potential for concrete applications of interest and value to CDC?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Does the applicant provide evidence of organizational capacity and skills to conduct research and training, identify and solicit strong competitive basic and applied research proposals from partners or organizational members to implement efficient review of proposals, and the ability to effectively manage and track the progress and performance of research and training activities? Are provisions in place that respect and protect the rights of people participating ?

- Are NCBDDD target populations included in development and implementation of research that is consistent with the principles of community-based participatory research (CBPR)?
- Does the application propose to use evidence-based interventions of strategies in the program plan? Are appropriate research strategies or components scalable?
- For the evaluation plan, are the outputs identified and are the measures/metrics to assess outcomes included? Does the applicant describe how the results will be disseminated and ultimately used?
- Are the primary health topics of NCBDDDD's target populations included in development and implementation of research and training to increase availability and use of health promotion resources , tools and inclusion strategies?
- Does the applicant propose to decrease the prevalence of birth defects, blood disorders, and developmental and other disabilities?
- Does the applicant propose to improve sustainability of programmatic or policy improvements?
- Does the applicant demonstrate experience in successfully organizing large stakeholder meetings for policy development?
- For the evaluation plan, are outputs identified and are measures/metrics to assess outcomes included?

Environment

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

- Does the organizational chart reflect an appropriate leadership model and delegation of work activities to ensure an effective organization? Do the existing and planned partnerships described indicate the applicant can achieve the research, program, and training goals and objectives of this FOA?
- To what extent are the proposed partnerships and infrastructure in place to support the planned activities, to ensure timely startup and implementation of activities?
- Does the applicant have experience conducting research with (1) states and territories, (2) professionals working with state public health agencies and (3) academic communities in the areas of birth defects, blood disorders, and developmental and other disabilities, and (4) consumers of these services?

2. Additional Review Criteria

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

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 , the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential

benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (http://www.cdc.gov/grants/additionalrequirements/index.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 (http:// www.cdc.gov /maso Policy /Policy_women.pdf and http:// www.gpo.gov /fdsys /pkg /FR-1995-09-15 /pdf/95-22950.pdf #page=1) and the policy on the Inclusion of Persons Under 21 in Research (http:// www.cdc.gov /maso /Policy /policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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

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.

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: http://www.cdc.gov/grants/additionalrequirements/index.html
New additional requirement: CDC requires awardees 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 funding opportunity announcement 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:
• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• 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.
Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

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

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 only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.

- Will receive a written critique.

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

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

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

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Diversity in populations disproportionately impacted by birth defects, blood disorders, and developmental and other disabilities (e.g. racial and ethnic minorities or low socioeconomic status populations).
- Availability of funds.
- Relevance of the proposed project to program priorities.

Review of risk posed by applicants.

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

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Awardee 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 funding opportunity announcement.

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

(1) Financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

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

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).
Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA. Specific requirements that apply to this FOA are the following:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2010

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access –;new requirement

AR-26: National Historic Preservation Act of 1966

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

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

October 1, 2009

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

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

AR-32: FY 2015 Enacted General Provisions

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

AR-25: Data Management and Access

CDC requires awardees for projects that involve the collection or generation of data with federal funds to develop, submit and comply with a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award and, to the extent appropriate, provide access to and archiving/long-term preservation of collected or generated data.

Data Management Plan

Consistent with the terms of and activities expected under the funding opportunity announcement (FOA), awardees must develop and submit a DMP generally during the project planning phase, but in any event, prior to the initiation of generating or collecting public health data. Accordingly, the DMP may be evaluated during the application, study proposal, or project review process or during other times in the project period. For FOAs that involve already defined projects which include data collection or generation at the time of application, applications submitted without the required DMP may be deemed non-responsive for award. For FOAs where CDC specifies that submission of the DMP is deferred to a later period, funding restrictions may be imposed pending submission and evaluation of the DMP. For awards where data collection or generation activities may become necessary during the project period, DMPs will be required to be submitted and evaluated during the project period of the award. These DMPs also will be required to comply with this AR. In all instances described above, the reviewing officials have to approve an acceptable DMP. Costs associated with developing and implementing a DMP, including costs of sharing, archiving and long-term preservation, may be included in the budget submissions for grants and cooperative agreements.

A DMP for each collection and/or generation of public health data funded by this award should include the following information:

- 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 (see below for additional information about access);
- 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 (see below for additional information regarding archiving).

Access to and Archiving of the Data

Awardees whose terms of award do not include submitting data to CDC are expected to plan and prepare for access to and archiving/long-term preservation of collected and/or generated data within the funding period, as set forth below. The final version of a collected and/or generated data set intended for release or sharing

should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data which should be made accessible within a year of the end of a collection cycle. In addition, awardees should ensure the quality of data they make accessible and seek to provide the data in a nonproprietary format. Awardees who fail to release public health data in a timely fashion may be subject to procedures normally used to address lack of compliance consistent with applicable authorities, regulations, policies or terms of their award.

For public use de-identified (removal of sensitive identifiable or potentially identifiable information) datasets, an accompanying data dictionary, and other documentation relevant to use of the data set should be deposited in a sustainable repository to provide access to the data. Data that cannot be de-identified can be provided on request under a data-use agreement.

Awardees will be required to inform the appropriate CDC point-of-contact identified in the award via an update to their DMP of the location of the deposited data. The DMP is a living document that should be updated throughout the life cycle of data.

For data underlying scientific publication, awardee should make the data available coincident with publication of the paper, unless the data set is already available via a release or sharing mechanism. At a minimum, release of the data set should consist of a machine-readable version of the data tables shown in the paper.

Requirements set forth in this policy are not intended to conflict with or supersede applicable grants regulations related to agency access to awardee data and records.

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

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

Either refer to the current Releasing and Sharing Data Policy AR-25 here (http://www.cdc.gov/grants/additionalrequirements/index.html#ar25) and/or replace it on the PGO website with the Data Access and Management policy and add the link above as an AR.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http://www.plainlanguage.gov/plLaw/index.cfm.

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

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

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

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.
Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.
If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.
Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and

policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation. This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).
The AR-25 http://www.cdc.gov/grants/additionalrequirements/index.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

4. Cooperative Agreement Terms and Conditions

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

- Providing oversight of all management and administrative aspects of the project, including maintaining an adequate staffing plan to support project activities.
- Working collaboratively with CDC scientists and partners on aspects of study design and analysis, including enhancement to the study protocols, and conduct.
- Obtaining the appropriate Institutional Review Board (IRB) approvals for research involving human subjects.
- Participating in periodic conference calls or meetings with CDC staff, including budgeting travel funds for travel to Atlanta, GA to conduct 2 site visits.
- Assuring and maintaining confidentiality of all relevant data and documents.
- Developing and implementing a dissemination plan for all research findings and interim reports.
- Coordinating and conducting each element of the research objectives.

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

There are two separate CDC scientific roles: Scientific Collaborator (SC) and Scientific Program Officer (SPO). CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- In this cooperative agreement, the SCs are partners with scientific and programmatic involvement during the conduct of the project through technical assistance, advice, and coordination. SCs with appropriate scientific and programmatic background and skill sets will be available to provide support to the research, program, and training activities conducted by the awardee. The SCs will:
    - Use their experience in studies of this nature to advise the project on specific questions regarding the project, and provide information on NCBDDD strategic priorities.
    - Respond to inquiries regarding such areas as data management, data analysis, or other methodological issues.
    - Provide scientific consultation and technical assistance on questions related to epidemiology, statistical and power calculations, and data storage and tracking formats used in other CDC-sponsored research that could be advantageous to the project.
    - Advise on the project processes for analysis, interpretation, and reporting of findings in the

literature.
- Obtain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.
- Provide relevant research findings and public health recommendations related to the project.

Additionally, a CDC NCBDDD Project Officer or other CDC staff may provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above.

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

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

Areas of Joint Responsibility between the awardee and its subrecipients should include:

- Develop a coordinated work plan, milestones, and timeline at the beginning of each project year for work including material dissemination, methods development, and summary reports or publications.
- Develop a meeting forum between the Coordinating Center, its network, and CDC to discuss ways to efficiently coordinate and leverage study activities and best practices.
- Identify and recommend solutions to unexpected study problems.

5. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the HHS Grants Policy Statement.
A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.
Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over $25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

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

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

B. Content of Reports

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

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

- Research Aims: list each research aim/project

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
b) Leadership/Partnership: list project collaborations and describe the role of external partners.

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

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

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

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

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:

- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- 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:

- Human Subjects Education Requirement
- Additional Reporting Requirements: Provide certification, for any new key personnel or other significant contributors involved in the design or conduct of research involving human subjects, that they have completed an educational program in the protection of human subjects.

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.
CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.
Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).
FFR (SF 425) instructions for CDC grantees are now available at http:// grants.nih.gov/ grants/forms.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://era.nih.gov/registration_accounts.cfm
FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.
Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.
The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: http:// era.nih.gov/ commons /index.cfm.
3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how

they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.•
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.
- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

Section VII. Agency Contacts

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

Application Submission Contacts

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

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

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

Scientific/Research Contact(s)

Natalie Darling

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention (CDC)

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-5740

Email: ndh6@cdc.gov

Peer Review Contact(s)

Jaya Raman, Ph.D

Scientific Review Official

Extramural Research Program Operations and Services

CDC

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-6511

Email: kva@cdc.gov

Financial/Grants Management Contact(s)

Ferrinnia (Toni) Augustus-High

Grants Management Officer (GMO)
Office of Financial Resources/Office of Grants Solutions

CDC

2920 Brandywine Road, M/S E-09
Atlanta, GA 30341

Telephone: 770-488-2906
Email: wef9@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

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

This program is authorized under Sections 301 and 317 [C] of the Public Health Service Act, (42 U.S.C., Section 241, 243, 247b(k)(2) and 247b-4) as amended.

APPENDIX 1 – Research Proposal Template

Research Proposal Template and Instructions

Each research proposal must be in the format described in this document using the general instructions for preparing the proposal and the detailed instructions provided for each section.

GENERAL INSTRUCTIONS:

- **Single spaced; 12 point font**
- **Not more than six typed pages**
- **Allowable formatting – bold, italics, bulleted or numbered lists**
- **Bullets or Arabic numbers may be used for references**
- **Do not underline**
- **Do not use tables**

FORMAT AND SECTION DESCRIPTIONS:

a. Project Title- No more than 200 characters.

b. Name and contact information of Principal Investigator(s).

c. Anticipated duration of project and level of funding requested.

d. Project description and objectives – state the purpose and intent of the project. Include any pertinent background information that establishes the need for the research.

e. Research Plan and Project Activities – provide a Research Plan that includes (1) description of the study design and methods, (2) description of the study population, (3) recruitment plan, (4) a proposed timeline, (5) dissemination plan, and (6) evaluation measures. Within the Research Plan, describe the types of activities/methods that will be used to achieve the research objectives. Further, describe the potential public health impact of this research project.

f. OMB and IRB – describe involvement of human subjects in the research and the approaches that will be used to ensure protection of all subjects, include: (1) Risk to subjects, (2) Adequacy of protection against risks, (3) Potential benefits of the proposed research to the subjects and others, (4) Importance of the knowledge to be gained. Indicate if it is anticipated that any data collection efforts will require OMB clearance.

g. Data Security – describe any data collection, management and analysis or dissemination activities and indicate if they may result in the development of a new information system or use of an existing information system. If it is anticipated that an information system will be used, please describe where the system will reside and who will have access to it.

h. Supporting Documentation – provide letters of support from collaborating organizations. Submit the CV of the Principal Investigator.

Appendix 2 "Questions from Potential Applicants and CDC Responses"

Q1. For the proposal, are we to assume that we will NOT be performing any preliminary reviews of the applications?

The FOA is conflicting on this subject, as follows:
-Page 5 of 41, bottom: In years two through five, the CDC will specify research project areas in the continuing application guidance and the grant recipient will forward all research proposals to the CDC to review, consider and select.
-Page 20 of 41, top: d) Describe the type of staffing required including the capacity to provide review of research proposals,
-Page 24 of 41, top: Does the applicant show core research and program capacity and identify at least one full time person with scientific capacity and responsibility to plan and coordinate research projects, review of project proposals, and project activities.

A1. For the initial submission of applications, preliminary reviews of proposed research project topics would

not have to be reviewed by the applicant in their initial submission.

Applicants can submit up to three research topic areas with their initial application for review (Section 1., 2. Approach, under Objective 2 and Year One Research on page 11 of the FOA; and Section IV, 6. Appendix on page 24 of the FOA under Year one research); however, applicants should describe how they would review research proposals submitted through their network of researchers to identify the highest quality proposals for forwarding to CDC for full scientific peer review in years 2-5 of the cooperative agreement. Applicants should describe how they will conduct an initial review of the applications submitted per topic area and identify the highest quality proposals per topic area.

Q2. For this statement (bottom of Page 6 of 41), "…therefore not more than 10% of the research project proposals can originate from the Coordinating Center's organization," we have the following questions:
A) Is it correct to assume that this does not count the 3 proposals that may be submitted with the application for possible funding beginning in Year 1?

B) Does the 10% refer to dollars or number of projects, and does this mean only the Core staff of the Coordinating Center itself, or does it apply to the entire affiliated institution(s)?

A2. (a) Yes, the 10% does not apply to those 3 initial research proposals submitted with the initial application. In years 2-5, only 10% of the total number of new research topic areas being requested by NCBDDD to be advertised for proposals may originate from the Coordinating Center's home organization and any affiliated organizations.

(b) The 10% refers to the total number of new topic areas being proposed by NCBDDD each year for advertising through the coordinating center. This 10% number will apply to the funded institution.

Q3. In the instructions on Page 40 of 41, referring to Appendix 1 - Research Proposal Template, it says not to use Tables. That is an unusual requirement for a research proposal. Is this an error?

A3. No, this is not an error. Each research topic proposal submitted by the applicant should be in narrative form up to 6 pages long (Page 24 under section Appendix – Year one research).

Q4. We need some clarity on the Data Management Plan (DMP). We understand that we need to include one within the Resource Sharing Plan section of the PHS 398 (page 15 of 41 of the instructions); however, do we need to have a separate DMP for each of the 3 research project proposals?

A4. A separate data management plan (DMP) for each research proposal will be required when applying for funding.

Q5. If yes, can we include the 3 separate ones DMPs as sub-sections of the center-wide DMP in the overall Resource Sharing Plan or must we include one for each project within its 6-page limit? In Appendix 1 – Research Proposal Template (Page 40-41 of 41), there is no mention of a DMP.

A5. Yes, the applicant may include the three separate DMPs including the research project titles as sub-sections of the central DMP in the Resource Sharing Plan section. Or, the applicant can submit each DMP within each project as long as it is included and referenced in the proposal. Either preference, it's up to the grantee.