

Centers for Disease Control

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

Research Approaches to Improve the Care and Outcomes of People Living with Spina Bifida
RFA-DD-19-001
Application Due Date: 02/13/2019

_____ _____

Signature Date

Research Approaches to Improve the Care and Outcomes of People Living with Spina Bifida

RFA-DD-19-001

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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)

Notice of Funding Opportunity (NOFO) Title

Research Approaches to Improve the Care and Outcomes of People Living with Spina Bifida

Activity Code

Amendment 1. Section VIII. Other Information - Added Appendix A. Questions from Potential Applicants and CDC Responses

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DD-19-001

Assistance Listings (CFDA) Number(s)

93.315

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this funding opportunity is to identify health care and clinic practices that are associated with the best outcomes for people living with spina bifida (SB) and to communicate and encourage adoption of best practices by SB clinics including providing needed educational/informational resources for the SB patient and provider communities, health care professionals, families, and educators.

Component A: Expand the work of the Spina Bifida Collaborative Care Network (CCN) to identify and encourage rapid adoption of best practices based on available evidence for care for persons with SB.

Component B: The National Spina Bifida Patient Registry (NSBPR) will collect and improve data quality of longitudinal data on children and adults with SB in order to identify health care and clinic practices that are associated with the best outcomes for people living with SB.

Component C: Implement and evaluate the Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida (UMPIRE Protocol). This iterative protocol aims to manage the urinary system in infants and young children so that their initial normal kidney function is preserved as much as possible.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DD-19-001, 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:	**01/14/2019**
Application Due Date:	**02/13/2019**

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

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

Scientific Merit Review:	**04/10/2019**
Secondary Review:	**05/20/2019**
Estimated Start Date:	**09/01/2019**
Expiration Date:	**02/14/2019**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

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

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide

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

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

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

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

(See Part 2, Section IV, 7. Page Limitations).

Executive Summary

Purpose. The purpose of this funding opportunity is to identify health care and clinic practices that are associated with the best outcomes for people living with spina bifida (SB) and to communicate and encourage adoption of best practices by SB clinics including providing needed educational/informational resources for the SB patient and provider communities, health care professionals, families, and educators.

- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.**
- Component A: It is anticipated that one award will be made to a single recipient for up to $600,000 in FY 2019.
    - Component B: It is anticipated that up to fourteen awards will be made to up to fourteen recipients for up to $68,000 each in FY 2019.
    - Component C: It is anticipated that up to nine awards will be made to up to nine recipients for up to $20,500 each in FY 2019.

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

- **Budget and Project Period.** The estimated total funding for all components (direct and indirect) for the first budget period, 9/1/2019 - 8/31/2020, will be $1,736,5000. The estimated total funding for all components (direct and indirect) for the entire Project Period, 9/1/2019 - 8/31/2024, will be $10,025,000.
- **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, 1.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the

skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

- **Number of PDs/PIs.** Applications may include more than one PI; however, the first PI listed on the application will be the "contact PI" for all correspondence. 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 for each component.
- **Application Type.** New
- **Special Date(s).** CDC will conduct one conference call for prospective applicants on December 13, 2018 from 2:00 pm - 3:30 pm EST. The conference call number is 1-855-644-0229 and Conference ID: 5069266. This session will provide information about the NOFO and will answer questions pertinent to preparing applications in response to this NOFO.
- Application Materials. See Section IV.1 for application materials. Please note that Form D is to be used when downloading the application package. http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf%20
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

T*his program is authorized under Sections 301 and 317C of the Public Health Service Act, (42 USC Sections 241 and 247b-4), as amended.*

1. Background and Purpose

Background

An estimated 160,000 people in the United States are currently living with spina bifida (SB), making it the most common permanently disabling birth defect. The care of persons with SB is complex, involving different organ systems and, correspondingly, different clinical specialists. Many of those affected by SB receive specialty care in one of the estimated 96 SB multidisciplinary clinics in the U.S.

In 2005 and 2006, a number of organizations working with the Spina Bifida Association (SBA) undertook an assessment of current care in programs/clinics that serve people with SB. The objectives of the assessment were to:

- obtain a clearer overall description of SB clinics in the U.S.,
- gain understanding of clinic operations and services, and
- elicit information related to strengthening the quality of care provided in clinics.

This assessment identified variation across clinic programs and notable gaps between what programs considered essential services and the services that they were actually delivering. As a result of this assessment, the Professional Advisory Council of the SBA endorsed the concept of building a Collaborative Care Network (CCN) and the establishment of the National Spina Bifida Patient Registry so that care would become more uniform across clinics and best practices would be identified and disseminated. In 2008, the National Spina Bifida Patient Registry (NSBPR) was established as a cooperative agreement with nine SB clinics across the US. Since that time, CDC has continued cooperative agreements with clinics to collect, analyze and publish findings from longitudinal data, including clinical interventions and health outcomes for persons with some of the more severe types of SB including myelomeningocele. As of July 2018, 14 funded clinics and 10 self-funded clinics participate in the NSBPR, and 15 manuscripts [Thibadeau (2013), Sawin (2015), Schechter (2015), Kim (2015), Dicianno (2015), Freeman (2017), Routh (2017), Routh (2018), Routh (2016), Liu (2018), Wiener (2017), Wiener (2018), Kim (2018), Kim (2018), Alibi (2018)] have been published using NSBPR data. Nearly 9,000 persons with spina bifida are currently enrolled in the NSBPR, with approximately 20% recording two visits and over 50% recording 3-8 visits. The project has been overseen by a Coordinating Committee (CC) comprised of Principal Investigators at the participating clinics, and CDC staff and scientists; data use is overseen by the Committee on Science and Publications (CSP) comprised of investigators at the participating clinics and CDC staff and scientists. (*CSP Guidance available upon request*)

In 2014, nine NSBPR clinics were funded to establish and implement the "Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida" (UMPIRE Protocol). The UMPIRE Protocol was established to manage and evaluate the urinary system in infants and young children so as to preserve initial normal kidney function.

In 2014, the CCN was established. Its structure includes a network of both NSBPR and non-NSBPR SB clinics (healthcare providers), SBA chapters (persons with SB and families), and other care providers for persons with SB, and it is governed by a board of directors that includes representatives from these entities as well as SBA staff and medical directors. The CCN provides input for NSBPR research priorities and supports the adoption of best practices identified via the NSBPR and the UMPIRE Protocol. As part of this mission, the CCN recently revised and published the Spina Bifida Health Care Guidelines for adults and children with SB [SBA, 2018].

Future Needs

Over the years, the NSBPR and the UMPIRE protocol have made strides towards identifying best practices for people living with spina bifida, but much work is still needed. Most of the NSBPR publications so far have been based on descriptive data. While these descriptions of what to expect have provided important contributions, longitudinal data are necessary to identify healthcare practices that are associated with the best outcomes, and more years of NSBPR and UMPIRE protocol data collection are necessary to compile these longitudinal data. Another need is to explore/describe the clinic attributes not currently collected by the NSBPR that are associated with good health outcomes.

Although the CCN has established mechanisms for connecting persons with spina bifida and clinicians caring for persons with spina bifida to emerging information about SB care, communication of new findings and the guidance of research priorities are ongoing needs. The

CCN is a necessary conduit for continued connection to the communities utilizing updated information and providing feedback to the NSBPR and UMPIRE Protocol researchers.

In summary, the foundation has been laid and much good work has been produced from NSBPR, the UMPIRE protocol, and the CCN, but more longitudinal data and communication of research findings are needed to identify and share the best ways to care for persons with spina bifida.

Purpose

The purpose of this funding opportunity is to identify health care and clinic practices that are associated with the best outcomes for people living with spina bifida (SB) and to communicate and encourage adoption of best practices by SB clinics including providing needed educational/informational resources for the SB patient and provider communities, health care professionals, families, and educators.

Healthy People 2020 and other National Strategic Priorities

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) of CDC, within HHS, is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2020" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This NOFO addresses “Healthy People 2020” priority area(s):

1. Improve access to comprehensive, quality health care services.
    - AHS-6: Reduce the proportion of individuals who are unable to obtain or delay in obtaining necessary medical care, dental care, or prescription medicines
2. Promote the health and well-being of people with disabilities.
    - DH-4: (Developmental) Reduce the proportion of people with disabilities who report delays in receiving primary and periodic preventive care due to specific barriers

Public Health Impact

Individuals affected by SB can expect to live full lives both in terms of quality and duration. This NOFO is intended to provide health care professionals with a big-picture view of the health status of patients with SB aggregated across clinics, to support them in making informed decisions about implementing available interventions that yield the best outcomes in the many areas of health and living affected by SB. When the NSBPR began in 2008, there was no organized communication among the health care professionals involved with SB clinics in the US. The NSBPR and CCN now connect many of the SB clinics throughout the US, and the NSBPR currently collects information on SB care and outcomes at 24 clinics. The projects proposed in this NOFO will continue to identify health care and clinic practices that are associated with the best outcomes for people living with spina bifida (SB) and to communicate and encourage adoption of best practices by SB clinics including providing needed educational/informational resources for the SB patient and provider communities, health care professionals, families, and educators.

Relevant Work

CDC has a long history of support for research about SB, rare disorders and health outcomes; over this time, approaches and tools have been developed and refined that have benefited SB research efforts. SB clinic researchers worked together with technical support form CDC to develop the following tools:

- Forms for clinics to use when abstracting SB patient data (Available upon request)
- Committee of Science and Publication Guidelines for Data Use (Available upon request)
- A five year protocol "Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida" (UMPIRE Protocol) (Available upon request)
- Forms for abstracting SB patient data about urologic health (Available upon request)

In addition, one main focus of CDC's SB work has been disseminating research via peer-reviewed publications. To date, 15 manuscripts [Thibadeau (2013), Sawin (2015), Schechter (2015), Kim (2015), Dicianno (2015), Freeman (2017), Routh (2017), Routh (2018), Routh (2016), Liu (2018), Wiener (2017), Wiener (2018), Kim (2018), Kim (2018), Alibi (2018)] have been published in peer reviewed journals using and summarizing NSBPR and UMPIRE Protocol data.

2. Approach

There are three components to this NOFO with separate, but synergistic approaches, each contributing uniquely to the overall purpose to identify health care and clinic practices that are associated with the best outcomes for people living with spina bifida (SB), and to communicate and encourage adoption of best practices by SB clinics including providing needed educational/informational resources for the SB patient and provider communities:

Component A. Collaborative Care Network (CCN)

The CCN approach is to bridge the gap between SB research and practice through the following: enhance and expand communication to the target populations and promote the adoption of best practices; identify, communicate and support exploration of research gaps/priorities by collecting and providing NSBPR researchers with information about SB patient and clinician research priorities and research gaps – and supporting exploration efforts when gaps are identified (e.g., little knowledge on sudden and unexplained deaths in patients with SB); and by determining and promoting attributes of NSBPR clinics that are associated with the best patient outcomes. Applicants for Component A should be able to assess crosscutting SB research needs and priorities that span NSBPR and non-NSBPR clinics that serve SB patients, and broadly promote the adoption of best practices.

Component B. National Spina Bifida Patient Registry (NSBPR)

The approach of the NSBPR is to collect high-quality longitudinal data on children and adults with SB who receive care in specialized SB clinics. The longitudinal aspect of data collection is critical for the analytic value of the NSBPR. In addition, initial data analyses have indicated that there are some opportunities for data quality checks and improvement on data collection. This NOFO provides a new focus on expanding longitudinal data collection and incorporating data quality measures in standard activities. Eligible clinics are those with a census of 200 eligible patients, committed to approaching all diagnosed patients for inclusion in the NSBPR and to developing proposals or a research plan in one of the areas for which data are being collected.

Applicants for Component B can be new clinics or clinics that have previously participated in the NSBPR.

Component C: The "Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida" (UMPIRE Protocol)

The approach of this component is to implement and evaluate the UMPIRE Protocol (*UMPIRE Protocol available upon request)*. This iterative protocol aims to manage the urinary system in infants and young children with myelomeningocele so that their initial normal kidney function is preserved as much as possible as they age. As with component B, the longitudinal aspect of data collection is critical in that many of the important outcomes will be measurable in persons who have been enrolled in the protocol for more than five years.

Objectives/Outcomes

The three components will employ individual but connected objectives to achieve outcomes that utilize the above approaches.

Component A. Collaborative Care Network (CCN)

Objectives/Outcomes:

Enhance Communication to Target Populations and Promote the Adoption of Best Practices among Health Care Providers

- Maintain and update the CCN Communication list that includes SB healthcare clinics in the US, independent SB care providers, SBA chapters, and families/adults with SB
- Create and implement a plan for promoting and disseminating SB health care guidance [SBA, 2018] for children and adults with SB, health care providers in SB clinics, and providers outside of the clinic structure; plan will include updating educational materials to reflect updated guidance
- Widely disseminate new findings from NSBPR data
- Create an editorial/visual brand for the Network that reflects its public health purpose to bridge the gap between SB research and practice; this effort should include communication elements and potentially an evaluation of the current naming convention

Identify, Promote and Support Exploration of Research Gaps/Priorities

- Identify and promote research priorities for the NSBPR according to the needs of the affected population and, the gaps identified in the healthcare guidelines [SBA, 2018]
- Support continued exploration when knowledge gaps are identified, including supporting efforts to learn more about recently reported cases of sudden and unexplained death in patients with SB

Use Outcomes Data to Identify Best Clinic Practices

- Develop and implement a plan to identify attributes of SB NSBPR clinics with the best outcomes at a given patient age (e.g. bowel and bladder continence, no skin breakdown, community ambulation as identified by analyses of NSBPR data)

- The data collection plan will collect systems-level and qualitative information to complement the quantitative NSBPR data. The plan and tools should be developed in consultation with systems-level and qualitative research experts and should consider the US Cystic Fibrosis Foundation's clinical practice benchmarking project for research design and tool examples [Boyle, 2014]
- The investigator is responsible for defining the scope, methods, and design for the data collection, but the awardee may request assistance from CDC
- The plan to identify attributes of best performing clinics is encouraged, but not required, to consider an exploration of the use of care coordination in the clinic
- Promote the adoption of clinical characteristics associated with the best outcomes

Component B. National Spina Bifida Patient Registry (NSBPR) Collect longitudinal data on persons with SB

Objectives/Outcomes:

Collect longitudinal data on persons with SB

- For currently enrolled NSBPR participants, collect data at annual visits according to protocol and submit data via the SB Electronic Medical Record (EMR)
- Approach all eligible participants (NSBPR eligible SB diagnoses include myelomeningocele, meningocele, lipomyelomeningocele, fatty/thickened filum, split cord malformation, and terminal myelocystocele), and, for those whose consent is obtained, collect data according to protocol, and submit data via the SB Electronic Medical Record (EMR). *Note: previous NSBPR data collection forms are available upon request*
- Each year, collect minimal non-identifiable data (e.g. sex, race/ethnicity, insurance status) on eligible patients who did not enroll in the NSBPR to test for potential differences with the eligible patients who enrolled
- Participate in quarterly NSBPR Coordinating Committee (CC) meetings via phone and up to two in-person meeting yearly, and other meetings and committees as appropriate.
- Conduct data quality checks and report findings from these checks per guidance from the NSBPR CC and the NSBPR Committee for Science and Publication
- Data coordinator participates in abstractor training (no travel) per guidance from the NSBPR CC and Committee for Science and Publications
- During the 5-year study period, conduct at least one data linkage with the National Death Index to identify deaths among the participants who are lost to follow up, per guidance from the NSBPR CC and with technical assistance from CDC
- Participate in analysis of NSBPR data, sharing data via presentations and publications, evaluating the work of the project, and/or participating with other awardees on committees and work groups

Clinics can participate in other data collection efforts including:

- Examining the uptake of the soon-to-be-released SB care guidance by using the NSBPR to evaluate practice and potentially outcomes pre- and post-guidance release

    - Identify a small number of clinical care metrics in the NSBPR that can be used to measure quality of care provided to SB patients
- Collecting and entering additional information on NSBPR participants who are lost to follow up
- Linking existing medical administrative datasets and NSBPR to enhance information on NSBPR participants
- Collecting additional information from clinics about facility, personnel and specialist costs, for cost and cost-effectiveness analysis of operating a spina bifida clinic
- Participating and reporting outcomes in SB Electronic Medical Record (EMR) of the intervention to prevent skin breakdown
- Participating in optional modules for additional data collection and submitting via the SB Electronic Medical Record (EMR) the following and other topics as identified (optional modules may become part of SB EMR as determined by CDC in collaboration with the NSBPR CC and NSBPR Committee for Science and Publication):
    - Sleep disordered breathing
    - Quality of life
    - Neurosurgical repair of myelomeningocele
    - Developmental and learning assessments for participants
    - Other topics as identified

Component C. Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida (UMPIRE Protocol)

Objectives/Outcomes:

Implement and Evaluate the UMPIRE Protocol

- For currently enrolled UMPIRE Protocol participants, collect data according to protocol and submit data via the SB Electronic Medical Record (EMR)
- Create a plan for approaching all infants with myelomeningocele SB who are 3 months old or younger and will get their care at a participating site for at least 6 months and enrolling those for whom parental consent is obtained in the Urologic Management to Preserve Renal Function Protocol for Young Children with Spina Bifida (developed in the previous funding cycle)
- Each year, collect minimal non-identifiable data (e.g. sex, race/ethnicity, insurance status) on eligible patients who did not enroll in the UMPIRE Protocol to test for potential differences with the eligible patients who enrolled
- Clinics will implement the UMPIRE Protocol among UMPIRE Protocol Participants, and if the participant clinic deviates from the protocol (which is allowed), submit a description of the deviation and the reason for it to through the SB EMR.
- UMPIRE Protocol PIs will participate in quarterly project calls to discuss analysis and revision of the current protocol for newborn to age 5 years and extending the protocol for years 6-10 years for returning participants (when applicable)
- UMPIRE Protocol PIs will attend at least one in-person meeting annually
- PIs will provide input on how UMPIRE Protocol data are to be analyzed and what the analysis results mean to inform evaluation and potential revision of protocol

- Participate in data quality checks per guidance from the UMPIRE Protocol CC

Support standardization of documenting urology test results

- Continue to promote consistency in measures across sites and in the interpretation of urology test results and classification of renal function

Clinics can participate in other data collection efforts including:

- Link existing medical administrative datasets to enhance information on UMPIRE Protocol participants
- Complete cost-effectiveness analysis of UMPIRE Protocol administration

Target Population

Component A. Collaborative Care Network (CCN)

The target population for the CCN is SB providers, clinics, and SBA chapters in the US, as well as children and adults who are living with SB and their families.

Component B. National Spina Bifida Patient Registry (NSBPR)

The target population for the NSBPR is children and adults with an eligible SB diagnosis who attend any of the SB clinics participating in the NSBPR**.**

Component C. Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida (UMPIRE Protocol)

The target population for this component is infants/young children with myelomeningocele who attend an SB clinic participating in the implementation of the protocol.

Collaboration/Partnerships

The applicant is expected to maintain existing partnerships and establish new partnerships, as needed, to accomplish the goals of the NOFO. These partnerships include clinicians and clinician groups who treat patients with SB and seek to disseminate information relevant to individuals with SB and their families. Applicants who are awarded funds under this cooperative agreement are expected to collaborate with other awardees and CDC under this award.

Evaluation/Performance Measurement

Component A. Collaborative Care Network (CCN)

The applicant is is expected to collaborate with CDC to develop and implement an evaluation plan throughout the duration of the cooperative agreement. This plan will evaluate the main project elements:

- Enhance communication to target populations and promote the adoption of best

practices among health care providers
- Identify, communicate and support exploration of research gaps/priorities
- Use outcomes data to identify best clinic practices

The applicant should state in their application that they would participate as active members of the committee in planning the evaluation component and in all evaluation activities specified in the plan.

Component B. National Spina Bifida Patient Registry (NSBPR)

The applicant is expected to collaborate with the NSBPR CC and CDC in data quality evaluation throughout the project period. This collaboration includes participating in data quality activities determined by the NSBPR CC and CSP in collaboration with CDC, which requires (1) responding to monthly data quality queries; (2) participating in periodic assessments of data quality as determined by project PIs and CDC; and (3) participating in data quality improvement training exercises. The applicant should state in their application that they will actively participate in planning and implementing the evaluation of data quality and in all activities specified in the plan.

Component C. Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida (UMPIRE Protocol)

The applicant is expected to collaborate with the UMPIRE Protocol CC and CDC in data quality evaluation throughout the duration of the cooperative agreement. This collaboration includes participating in data quality improvement exercises as determined by the UMPIRE Protocol PIs and CDC, which requires (1) responding to quarterly data quality queries and updating database accordingly; and 2) participating in periodic assessments of data quality as determined by project PIs and CDC. The applicant should state in their application that they would actively participate with CDC in planning the evaluation and conducting all activities specified in the plan.

Translation Plan

Component A. Collaborative Care Network (CCN)

At a minimum, summaries of NSBPR findings should be shared with the sources of information; i.e., SB clinics, SBA chapters, adults with SB and relevant health care professionals, using the World Wide Web, social media, and meetings of participating partner organizations. This sharing is expected to include findings published from the other two components (the NSBPR and the UMPIRE Protocol) as well as healthcare guidelines [SBA, 2018]

Component B. National Spina Bifida Patient Registry (NSBPR)

Findings should be shared with study subjects and specialized researchers via professional meetings, publications in peer-reviewed journals, and with SB clinical centers directly via the

SB CCN.

Component C. Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida (UMPIRE Protocol)

Findings should be shared with SB clinics via the CCN, the corresponding professional societies, especially the Society of Pediatric Urology; and published in peer-reviewed journals.

OMB/PRA is not expected to apply; If an award under this NOFO changes the aim or scope that was previously reviewed, an updated Project Description form and OMB-PRA determination will be resubmitted.

References:

- Guidelines for the Care of People with Spina Bifida (SBA), October 2018: http://spinabifidaassociation.org/wp-content/uploads/2018/10/GFPWSB-Update-102518.pdf
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Section II. Award Information

Funding Instrument Type:	Cooperative Agreement A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist,

guide, coordinate, or participate in project activities.

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

Estimated Total Funding: $1,736,500
The estimated total funding for all components (direct and indirect costs) for the first budget period, 9/1/2019 - 8/31/2020, is $1,736,500.

- Component A: The estimated total funding for all components (direct and indirect costs) for the first budget period is up to $600,000 in FY 2019. Award Floor amount is $0 and Award Ceiling amount is $800,000.
- Component B: The estimated total funding for all components (direct and indirect costs) for the first budget period is up to $68,000 each in FY 2019. Award Floor amount is $0 and Award Ceiling amount is $70,000.
- Component C: The estimated total funding for all components (direct and indirect costs) for the first budget period is up to $20,500 each in FY 2019. Award Floor amount is $0 and Award Ceiling amount is $25,000.

The estimated total funding for all components (direct and indirect) for the entire project period, 9/1/2019 - 8/31/2024, is $10,025,000.

Anticipated Number of Awards: 24
Component A: It is anticipated that one award will be made to a single recipient.

Component B: It is anticipated that up to fourteen awards will be made to up to fourteen recipients.

Component C: It is anticipated that up to nine awards will be made to up to nine recipients.

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

Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications that qualify.

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

Award Ceiling: $800,000 Per Budget Period
Award Floor: $0 Per Budget Period
Total Period of Performance Length: 5 year(s)

Throughout the Period of Performance, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as

documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Eligibility Category:

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

For an applicant to be considered they must be responsive to the information here.

Component A. Collaborative Care Network (CCN)

- Applicant must demonstrate existing relationship and collaboration with SBA chapters and clinics across the US as shown by activities such as joint meetings, collaboration on projects, committee participation

Component B. National Spina Bifida Patient Registry (NSBPR)

- Applicant must have documented evidence of treatment of a minimum of 200 patients in 2017 or 2018 with NSBPR eligible diagnoses (myelomeningocele, meningocele, lipomyelomeningocele, fatty/thickened filum, split cord malformation, and terminal myelocystocele) as evidenced by the provision of a 2017 or 2018 patient census for the SB clinic that includes age, gender, race/ethnicity, and diagnosis
    - Note: more than one clinic (e.g. smaller clinics, pediatric/adult clinics) can join together as one NOFO applicant
- Applicant must demonstrate access to patients with SB and commitment to the collection of the data elements in the NSBPR as demonstrated by a letter of commitment from a representative of the participating clinic(s) to participate as described

Component C. Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida (UMPIRE Protocol)

- Applicant must see at least four infants up to 3 months old with spina bifida annually in the clinic as demonstrated by the provision of a clinic census that lists infants up to 3 months old treated at birth in the past 3 years, averaging 4 each year with a diagnosis of myelomeningocele
- Applicant must include a pediatric urologist as part of the research team

If your application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

If your application is incomplete or non-responsive to these requirements, it will not enter into the review process. Applications will be deemed unresponsive if the proposed budget is greater than the ceiling amounts of this NOFO.

Component A applicants must provide the following:

- Documentation of existing relationship with five or more SBA chapters and clinics across the US as evidenced by meeting minutes, letters of support, and reports of collaborative projects coordinated by the applicant
- Evidence of relationships with five or more health care professionals across the US that represent SB clinics and SB practices demonstrated by meeting minutes from an established functioning committee and/or letters of support from committee participants.

Component B applicants must provide the following:

- Documentation of number of patients by diagnosis in 2017 or 2018 indicating that at least 200 patients attended the clinic with one of the following diagnoses: myelomeningocele, meningocele, lipomyelomeningocele, fatty/thickened filum, split cord malformation, or terminal myelocystocele.
    - Note: more than one clinic (e.g. smaller clinics, pediatric/adult clinics) can join together as one NOFO applicant
- Documentation of access to patients with SB and to the collection of the data elements in the NSBPR as demonstrated by letters of commitment from a representative of the participating clinic(s) to participate as described

Component C applicants must provide the following:

- Evidence of treating at least four infants up to three months old with spina bifida annually in the clinic as demonstrated by the provision of a clinic census that lists infants up to three months old treated at birth in the past 3 years, averaging 4 each year with a diagnosis of myelomeningocele
- Applicant must include a pediatric urologist as part of the research team

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

Evidence of these Special Eligibility Requirements should be placed in Appendix A of the application.

6. Required Registrations

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

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

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

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

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

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

SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

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

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

9. Cost Sharing

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

10. Number of Applications

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

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

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application

Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.
When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

In conjunction with the SF424 (R&R) components, CDC grant 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. 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: **01/14/2019**

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

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

- Name of the Applicant
- Descriptive title of proposed research
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of other key personnel
- Participating institutions
- number, title of this NOFO, Component

The letter of intent should be sent to:

Marcella Law, MPH

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-5416

Email: mah7@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan.**

8. Consortium/Contractual Arrangements
9. Letters of Support
10. Resource Sharing Plan(s)
11. Authentication of Key Biological and/or Chemical Resources
12. Appendix

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• 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

The applicants research plan should address activities that will be conducted over the 5 year project period. The Research Plan narrative is comprised of components 2 and 3 above. NOTE: that the research Strategy is divided into three parts: 1) Significance, 2) Innovation, and 3) Approach.

The applicant's research plan should include the following items:

Component A. Collaborative Care Network (CCN)

- Provide specific descriptions and approaches to accomplish the objectives as defined in objective/outcome section (Enhance Communication to Target Populations and Promote the Adoption of Best Practices among Health Care Providers; Identify, Communicate and Support Exploration of Research Gaps/Priorities; Use Outcomes Data to Identify Best Clinic Practices) and the evaluation as defined in Evaluation/Performance Measurement section
- Include staffing plan that defines the roles, responsibilities and qualifications of each team member and the expected contributions of key/collaborative partners
- Provide plans for travelling one PI and one awardee from leadership team to two annual project review meetings (and other team members per grantee discretion)

- Provide detailed timeline including realistic and measurable milestones for proposed activities and include a budget linked to these activities and milestones
- Descriptions/approaches for accomplishing the goals, objectives and intent of this component should include the following:
    - Plans for utilizing existing partnership and relationships with research, clinical and professional organizations with similar goals of the CCN and evidence of these existing relationships/partnerships
    - Coordinated communication between SB clinics, SBA Chapters, and other interested entities and evidence of previous experience in these areas
    - Plans for utilizing established relationships with leaders of the SB professional community that include health care professionals that represent SB clinics and SB practice
    - Number of SB clinics and SBA Chapters with which communication has been established

Component B. National Spina Bifida Patient Registry (NSBPR)

- Describe the clinic or clinics (if combined for application); the array of services offered by disciplines such as urology, nursing, neurosurgery, orthopedics, physiatry, physical and occupational therapies, social work; and the process by which the services are offered and delivered to individuals affected by SB
- Describe the demography of the patient catchment area
- Describe the current patient population by diagnosis, race/ethnicity, gender, and age
- Describe the year-to-year return rate of patients in the spina bifida clinic with NSBPR eligible diagnoses (myelomeningocele, meningocele, lipomyelomeningocele, fatty/thickened filum, split cord malformation, and terminal myelocystocele) over a five year period
    - Provide a table that depicts year to year return. The table should include the following: number of SB patients seen in the clinic in 2017 or 2018, the number of SB patients in the clinic with two annual visit records, and the number of SB patients in your clinic with five annual visit records
- Describe previous experience, if any, with collecting longitudinal data on outcomes and interventions among persons with SB and/or other complex medical conditions
    - Provide a table that includes the following: brief description of the data collection, number of years of data collection, publication citations and other data use
- Describe previous experience, if any, with collecting data for the NSBPR and entering into SB Electronic Medical Record (EMR)
    - Provide a table that includes the following: brief description of the data collection, number of years of data collection, number of NSBPR patients currently enrolled by age, publication citations and other data use
- Describe the approach to manage encounters with all patients that are eligible for the NSBPR, including the collection of basic demographic and clinical data on those patients approached who declined to participate
- Describe proposed approach to collect, manage, and address quality control of NSBPR data

- Provide a staffing plan that defines the roles, responsibilities and qualifications of each member of the team and expected contributions of key/collaborative partners
- Provide plans for linking persons who are lost to follow up with the National Death Index one time during the project period
- Provide detailed timeline including realistic and measurable milestones for proposed project activities and a budget linked to these activities and milestones
- Provide plans for travelling one PI to up to two annual project review meetings (and other team members per grantee discretion)
- Provide plans for analyzing data, sharing data via presentations and publications, evaluating the work of the project, and/or participating with other awardees on committees and work groups

Component C. Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida (UMPIRE Protocol)

- Describe the process by which newborns and children up to age 10 years who are affected by myelomeningocele are managed in the clinic, including how missed visits are handled in clinic
- If applicable, describe the UMPIRE Protocol patient population (patients, newborn to age 10 years in the clinic with a diagnosis of myelomeningocele) by race/ethnicity and gender
- Describe the year-to-year return rate of infants and children <= 3 months to 10 years of age in the spina bifida clinic with a diagnosis of myelomeningocele over a ten year period
    - Provide a table that depicts year to-year return. The table should include the number of infants < =3 months old with myelomeningocele seen in the clinic in 2017 or 2018, the number children 0-5 years with myelomeningocele in the clinic with two annual visit records, the number children 0-5 years with myelomeningocele in your clinic with five annual visit records, and the number of children 6-10 years with eight or more annual visit records
- Describe the approach to the collection, management, quality control and analysis of UMPIRE Protocol data
- Describe previous experience, if any, with collecting longitudinal data on urologic outcomes
    - Provide a table that includes the number of years of data collection, publication citations, and other data use
- Describe previous experience, if any, with collecting data for the UMPIRE Protocol and entering into SB Electronic Medical Record (EMR)
    - Provide a table that includes the number of years of data collection, number of patients currently enrolled in the UMPIRE Protocol by age, publication citations, and other data use
- Provide a staffing plan that defines the roles, responsibilities and qualifications of each team member and expected contributions of key/collaborative partners
- Provide plans for travelling one PI to up to two annual project review meetings (and other team members per grantee discretion)
- Describe the role, responsibilities and time commitment for the pediatric urologist

dedicated to this project

- Provide detailed 5-year timeline including realistic and measurable milestones for proposed activities and a budget that is linked to these activities and milestones
- Provide plans for data analysis, the sharing of data via presentations and publications, the evaluation of the work of the project, and/or participation with other awardees on committees and work groups

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.
CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf.

9. Submission Dates & Times

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

ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.
Applicants are able to access, view, and track the status of their applications in the eRA Commons.
Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.
Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).
Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week (closed on federal holidays)
If the applicant encounters problems that prevent the ability to submit an application which cannot be resolved by Grants.gov or NIH eRA Service Desks, then applicants must contact CDC Technical Information Management Section (TIMS) at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date. Therefore, it is important that applicants complete the application submission process well in advance of the due date time.
After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

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

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

    a. If the status states "**rejected**", do #2a or #2b

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

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

possible.

Due Date for Applications: **02/13/2019**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

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

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained.

- Human Subjects Education Requirement documentation is provided for any new key personnel or other significant contributors involved in the design or conduct or research involving human subjects.

This NOFO was determined to not require OMB-PRA approval. If an award under this NOFO changes the aim or scope that was previously reviewed, an updated Project Description form and OMB-PRA determination will be resubmitted.

Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individual/entities are subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to coordinate an OMB/PRA approval request).

Reimbursement of pre-award costs is not allowed. All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf or speak with your Grants Management Specialist (GMS).

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

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

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

Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders:

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

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

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications:

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

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

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or

clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Component A

- What are the numbers of SB clinics and SBA Chapters with with which communication has already been established

Components A, B and C

- Does the project address an important problem related to the health and participation of people with spina bifida?
- What is the potential impact of this work on the health of the population living with SB?
- Does the clinic or organization have a demonstrated record of being a leader/influencer in the field of spina bifida research and/or communication?

Component B and C

- Does the project provide plans for analyzing data, sharing data via presentations and publications, evaluating the work of the project, and/or participating with other awardees on committees and work groups?

Investigator(s)

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

Component A

- Does the PI have a record of accomplishment working with SB clinics across the US, SBA chapters across the US, and the population living with SB?
- Does the team have experience creating and maintaining up to date information and educational resources for both lay and professional members of the SB community?
- Does the communication experience include internet resources, social media, and print resources and/or organizing and facilitating meetings?

Component B

- Does the investigator demonstrate ability and previous experience with collecting and using/analyzing longitudinal data (including publications, if applicable) on outcomes and interventions among persons with SB? Does the SB investigator have previous experience collecting and using/analyzing data for the NSBPR including history of enrollment of persons in the NSBPR?

- Does the PI have a record of research that has advanced the field of SB clinical care?
- Has the applicant demonstrated committed relationships with relevant specialists who will provide access to patients with SB and to the collection of data for the NSBPR?

Component C

- Does the clinic demonstrate ability and previous experience with collecting and using/analyzing longitudinal data (including publications, if applicable) on urologic outcomes of patients with spina bifida? Previous experience with collecting and using/analyzing data from the UMPIRE Protocol including history of enrolling UMPIRE Protocol patients?
- Is the pediatric urologist closely involved in the initial (hospital) care when the affected newborn presents at the hospital?
- Does the Principal Investigator have a record of research that has advanced the management of clinical aspects of SB?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Component A, B and C

- Does the project have the potential to improve the clinical care of people affected by SB?
- Does the applicant identify innovative partners with whom to collaborate?

Component A

- Is the approach to identify and establish effective communication mechanisms with adults with SB innovative yet practical with likelihood of success?
- Is the approach to identify collaboration opportunities between SBA chapters and SB clinics innovative and practical?
- Does the applicant provide evidence of previous innovative approaches to communication and promotion of best practices among health care providers and/or other Component A project objectives?

Component B

- Does the applicant demonstrate innovative ideas/approaches for analyzing data, sharing data via presentations and publications, and/or evaluating the work of the project?

Component C

- Does the project have the potential to increase efficiency or lead to cost savings in the care of patients with SB?

Approach

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

Component A, B and C

- Are outputs identified and are measures/metrics to assess outcomes included?

Component A

- Does the plan address the three objectives: Enhance Communication to Target Populations and Promote the Adoption of Best Practices among Health Care Providers; Identify, Communicate and Support Exploration of Research Gaps/Priorities; Use Outcomes Data to Identify Best Clinic Practices
- Do the communication plans include stakeholders and describe approaches and audiences?

Component B

- Does the applicant adequately demonstrate successful collection of longitudinal data on outcome and interventions among persons with SB?
- Is the clinic structure multidisciplinary with at least two relevant disciplines represented at each clinic or does the applicant provide documentation of commitment by relevant disciplines to treat patients with SB and to the collect NSBPR data elements?
- Does the applicant provide documentation of a sufficient number of NSBPR eligible patients?
- Does the applicant demonstrate previous success with collecting data and enrolling persons in the NSBPR protocol?

Component C

- Does the applicant demonstrate previous success with collecting data and enrolling persons in the UMPIRE protocol?

Component B and C

- Does the applicant demonstrate a high rate of annual return visits within the patient

population at the spina bifida clinic?
- Does the plan to approach all eligible participants look adequate, including a plan to provide demographic data on those who declined?
- Is the plan to report and share findings realistic?
- Are plans to include quality control measures throughout the project period enumerated?

Environment

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

Component A, B and C:

- Does the project utilize critical partnerships or collaborations? Does the project support key stakeholder involvement throughout the research process?

Component B

- Does the population of patients in the clinic include a diversity of ages?

Component B and C

- Does the clinic have partnerships in place to support data collection and has the clinic previously worked together with partners to support data collection?
- Does the clinic demonstrate a level of commitment to support data collection?
- Does the population of the clinic represent diversity of race/ethnicity?
- Does the clinic provide evidence of consecutive years of clinic visits for patients with eligible diagnoses?

2. Additional Review Criteria

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

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the

justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (https://www.cdc.gov/grants/additionalrequirements/ar-1.html).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following 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 (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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

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

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

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

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: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

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

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

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

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

• 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
The budget can include both direct costs and indirect costs as allowed.
Indirect costs could include the cost of collecting, managing, sharing and preserving data.
Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.
If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.
As part of the scientific peer review, all applications:

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

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

Component B and Component C

- Diversity in the geographic distribution of sites across the US

- Availability of previously collected longitudinal data to enhance NSBPR and/or UMPIRE pooled data
- Diversity in clinic populations – racial/ethnic diversity and range of ages (pediatric and adult)

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

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

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

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

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

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

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 NOFO.

Specific requirements that apply to this NOFO 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: Research Definition

AR-32: Appropriations Act, General Provisions

AR-36: ; Certificates of Confidentiality

ARs applicable to Conference Awards:

AR-20: Conference Support

AR-27: Conference Disclaimer and Use of Logos

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

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 (NOFO), 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 NOFOs 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 NOFOs 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).

<u>Access to and Archiving of the Data</u>

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/grants/additionalrequirements/index.html#ui-id-17

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 NOFO:

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

Federal Funding Accountability and Transparency Act of 2006 Federal Funding

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

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

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

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

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs

without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

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

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

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

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

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

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

The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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

4. Cooperative Agreement Terms and Conditions

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

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

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

- Assuring and maintaining confidentiality of all relevant data and documents
- Ensuring that the research protocol complies with the terms and conditions of human subjects protection and preparing and coordinating the submission of the protocol(s) to the grantee's IRB(s) if needed (grantee is responsible for obtaining IRB approval for all collaborators)
- Maintaining an adequate management and staffing plan to support all project activities

Component A

- Conducting activities in order to achieve the stated goals and objectives of the project
- Attending an annual project review meeting, and any additional working meetings, with CDC

- Establishing and maintaining communication with key partners
- Creating and implementing communication and education plans for SB clinics (healthcare providers), SBA chapters (persons with SB and families), and other relevant parties including physician groups to promote the adoption of best practices that improve the care for children and adults with SB
- Collecting and sharing input into research priorities for the NSBPR, identifying and communicating knowledge gaps as defined by healthcare providers as well as research priorities of the SB community, and supporting exploration of gaps.
- Creating and implementing a plan for characterization SB clinic attributes with best the outcomes and promotion of clinic characteristics associated with best outcomes
- If an award under this NOFO changes the aim or scope that was previously reviewed, and it is determined that an updated Project Description form and OMB-PRA determination will need to be resubmitted, all necessary OMB documentation (research documents) will need to be finalized for submission within the first year of funding

Component B

- For currently enrolled NSBPR participants, collecting data at annual visits according to protocol and submitting data via the SB Electronic Medical Record (EMR)
- Participating fully in enrollment of new patients; Collecting de-identified patient data by the review of patient medical records and during SB multidisciplinary clinic visit interviews
- Entering longitudinal data on all consenting participants, both those who were enrolled previously in the NSBPR (if applicable) and newly enrolled patients.
- Collecting and reporting minimal non-identifiable data (e.g. sex, race/ethnicity, insurance status) annually on eligible patients who did not enroll in the NSBPR to test for potential differences with the eligible patients who enrolled
- Entering data into the EMR specifically designed for use in SB clinics, so that the information that is transmitted electronically to the central repository will be in a standardized, reliable format (collected NSBPR data will be edited and combined into a uniform de-identified dataset for use by the awardees in their approved data analyses)
- Following the data protocol
- Obtaining necessary consent forms
- Responding in a timely manner to questions regarding the quality and validity of data submitted.
- One time during 5-year project period, participate in NSBPR and the National Death Index data linkage exercise for participants who are lost to follow up
- Attending up to 2 annual project review meetings, and any additional working meetings, with CDC

- Clinics can participate in other data collection efforts including:
    - Examining the uptake of the soon-to-be-released SB care guidance by using the

NSBPR to evaluate practice pre- and post-guidance release
- Collecting and entering additional information on NSBPR participants who are lost to follow up
- Linking existing medical administrative datasets and NSBPR to enhance information on NSBPR participants
- Collecting additional information from clinics about facility, personnel and specialist costs, for cost and cost-effectiveness analysis of operating a spina bifida clinic
- Participating and reporting outcomes in SB Electronic Medical Record (EMR) of the intervention to prevent skin breakdown
- Participating in optional modules for additional data collection and submitting via the SB Electronic Medical Record (EMR) the following and other topics as identified (optional modules may become part of SB EMR as determined by CDC in collaboration with the NSBPR CC and NSBPR Committee for Science and Publication):

    - Sleep disordered breathing
    - Quality of life
    - Neurosurgical repair of myelomeningocele
    - Developmental and learning assessments for participants
    - Other topics as identified

- Facilitating communications to promote the exchange of information among health care providers
- Working collaboratively with the other funded sites and NCBDDD to achieve the goals and objectives for the study
- The Project Director/Principal Investigator for each project will serve on the program Coordinating Committee and sub committees as appropriate and participate in committee conference calls
- Participating in presentations and publications to share the work and results of the NSBPR

Component C

- For currently enrolled UMPIRE Protocol participants, collecting data according to protocol and submitting data via the SB Electronic Medical Record (EMR)
- Creating a plan for approaching all infants with myelomeningocele SB who are 3 months old or younger and will get their care at a participating site for at least 6 months, and after obtaining parental consent, enrolling them in the UMPIRE Protocol (developed in the previous funding cycle)
- Following the existing five-year protocol and the six-to-ten year protocol (when developed), including providing documentation when protocol deviation occurs
- Entering UMPIRE Protocol data into the EMR specifically designed for use in SB clinics, so that the information that is transmitted electronically to the central repository will be in a standardized, reliable format (collected UMPIRE Protocol data will be edited and combined into a uniform de-identified dataset for approved data analyses)

- Collecting and reporting minimal non-identifiable data (e.g. sex, race/ethnicity, insurance status) on eligible patients who did not enroll in the UMPIRE Protocol
- Attending an annual project review meeting, and any additional working meetings, with CDC
- Sharing process and outcomes with appropriate audiences via publication and presentation
- Continue to promote consistency in measures across sites and in the interpretation of urology test results and classification of renal function
- Clinics can participate in other data collection efforts including:
    - Linking existing medical administrative datasets to enhance information on UMPIRE Protocol participants
    - Completing cost-effectiveness analysis of UMPIRE Protocol administration

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

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

Component A

- Provide guidance and technical assistance on the project activities as needed
- If OMB review and/or approval is necessary, CDC will lead development of the information collection request.

Components B and C

- Support the grantee activities in data management, data monitoring and data quality checks, data analysis, intervention design, formats for presenting research findings, and in comparing project-developed evaluation formats with other research projects and activities known to CDC
- Provide training in the use of the NSBPR tool/questionnaire and data entry
- Provide scientific consultation and technical assistance on epidemiology, statistical and power calculations, and data storage and tracking formats used in other CDC-sponsored research that could be advantageous to the project
- Refine and standardize data into a uniform dataset annually, in the aggregate and provide to the awardees
- CDC will assist in the analyses, interpretation, and reporting of findings in the literature
- Provide access and training for use of the SB EMR

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

Additionally, an HHS/CDC agency Program Official will be responsible for the normal

scientific and programmatic stewardship of the award. The SPO will be:

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

Areas of Joint Responsibility include:

Component A

- A steering committee will work collaboratively on implementation of the CCN Project tasks including the plan for characterization of practices in SB clinics with the best outcomes and promotion of clinic characteristics associated with best outcomes.

- This CCN steering committee will be composed of the grantee, CDC and advisors from the field: SBA chapters, SB clinics, and people affected by SB

Component B

- A Coordinating Committee (CC) consisting of the PD/PI from each institution and CDC staff and scientists will oversee the planning and implementation of the cooperative aspects of the study. The primary function of the CC will be to guide the analysis of the NSBPR data, identify research opportunities, and provide overall direction to the program. Organizations serving as sub-contractors under awarded projects are not considered members of the CC.
- The CC will address issues of common concern throughout the life of the project, including: 1) make recommendations on the study protocol , data collection approaches, and data elements; 2) discuss common protocols as they relate to SB data; 3) discuss issues related to the target populations that have been or will be recruited; 4) monitor adequate enrollment at the study sites and success of enrollment; 5) identify and recommend solutions to unexpected study problems; 6) how to address any data quality concerns identified and 7) discuss ways to efficiently coordinate study activities and best practices
- The CC with support from the CDC will coordinate data collection, data cleaning exercises, and data analyses
- The CC with support from the CDC will coordinate the linkage with the National Death Index
- All research analyses and proposals for use of aggregate study data must be submitted in writing to the CC for review and final approval, using a specific Data Analysis Proposal template and will be reviewed and approved by the Committee for Science and Publications before data analysis begins
- All publications including abstracts which use aggregate study data must be submitted and approved by the Committee for Science and Publication before journal submission
- Each full member of the CC will have one vote. The CC will meet in person up to twice

annually (in conjunction with the annual SBA meeting when possible) and will confer as needed by phone at least quarterly.

Component C

- The UMPIRE Protocol Coordinating Committee (CC) consisting of grantee urologists/PIs from each institution and CDC staff and scientists will oversee the implementation of the evaluation of the Urologic Management Protocol to Preserve Renal Function. This group will oversee the implementation of the protocol at funded sites, the analysis of the data, the modification of the protocol based on the data, and provide overall direction to the implementation of the protocol and the interpretation of resultant data to result in an overall recommendation
- The CC will address issues of common concern throughout the life of the project, including: 1) make recommendations on the protocol and data collection approaches including extending the care and data collection guidelines for years 6-10; 2) discuss issues related to the target population that has been or will be recruited; 4) monitor adequate enrollment at the study sites and success of enrollment; 5) identify and recommend solutions to unexpected study problems; and 6) discuss ways to efficiently coordinate study activities and best practices; and 7) recommend data quality checks and cleaning exercises
- The CC with support from the CDC will coordinate data collection, data cleaning, and analyses. All research analyses and proposas for the use of study data must be submitted in writing to the CC for review and final approval
- Each full member of the CC will have one vote. The CC will meet in person annually and will confer as needed by phone at least quarterly

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two

elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

An annual progress report as required.

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

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends**.

3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance**.

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness

included in the current budget period proposal.
- Research Aims: list each research aim/project

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

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

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

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

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

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

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

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

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

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

- Additional Reporting Requirements:

https://era.nih.gov/docs/Commons_UserGuide.pdf

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect
any unliquidated obligations. There must be no discrepancies between the
final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

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

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

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

- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups,

researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the period of performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

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

Section VII. Agency Contacts

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

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

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

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

Scientific/Research Contact(s)

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Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
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Financial/Grants Management Contact(s)

Heidi Williams or Sharon Cassell
Grants Management Specialist
Office of Grant Services
Centers for Disease Control and Prevention
2920 Brandywine Road, GHSecB, Team 1
Atlanta, GA 30341

Telephone: Heidi, 770.488.2626 or Sharon, 770.488.2703

Email: Heidi, isa2@cdc.gov or Sharon, zpr0@cdc.gov

Section VIII. Other Information

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

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

Questions and Answers from Potential Applicants and CDC Responses Question and Answers

1. Pre- Application Call Questions

QUESTION 1: Is a separate DUNS number needed if one site collaborates with another in the application process?

ANSWER 1: No, a separate DUNS number is not necessary. Only one application per institution (normally identified by having a DUNS number is allowed for each component.

QUESTION 2: How to access the link for notifications within the grants.gov website?

ANSWER 2: Callers were instructed that they can contact L.C. Browning (TIMS) at 770-488-2700, or imu8@cdc.govif they have trouble accessing the link.

QUESTION 3: Are there any restrictions to an institution applying for more than one component with the plan of a different P.I. for each component and different aims and goals?

ANSWER 3: The application for more than one component is welcome. Components are stand alone in this application process. A separate application is needed for each component. For each component the applicant needs to outline the key staff members who will participate in specific activities. The applicant organization can also partner with Individuals in another organization.

QUESTION 4: Do clinics need to apply for both Components B and C?

ANSWER 4: Clinics do not have to apply for Component B to apply for Component C.

QUESTION 5: Where are the application form elements on the website?

ANSWER 5: The system should prompt users via a link, but if users cannot find it, they can contact the Grant Assurances office by email at grantassurances@cdc.gov . The Grant Assurances office will provide the information needed and assist with completing the assurance documents.

QUESTION 6: Is there an IRB requirement in Component A?

ANSWER 6: It depends on the activities the applicant proposes to accomplish and if human subjects are involved.

QUESTION 7: Where are the items required for the application listed and how are the documents submitted?

ANSWER 7: Line 12 is the place that lists the required items for application and attachments are uploaded. The system should prompt the user to upload documents in PDF format. PDF files such as the cover letter, cost agreement, budget narrative, etc. will need to be uploaded in this location.

QUESTION 8: Is an approved IRB required in the application?

ANSWER 8: No, an approved IRB is not required at the time of application, but an explanation including management of human subjects should be addressed along with the planned approach for getting IRB in place. An approved letter from the IRB can be included, but is not necessary.

2. Other questions from applicants

QUESTIONS 9: Is it sufficient for a P.I. to write the letter of commitment from a participating clinic? Or is it necessary for someone else to compose the letter?

ANSWER 9: The NOFO does not specify who should write the letter. It is recommended that a staff member should compose the letter who can demonstrate ability to access patients with SB and commitment to the collection of the data elements in the NSBPR.

QUESTION 10: It states that you need to document that 200 patients go to the spina bifida clinic annually. I wanted to clarify whether the patients need to be seen at a spina bifida-specific clinic, or if they just need to be followed by providers at that institution? I am not exactly sure how many patients we have in our SB clinic, but I am guessing it is less than 200 since it is still a relatively new clinic. However, based on a research study I did a few years ago, I know there are hundreds of patients with SB who get their care at the University, but not as a part of a spina bifida-specific clinic.

ANSWER 10: For an applicant for Component B to be considered, they must be responsive to

the following Special Eligibility Criteria:

- Applicant must have documented evidence of treatment of a minimum of 200 patients in 2017 or 2018 with NSBPR eligible diagnoses (myelomeningocele, meningocele, lipomyelomeningocele, fatty/thickened filum, split cord malformation, and terminal myelocystocele) as evidenced by the provision of a 2017 or 2018 patient census for the SB clinic that includes age, gender, race/ethnicity, and diagnosis

- Note: more than one clinic (e.g. smaller clinics, pediatric/adult clinics) can join together as one NOFO applicant

- Applicant must demonstrate access to patients with SB and commitment to the collection of the data elements in the NSBPR as demonstrated by a letter of commitment from a representative of the participating clinic(s) to participate as described

For clarification, the combining or collaborating of clinics is permitted to achieve the minimum of 200 patients as described in the NOFO. The NOFO does not include specific details on the combining or collaborating of clinics, thus, individual specialty clinics within an institution could be included. Note the additional eligibility criteria of demonstrating access to patients with SB and commitment to the collection of the data elements in the NSBPR are required components for all participating clinics.

QUESTION 11: I wanted to ask where we can find on the grant synopsis website the list of attachments that was read out on the call including the following:

- Budget Narrative
- IRB approval (optional)
- Letters of Support
- Certifications
- Assurances

ANSWER 11

- Budget Narrative: There is no form for a budget narrative in this NOFO. The FORMS-E package does not have the Budget Narrative included.
- IRB approval (optional): The grantee is responsible for obtaining IRB approval for all collaborators: See page 54 of 58, the bullet reference IRB Approval Certification

· Letters of Support: This is for the applicant to provide to the CDC: See Page 18 of 58

· ASSIST is not set up to click the tab and additional forms will not appear. The applicant has to go into ASSIST for each component. The applicant has to make sure they use a different title for each component in the SF 424 on Line 11 Descriptive Title of Applicant's Project.

QUESTION 12 Do all 200 patients with spina bifida seen at our institution in 2017 or 2018 need to have been seen in the spina bifida multidisciplinary clinic or spina bifida specific clinic? Or does it count if they were seen in an individual provider's clinic that was not a spina bifida-specific clinic? We have over 750 patients with spina bifida followed at our institution, but because our multidisciplinary clinic is relatively new, it is smaller (but growing). I am currently applying for a K23 award from the NICHD with the goal of improving reproductive health education for women with spina bifida. Does this preclude me from being the PI on this grant?

ANSWER 12: First questions: see above Answer10. Second questions: In Part I. Overview, Executive Summary, eligible PIs are described for this NOFO. We cannot comment on PI requirements for other announcements**.**

QUESTION 13: What I really want to know is are you funding new clinics?

ANSWER 13: Component C is open competition. This NOFO is separate from any previous NOFO; any applicants are welcome to apply.

Any qualified applicant is welcome to apply. Please note the Special Eligibility Requirements for Component C in Section III. Eligibility Information.

QUESTION 14: In a research proposal for the grant, does the hypothesis need to be able to be answered with only the data fields we have been collecting thus far, or could we pose a hypothesis that could potentially be answered with the registry if we were to add data fields. Or could we propose in the response a question we might pursue with the smaller group of institutions who seem more committed to entering in more data than is required.

ANSWER 14: The discussion of the proposal is in Section IV of the NOFO. It is recommended that the description should identify if data fields utilized in the proposed research are included or beyond the current NSBPR data fields.

QUESTION 15: What data elements need to be collected on patients? I would like to make sure there will be no issue collecting all of them before we proceed.

ANSWER 15: Data entry forms are available upon request.

QUESTION 16: I assume the $68,000 budget for the first year includes both direct and indirect costs. You have them listed as such in the following paragraph referencing the address cost, but I wanted to make sure that I was clear on the individual clinic budgets

Also, budget limits for year 1 are listed; what about the subsequent years of the grant? I have usually had to submit a budget under a total project cap in prior grants; has this changed?

ANSWER 16: Section 2 of the NOFO outlines estimated total funding for initial budget period and the entire project period; it does not specify each budget period.

Future year funding depends on the availability of funds, evidence of satisfactory progress by the recipient, and CDC's determination that continued funding is in the best interest of the Federal government.

QUESTION 17: At our institution, we have a pediatric multi-disciplinary spina bifida clinic, however due to family's preference or that they do not need to see >2 specialist, we have many patients who will often receive care outside of the multi-disciplinary SB clinic and instead see specialist separately. The institution also cares for many adult spina bifida patients outside of formal multi-disciplinary clinic setting.

My question is would we be able to include patients seen outside of the multi-disciplinary clinic, but who still receive consistent care from specialists in that 200 minimum census?

ANSWER 17: See above ANWER10.

QUESTION 18: Urology folks are very interested in applying for component C and indicate that most everything in the UMPIRE protocol they currently have as standard of care. However they note that DMSA scan radiotracer is not readily available. Is this something that the other component C participants note and/or in this problem or the application.

ANSWER 18: The NOFO does not require Component C applicants to have DMSA capability. Further, deviations to the UMPIRE Protocol are allowed.

QUESTION 19a-19c

1. Is this component (C) ONLY for those sites who under the previous funding cycle who developed and tested the UMPIRE protocol? In the anticipated number of awards section it the RFA anticipates up to nine sites--are these slots already taken?
2. Along with that, as we were not selected during the last funding cycle are we able to submit an application for component C?
3. We do follow most of the UMPIRE protocol with minimal changes. (Our urologists were some of the original contributors to the urologic protocol and data collection design for NSBPR.) In this case can we include our current patients now followed by urology and entered into the NSBPR--or do we have to "grow" a new patient population specifically under the UMPIRE protocol?

ANSWER 19:

1. Component C is open competition. This NOFO is separate from any previous NOFO; any applicants are welcome to apply.
2. Any qualified applicant is welcome to apply. Please note the Special Eligibility Requirements for Component C in Section III. Eligibility Information.

3. As the NOFO states (see page 51, Section VI.4): "The UMPIRE Protocol Coordinating Committee (CC) consisting of grantee urologists/PIs from each institution and CDC staff and scientists will oversee the implementation of the evaluation of the Urologic Management Protocol to Preserve Renal Function. This group will oversee the implementation of the protocol at funded sites, the analysis of the data, the modification of the protocol based on the data, and provide overall direction to the implementation of the protocol and the interpretation of resultant data to result in an overall recommendation." The UMPIRE Protocol CC would need to decide a question about enrollment of patients in clinics that followed the UMPIRE protocol but were not part of the original UMPIRE participants.

QUESTIONS 20: Can the same PI at our institution, be contact PI for both Component B and Component C? Or is she only allowed to be contact PI for one Component/application?

ANSWER 20: The PI can be the same or different for Component B and Component C

QUESTIONS 21: It's our understanding that each Component (B and C) needs to be submitted as a separate application with all application requirements, correct?

Does this mean we will set up 2 ASSIST accounts, one for each Component, and submit two full applications with two separate budgets?

ANSWER 21

1. Separate applications are required if applying for multiple components. The application Guide and other application resources are referenced in Section IV. If the applicant is applying for separate components using separate applications. Once they are processed there will be separate Grant numbers.
2. OGSTIMS email address is: ogstims@cdc.gov . For Grant Assurance email address is grantassurances@cdc.gov

QUESTION 22: In our Letter of Intent, we understand it is non-binding, but can key personnel change between the LOI submission and the actual grant submission? We may change certain Co-Investigators.

ANSWER 22: Yes, there can be changes in key personnel between the LOI and the application.

QUESTIONS 23: If we are currently an awardee for the NSBPR grant, is the progress report due when we submit the new application on 2/13/19? Or do we not need to submit the progress report until a later date?

ANSWER 23: The Year 5 Notice of Grant Award provides information as to when the Final Progress Report is due.

QUESTIONS 24:

When I submitted my proposal in 2014 I needed to include the following information in my grant proposal:

1) Schedule of intervention services provided in the clinic

2) Disciplines that are a part of the clinic

Do you have this information on every clinic that participates in the registry? I would like to use this information along with data that is in the registry in my research.

ANSWER 24: Information received in an application submitted to CDC is confidential. No information from the applications may be shared.

QUESTION 25: For the question of describing the current patient population by diagnosis, race/ethnicity, gender and age – Do you want to know how many patients we have with each certain diagnosis or do you just want a list of the diagnoses we see in our clinic?

Could you explain exactly what you're looking for in the Year-to-Year return rate of patients? The majority of our patients come to clinic every year or every two years. Do you want a percentage of how many come annually vs how many come every two years?

For both that question/explanation and the one asking for a table that depicts year to year return, it's asking for a five year period. May that be six? As I stated before, our patients come every one or two years. Six would better capture our rate of return but we don't want to give misleading or incorrect information.

ANSWER 25: For question one (see page 24, Section IV.5), the NOFO asks that you "Describe the current patient population by diagnosis, race/ethnicity, gender, and age." Exactly how clinics should describe all variables (diagnosis, race/ethnicity, gender and age) is not specified; clinics have individual discretion for how to present these data.

For the year-to-year return, "two visits" means a minimum of two visits. For "annual visit records," the NOFO does not specify that the annual visits need to be in consecutive years. The NOFO does not specify how the data should be presented. If the clinic presents the data differently in the application that the NOFO requests, an explanation of why would be advisable.

QUESTION 26: The RFA states that we must "conduct at least one data linkage with the National Death Index to identify deaths among the participants who are lost to follow up, per guidance from the NSBPR CC and with technical assistance from CDC." No information is

given in the RFA about what guidance or technical assistance the CDC will provide. My questions are as follows:

- Can you please provide more information about what guidance or technical assistance the CDC will provide? In order to describe the research methodology in the grant, it is important to know the CDC's role.
- The RFA does not provide guidance on budget with regard to the Index. The National Death Index requires payments to process requests. Can you please provide guidance on whether we are supposed to add budget line items to cover these costs, or are these costs being covered by CDC?
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- **Answer 26:** The NOFO Section I states, linkage will occur "per guidance" from the NSBPR Coordinating Committee (CC), which is comprised of "Principal Investigators at the participating clinics and CDC staff and scientists." The NSBPR CC will decide particulars including timing for the death linkage project together. CDC's technical assistance will be guided by the NSBPR CC plans and could include completion and submission of the National Death Index application for all clinics.
- The costs for linkage do not have to be included in year 1 budget. The costs for linkage will be specified in funding guidance for subsequent years, but estimates for linkage costs are enumerated on the NDI website here https://www.cdc.gov/nchs/data/ndi/ndi_user_fees_worksheet.pdf
-

QUESTION 27: I have a couple of (hopefully) quick questions about the RFA. Specifically, for Component B, I have the following questions:

- There is a requirement to complete one search through the National Death Index to see if anyone lost to follow-up is in that index. However, there is no definition of "lost to follow-up". Because there is a cost associated with this search, and because the cost is per year per individual, any guidance on how sites need to define "lost to follow-up" would be helpful.
- In the guidance, it states that PIs should plan for up to 2 trips associated with the project annually. This is a change from the last 3 funding cycles, which expected people to budget for 1 trip. Could you please verify that each site should be budgeting for two annual trips?

ANSWER 27:

- Section I of the NOFO states the National Death Index data linkage will occur "per guidance" from the NSBPR Coordinating Committee (CC), which is comprised of "Principal Investigators at the participating clinics and CDC staff and scientists." The NSBPR CC will decide particulars including exact definitions for lost to follow up for the project period. The costs for linkage do not have to be included in year 1 budget. The

costs for linkage will be specified in funding guidance for subsequent years, but estimates for linkage costs are enumerated on the NDI website here https://www.cdc.gov/nchs/data/ndi/ndi_user_fees_worksheet.pdf

- It is anticipated that in-person meetings will occur annually as in past years, but if the two annual meetings occur in same fiscal year due to scheduling differences (e.g. October 2019 and September 2020) the NOFO will allow for this flexibility.

QUESTION 28: In Section II, On page 15, Is the budget limitation $70,000 for our overall project? It just says the total funding is up to 68K but the ceiling is 70K. Why is there a 2K discrepancy?

There is a discrepancy where on page 22 versus page 23, where on page 22 it says the research strategy is organized into 3 headings, but on page 23, it says it's the research plan. Which is it? Is the research plan what contains the research strategy?

Is it required that we submit using ASSIST? On page 2 is says ASSIST is preferred, but then on page 26, it says Organizations must submit applications using the ASSIST submission process. We just want to make sure we submit using the appropriate channel.

ANSWER 28: The NOFO indicates that the Year 1 ceiling is 70,000, thus, applicants may submit a budget for up to 70,000. Estimated funding for this comp is 68,000 for Year 1. The NOFO states: "The applicant's research plan should address activities that will be conducted over the 5 year project period. The Research Plan narrative is comprised of components 2 and 3 above. NOTE: that the research Strategy is divided into three parts: 1) Significance, 2) Innovation, and 3) Approach."

Components 2 and 3 are as follows: "2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health. 3. Research Strategy – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and time line." The Research Plan includes the specific aims and the research strategy.

Submitting from Workspace, SYSTEM-To-System, or ASSIST are acceptable. However, submitting electronic application via ASSIST is PREFERRED.

QUESTION 29:

- During the information phone call on December 13th it was mentioned that there are 3 assurance documents that would need to be included in the application that we needed to obtain. The person speaking on the phone mentioned we could email or call for these

documents.
- We were also hoping to see any of the optional modules that may become part of the SB EMR mentioned in this NOFO on page 10, should there be any to view.

ANSWER 29:

- **The 3 assurance documents are attached below:**

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1. The Optional modules that may become part of the SB EMR mentioned in this NOFO on page 10, are still in development by the NSBPR Coordinating Committee (CC) and are not currently available.

QUESTION 30: Second question for clarification on page 25 of RFA-DD-19-001, Comp C, 3rd bullet point, table description:

- Please clarify if you are asking for "the number of children 0-5 years with myelomeningocele in the clinic with a minimum of two annual visit records", or "with only two annual visit records".
- For this same cohort of 0-5 years olds, is it a correct interpretation that you are looking for all who had ("a minimum of" vs "only") two visits "over a ten year period" ending in 2017 or 2018?

- Do those two visits need to be in consecutive years, or any two visits, as long as there were two visits in a ten year period?
- Does one of those two visits need to have been in 2017 or 2018?

ANSWER 30: For the first and second question in Section IV of the NOFO, "two visits" means a minimum of two visits. For "annual visit records," the NOFO does not specify that the annual visits need to be in consecutive years nor include 2017 or 2018.

QUESTIONS 31: "Describe the UMPIRE Protocol patient population (patients, newborn to age 10 years in the clinic with a diagnosis of myelomeningocele) by race/ethnicity and gender."

Would you please clarify if this line is looking for a simple snapshot of patients seen by the SB clinic in 2018 only, aged newborn to age 10?

Or should we supply data for both 2017 and 2018? Or are there other implied but not clearly

stated criteria here we should know about?

I understand it is a different question from the year-to-year return question; I just want to make sure we are correctly interpreting what is being asked.

ANSWER 31: The NOFO on page 25, Section IV.5, asks that you ""describe the UMPIRE Protocol patient population … by race/ethnicity and gender," Exactly how clinics should describe race/ethnicity and gender is not specified; clinics have individual discretion for how to present these data.

QUESTION 32: This question is about the requirement for including an aim regarding the National Death Index. From our understanding, we need to match our deceased and loss to follow up with the National Death Index, but the details of this process is not clear. Would you be able to clarify for me what is being requested for this section?

Answer 32: See Answer 26**https://www.cdc.gov/nchs/data/ndi/ndi_user_fees_worksheet.pdf**

QUESTION 33: We are applying for Component B – the National Spina Bifida Patient Registry. Is this considered collection of public health data and require a Data Management Plan to be submitted in the grant?

ANSWER 33: Yes, components B and C of the NOFO would collect public health data that would require a data management plan.

QUESTION 34: There is no information about budget for subsequent years – is there a provision to increase the budget during years 2-5 by cost of living for example? Or should I assume it is limited to the $68K for Year I?

ANSWER 34: The FY 2019 estimated total funding of $68K is based on the available funds to award. Although there is no definitive funding amount for future years, an applicant could utilize the $68K FY 2019 estimate for planning purposes.

QUESTION 35: Should we use Form D or Form E. On page 4 of the NOFO there is a bulleted point that states that we should use Forms D when downloading the application package and then provides the link to that package. However when you click the link- you are taken to a web address that is no longer valid. Everywhere else in the NOFO it refers to Forms E (i.e. page 20, 22,23,26).

ANSWER 35: Form E is the most updated version of application instructions and this version should be used (Page 4 should have referred to Form E). Here is a link to Form E https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf

QUESTION 36: Are we applying under the new Common Rule? Since under new Rule It might be exempt from human subjects research, or should just consider it human subjects research? if it's not human subjects research, is there a specific exempt category you

recommend and how much of the Human Subjects section of PHS398 needs to be completed?

ANSWER 36: Local institution's IRB will be able to provide advice on revised requirements related to the new Common Rule.

QUESTION 37: Should all the main specialty providers in the multidisciplinary clinic be included as Key Personnel since they help collected? Or can they be listed as Other Significant Contributors?

ANSWER 37: CDC defers to the institution to make determinations about who is included as key personnel. We only ask the bio sketch is provided for key personnel.

QUESTION 38: If we are going to collect some additional clinical data that will be stored in a local REDCap research database, do we need to have a separate data management plan for this?

ANSWER 38: Local data that is not part of the SB EMR project should not be included in the data management plan.

QUESTION 39: Should we include the CDC data forms in the Appendix?

ANSWER 39: The NSBPR and UMPIRE Protocol forms are not necessary to include in the appendix.

QUESTION 40: Is it recommended to include the blank consent/assent forms in the Appendix?

ANSWER 40: Consent and assent forms are not necessary to include in the appendix.

QUESTION 41: Do all Other Significant Contributors need a biosketch?

ANSWER 41: A Biosketch is needed for only key personnel

QUESTION 42: Can we attach a publication in the Appendix that is currently in re-submission status to a journal?

ANSWER 42: This is up to the applicant to determine what would be helpful for the application.