U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA
Health Resources & Services Administration

Maternal and Child Health Bureau
Division of Services for Children with Special Health Needs
Genetic Services Branch

Newborn Screening Data Repository and Technical Assistance Program

Funding Opportunity Number: HRSA-18-080
Funding Opportunity Type(s): Competing Continuation, New
Catalog of Federal Domestic Assistance (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

Application Due Date: May 22, 2018

MODIFIED on April 3, 2018: update to incorporate new SAM.gov registration requirements (page 17) and enactment of the Consolidated Appropriations Act, 2018 (pages 14 and 18).

*Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!
HRSA will not approve deadline extensions for lack of registration.
Registration in all systems, including SAM.gov and Grants.gov,
may take up to 1 month to complete.*

Issuance Date: March 22, 2018

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Authority: Public Health Service Act, § 1109(a)(1), (2), (3), and (4) (42 U.S.C. 300b-8(a)(1), (2), (3), and (4))

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2018 for the Newborn Screening Data Repository and Technical Assistance Program to enhance, improve and expand the newborn screening system by supporting state public health newborn screening programs, public health professionals, families, and primary and specialty care practitioners.

The FY 2018 President's Budget does not request funding for this program. This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds a timely manner. You should note that this program may be cancelled prior to award recommendations.

Funding Opportunity Title:	Newborn Screening Data Repository and Technical Assistance Program
Funding Opportunity Number:	HRSA-18-080
Due Date for Applications:	May 22, 2018
Anticipated Total Annual Available FY 2018 Funding:	$1,500,000
Estimated Number and Type of Award(s):	Up to one cooperative agreement
Estimated Award Amount:	Up to $1,500,000 per year
Cost Sharing/Match Required:	No
Period of Performance:	July 1, 2018 through June 30, 2023 (5 years)
Eligible Applicants:	A state or a political subdivision of a state; a consortium of two or more states or political subdivisions of states; a territory; a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or any other domestic entity with appropriate expertise in newborn screening, as determined by the Secretary. See Section III-1 of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide,* available online at http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this NOFO to do otherwise. A short video explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Technical Assistance

HRSA has scheduled the following technical assistance webinar:

Webinar

Day and Date: Wednesday, April 18, 2018
Time: 2 p.m. – 3 p.m. ET
Call-In Number: 1-866-723-2075
Participant Code: 51349380
Weblink: https://hrsa.connectsolutions.com/hrsa18080nbsta/

Please provide questions to the HRSA project officer prior to the scheduled webinar.

To access the archived webinar recording, please visit the HRSA MCHB Funding Opportunities Webpage: https://mchb.hrsa.gov/fundingopportunities/Default.aspx.

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I. Program Funding Opportunity Description

1. Purpose

This program announcement solicits applications for the Newborn Screening Data Repository and Technical Assistance Program.

The purpose of this cooperative agreement is to enable the recipients to:

1) Enhance, improve and expand the ability of states and local public health agencies to provide screening, counseling, or health care services to newborns and children having or at risk for heritable disorders;
2) Assist in providing health care practitioners and newborn screening laboratory personnel with education in newborn screening and training in relevant and new technologies in newborn screening and congenital, genetic and metabolic disorders; and
3) Establish, maintain, and operate a system to assess and coordinate follow-up and treatment relating to congenital and genetic (including metabolic) disorders identified through newborn screening.

To fulfill these criteria, the recipient will provide technical assistance to state and local public health agencies, health care professionals, newborn screening laboratory personnel, and other newborn screening stakeholders on the implementation of state-based public health newborn screening. This may be accomplished through resource development, state education and training, policy initiatives, disorder surveillance, evidence-based data collection, evaluation, and collaborative efforts with stakeholders, including federal and non-federal partners.

Program Goals

The overall goal of the Newborn Screening Data Repository and Technical Assistance Program is to reduce morbidity and mortality caused by heritable disorders in newborns and children by enhancing, improving and expanding the newborn screening system. The expected impact of the program is improved health and well-being for infants at-risk for or affected with conditions identified through the newborn screening system.

Program Objectives

Recipients are responsible for collecting data on the objectives below for the purposes of monitoring and evaluating the overall effectiveness of the program. Recipients are required to report on the program objectives every year of the project. Within the first year of the award, the recipients must establish and provide baselines for these objectives to HRSA.

- By 2019, create a national newborn screening data repository to standardize, maintain, and analyze quantitative newborn screening quality indicators, public health case definitions and other data related to newborn screening; and to collect,

analyze, and disseminate newborn screening data and information to assist states evaluate the performance of their newborn screening programs.

- By 2019, have a system in place to support states' efforts to implement conditions as they are added to the [Recommended Uniform Screening Panel (RUSP).](#)
- By 2023, increase from baseline to 90 percent the number of states and territories with a data use agreement in place to submit newborn screening data and information about their newborn screening program into the repository.
- By 2023, increase from baseline to 90 percent the number of participating states and territories contributing data to the repository on all measures.

Program Requirements

In order to achieve the goals and objectives of the Newborn Screening Data Repository and Technical Assistance Program, the recipient will establish a national infrastructure by conducting the following activities:

- Create a steering committee consisting of representatives of state newborn screening programs, public health, primary and specialty care practitioners, individuals or families with conditions detected by newborn screening, experts on privacy rights, and other newborn screening stakeholders to advise the project and identify best practices and areas of need within the newborn screening system.
- Develop and maintain newborn screening case definitions and quality indicators to measure the performance of newborn screening programs in partnership with state newborn screening programs and other newborn screening stakeholders.
- Develop, establish, and maintain a central web-based repository that includes:
  - Information on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators.
  - Aggregated data from state newborn screening programs on newborn screening quality indicators.
  - State newborn screening program information, materials, best practices, policy initiatives, and resources on newborn screening for state newborn screening programs, public health officials, and primary and specialty care practitioners.
- Initiate and implement data use agreements with state and territorial newborn screening programs regarding collected aggregated data on their newborn screening quality indicators
- Collect, standardize and analyze aggregate quantitative and qualitative data from state and territorial newborn screening programs.
- Monitor and track annually, the challenges and barriers that states may encounter throughout the data collection process for entering data into the data repository.
- Provide feedback, education, training and technical assistance to individual state and territorial newborn screening programs. This includes conducting onsite technical assistance at the request of states, providing a comprehensive report identifying areas of strengths and potential improvements, and assisting with quality improvement activities to strengthen the program.
- Provide technical assistance, education, and training to public health professionals, and primary and specialty care practitioners on newborn screening best practices (pre-analytic, analytic, and post analytic) and condition-specific issues.

- Develop and implement a program to assist states in adding screening for conditions on the RUSP and as to which the state has encountered challenges in implementing effective screening programs.
- Develop HL7 or other health information technology guides to support efforts to incorporate electronic messaging and ease data transfer between states and hospitals/birthing centers.
- Implement activities that will strengthen the integration of child health information systems among newborn screening programs, public health, and clinical practice.
- Develop a process to assess newborn screening in the United States through data collection and analysis, literature review, or other methods to identify best practices, areas in need of improvement, emerging issues, or emerging screening technologies (e.g., reaching high-risk populations or identifying gaps in evidence) and disseminate findings.
- Support an annual in-person meeting of state newborn screening programs, family leaders, and other newborn screening stakeholders, including families, to discuss and disseminate information about current and emerging newborn screening topics/issues.
- Publish a State of Newborn Screening Report in years 1, 3, and 5, of the project that includes aggregate data on conditions screened, number of out-of-range results, number of true positives and other quality indicators of newborn screening. The report should identify successes and challenges in newborn screening.
- Collaborate with other federally funded programs related to newborn screening to reduce duplication such as the HRSA-funded newborn screening programs including The Newborn Screening Family Education Program, the Newborn Screening Clearinghouse, and the Quality Improvement in Newborn Screening Program (HRSA-18-070); the National Institutes of Health (NIH)-funded Newborn Screening Translational Research Network; and the Centers for Disease Control and Prevention (CDC)-funded Newborn Screening Quality Assurance Program.
- Develop an evaluation plan to measure the impact of the Newborn Screening Data Repository and Technical Assistance Program.
- Develop a sustainability plan for the project to support the project beyond federal funding period.

2. Background

This program is authorized by Public Health Service Act, § 1109(a)(1), (2), (3), and (4) (42 U.S.C. 300b-8(a)(1), (2), (3), (4)), which require HRSA, as the Secretary's delegate, to award grants to eligible entities to enable such entities to carry out the purpose as listed above.

Newborn screening is an effective state and territorial public health program that saves and improves the lives of thousands of babies each year in the United States. Four million newborns each year are tested for at least 29 conditions on the RUSP, a list of conditions adopted by the Secretary of Health and Human Services and recommended for states to screen for in their newborn screening programs. These conditions require early screening, intervention and treatment to mitigate brain and organ damage, severe illness, and life-threatening complications associated with these conditions.

Funded since 2012, the Newborn Screening Data Repository and Technical Assistance Program has standardized national newborn screening quality measures used by state newborn screening programs and allowed for consistent categorization and tracking of follow-up of identified newborns at the local, regional, and national levels. The program conducted technical assistance and training for state newborn screening programs to improve the quality of the newborn screening process and begin screening for new conditions.

As new technology becomes available and new research evolves on conditions that could be screened for at birth, the goal of this funding opportunity is to build upon the previous program's accomplishments and provide technical assistance specific to the needs of states and territories to ensure that their newborn screening program is running optimally. This funding will support more states with comprehensive evaluations, webinars and other forms of technical assistance to enhance and improve their newborn screening systems. Currently, most states are screening for 29 out of the 34 conditions on the RUSP. Many states need assistance in implementing the remaining five (5) conditions. This new funding will also help states implement screening for new conditions when added to the RUSP. HRSA expects the recipient will collaborate with the Quality Improvement in Newborn Screening Program (HRSA-18-070).

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: Competing Continuation, New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement, as opposed to a grant, is an award instrument of financial assistance where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

HRSA Program involvement will include:
In addition to the usual monitoring and technical assistance provided under the cooperative agreement, HRSA Program responsibilities shall include:
- Participation in meetings conducted during the period of the cooperative agreement.
- Ongoing review of activities and procedures established and implemented for accomplishing the scope of work.
- Review of products and project information prior to dissemination.
- Review of information on project activities.
- Assistance establishing and facilitating effective collaborative relationships with federal and state agencies, HRSA-funded grants, and other entities that may be relevant to the project's mission.
- Provision of information resources.
- Ensure compliance with NOFO requirements.

The cooperative agreement recipient's responsibilities will include:
- Completing activities proposed in response to the NOFO.
- Collaborating with HRSA on ongoing review of activities, procedures and budget items, information/publications prior to dissemination, contracts and interagency agreements.
- Providing ongoing, timely communication and collaboration with the federal project officer.
- Providing the federal project officer opportunity to review documents and products prior to dissemination.
- Working with the federal project officer to review information on project activities as described within this award announcement.
- Establishing contacts that may be relevant to the project's mission such as federal and non-federal partners, and other HRSA projects that may be relevant to the project's mission.
- Collaborating with other federally funded programs on newborn screening to create synergies of effort and to reduce duplication.
- Providing assurances that the amounts received under this program will be used to implement the guidelines and recommendations of the [Advisory Committee on Heritable Disorders in Newborns and Children](#)[1] that are adopted by the Secretary and support the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.
- Ensuring that data collected is maintained on a central, web-based database that is publicly available, free of charge, for use, without restrictions, by the public.
- Describing privacy and security measures for the data repository.
- Providing, prior to the end of the period of performance and at times designated by HRSA, to HRSA or HRSA's designee, all collected data, a data dictionary, source code, software and any other metadata that supports the usability or functionality of the collected data.

Data Rights

All publications the cooperative agreement recipient develops or purchases with funds awarded under this announcement must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the cooperative agreement recipient owns the copyright for materials that it develops under this cooperative agreement, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced under this cooperative agreement and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes (e.g., to make it available in government-sponsored databases for use by other researchers). The specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the Notice of Award (NOA). Data and copyright-protected works developed by a sub-recipient also are subject to the Federal Government's copyright license and data rights.

Collected data and data dictionary have long-term value for historical and comparative purposes, HRSA intends to exercise its rights under 45 CFR § 74.36(c) to ensure that

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[1] https://www.hrsa.gov/advisory-committees/heritable-disorders/about/index.html

HHS-funded newborn screening data repositories are as comprehensive as possible for the benefit of the newborn screening community and members of the public. Accordingly, the data collected under this cooperative agreement must be made publicly available, free of charge, for use without restrictions by the public. Furthermore, not later than the end of the period of performance and at other times required by HRSA, the recipient must provide to HRSA, or HRSA's designee, the collected data, a data dictionary, source code, software and any other metadata that supports the usability or functionality of the collected data. (See cooperative agreement recipient's responsibilities in Section II. Award Information. 1. Type of Award.)

2. Summary of Funding

HRSA expects approximately $1,500,000 to be available annually to fund one recipient. You may apply for a ceiling amount of up to $1,500,000 total cost (includes both direct and indirect, facilities, and administrative costs) per year. The actual amounts available will not be determined until enactment of the final FY 2018 federal appropriation. The FY 2018 President's Budget does not request funding for this program. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. The period of performance is July 1, 2018 through June 30, 2023 (5 years). Funding beyond the first year is dependent on the availability of appropriated funds for the Newborn Screening Programs in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles and Audit Requirements at 45 CFR part 75.

III. Eligibility Information

1. Eligible Applicants

A state or a political subdivision of a state; a consortium of two or more states or political subdivisions of states; a territory; a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or any other domestic entity with appropriate expertise in newborn screening.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this announcement.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in *Section IV.4* non-responsive and will not consider it for funding under this announcement.

NOTE: Multiple applications from an organization are not allowable.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA *requires* you to apply electronically. HRSA encourages you to apply through Grants.gov using the SF-424 workspace application package associated with this NOFO following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing this notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) or workspace application package. This allows Grants.gov to email organizations in the event HRSA changes and/or republishes the NOFO on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the For Applicants page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

Section 4 of HRSA's *SF-424 Application Guide* provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide* except where instructed in the NOFO to do otherwise. You must submit the applications in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the *Application Guide* for the Application Completeness Checklist.

Application Page Limit
The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under the announcement.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
3) Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in Attachment 9: Other Relevant Documents.

See Section 4.1 viii of HRSA's *SF-424 Application Guide* for additional information on all certifications.

Program-Specific Instructions
In addition to application requirements and instructions in Section 4 of HRSA's *SF-424 Application Guide* (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), include the following:

i. Project Abstract
See Section 4.1.ix of HRSA's *SF-424 Application Guide*.

ii. Project Narrative
This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Successful applications will contain the information below. Please use the following section headers for the narrative:

▪ *INTRODUCTION -- Corresponds to Section V's Review Criterion) (1) Need*
This section must briefly describe the purpose of the proposed project. You must include a discussion that demonstrates an expert understanding of the goals, requirements, and objectives of the program.

Describe the purpose of the proposed project including a brief discussion of the newborn screening system and the needs of state newborn screening programs.

▪ *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion (1) Need*

- Describe the status, issues, and barriers related to achieving an effective, timely, and accurate newborn screening system.

- Describe and document the parts of the newborn screening system that will be targeted through this project and their unmet educational, resource and support needs.
- Use and cite demographic data whenever possible to support the information provided. Include any relevant barriers in the service area that the project hopes to overcome as well as the specific needs and barriers that states experience in newborn screening.

- *METHODOLOGY -- Corresponds to Section V's Review Criterion (2) Response*

  - Propose methods that you will use to address the stated needs and meet each of the previously described program requirements, objectives and expectations in this NOFO. As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination.
  - Describe the methods that you would use in the development of effective tools and strategies for technical assistance training, outreach, collaborations, clear communication, and information sharing/dissemination.
  - Include a plan to disseminate reports, products, and/or project outputs to provide project information to key target audiences and the public.
  - Propose a plan for sustainability for the project beyond federal funding period.

Be sure to include how you will achieve the following activities:
  o Establish a national infrastructure that will:
    o Create a steering committee consisting of representatives of state newborn screening programs, public health, primary and specialty care practitioners, individuals or families with conditions detected by newborn screening, and other newborn screening stakeholders that will guide the project and identify best practices and areas of need within the newborn screening system.
    o Develop and maintain newborn screening case definitions and quality indicators to measure the performance of newborn screening programs in partnership with state newborn screening programs and other newborn screening stakeholders.
    o Develop a central web-based repository that includes:
      - Information on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators.
      - Aggregate data from state newborn screening programs on newborn screening quality indicators
      - State newborn screening program information, materials, best practices, policy initiatives, and resources on newborn screening for state newborn screening programs, public health officials, and primary and specialty care practitioners.
    o Implement data use agreements with state and territorial newborn screening programs to collect aggregated data on their newborn screening quality indicators.

o Collect, standardize and analyze aggregate quantitative and qualitative data from state and territorial newborn screening programs.
o Monitor and track, annually, the challenges and barriers that states may encounter throughout the data collection process for entering data into the data repository.
o Provide feedback, education, training and technical assistance to individual state and territorial newborn screening programs. This includes conducting onsite technical assistance at the request of states, providing a comprehensive report identifying areas of strengths and potential improvements, and assisting with quality improvement activities to strengthen the program.
o Provide technical assistance, education, and training to public health professionals, and primary and specialty care practitioners on newborn screening best practices (pre-analytic, analytic, and post analytic) and condition-specific issues.
o Develop and implement a program to assist states in adding conditions that are on the RUSP.
o Develop HL7 or other health information technology guides to support efforts to incorporate electronic messaging and ease data transfer between states and hospitals/birthing centers.
o Implement activities that will strengthen the integration of child health information systems among newborn screening programs, public health, and clinical practice.
o Develop a process to assess newborn screening in the United States through data collection and analysis, literature review, or other methods to identify best practices, areas in need of improvement, emerging issues, or emerging screening technologies (e.g., reaching high-risk populations or identifying gaps in evidence) and disseminate findings.
o Support an annual in-person meeting of state newborn screening programs, family leaders, and other newborn screening stakeholders, including families, to discuss and disseminate information about current and emerging newborn screening topics/issues. In addition, travel to or support key meetings to discuss and disseminate information about current and emerging newborn screening topics/issues. Describe how the proposed travel and/or meeting(s) are needed to support the goals and requirements of the program.
o Publish a State of Newborn Screening Report in years 1, 3, and 5, of the project that includes aggregate data on conditions screened, number of out-of-range results, number of true positives and other quality indicators of newborn screening. The report should identify successes and challenges in newborn screening.
o Collaborate with other federally funded programs related to newborn screening to reduce duplication such as the HRSA-funded newborn screening programs including The Newborn Screening Education and Family Support Center, the Newborns Screening Clearinghouse, and the Quality Improvement in Newborn Screening Program (HRSA-18-070); NIH-funded Newborn Screening Translational Research Network; and the CDC Newborn Screening Quality Assurance Program.

- *WORK PLAN -- Corresponds to Section V's Review Criteria) (2) Response (4) Impact and (5) Resources/ and Capabilities*

  - Describe the activities or steps that you will use to achieve each of the requirements and objectives proposed during the entire period of performance in the Methodology section. Use a timeline that includes each activity and identifies responsible staff. Identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application and further, to the extent to which these contributors reflect the cultural, racial, linguistic and geographic diversity of the population and communities served.
  - Identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application.

  Logic Model: You must submit a logic model for designing and managing the project (Attachment 1). A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this announcement, the logic model should summarize the connections between the:
  - o Goals of the project (e.g., objectives, reasons for proposing the intervention, if applicable)
  - o Assumptions (e.g., beliefs about how the program will work and support resources. Base assumptions on research, best practices, and experience.)
  - o Inputs (e.g., organizational profile, collaborative partners, key staff, budget, other resources)
  - o Target population (e.g., the individuals to be served)
  - o Activities (e.g., approach, listing key intervention, if applicable)
  - o Outputs (i.e., the direct products or deliverables of program activities), and
  - o Outcomes (i.e., the results of a program, typically describing a change in people or systems).

- *RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion (2) Response*

  - Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges.
  - Specifically, discuss the approaches of resolving challenges for the following:
    - o Establishing partnerships with different stakeholders
    - o Supporting states' data collection efforts

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria (3) Evaluative Measures and (5) Resources/Capabilities*

  - Describe the plan for the program performance evaluation to monitor ongoing processes and the progress towards the goals and objectives of the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key staff, budget, and other resources), key processes, and expected outcomes of the funded activities. The program performance evaluation should include monitoring of ongoing processes and the progress towards the goals, program requirements, and objectives of the project listed under Section I.1 in this NOFO, including specific, measurable, attainable, and realistic and time bound (SMART) objectives.
  - Describe the data collection strategy to collect, analyze and track data to measure process and impact/outcomes, and explain how the data will be used to inform program development and service delivery.
  - Describe any potential obstacles performance evaluation and your plan to address those obstacles.
  - Describe a plan to use data to demonstrate the impact of the program.
  - Describe the systems and processes that will support your organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management).

  Technical Support Capacity:

  - Describe the technology capacity in place to develop, implement, and host an online, interactive forum organized in a clear format for multiple audiences that promotes information sharing and dissemination of authoritative and/or evidence-based information.
  - Include a description and/or diagrams explaining how you will evaluate and make available information from various credible sources in the Newborn Screening Data Repository and Technical Assistance project. If applicable, include diagrams that show the flow of data from disparate systems.
  - Describe privacy and security measures that will be in place for the data repository.

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion (5) Resources/Capabilities*

  - Succinctly describe your organization's current mission and structure, scope of current activities, including an organizational chart, and describe how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations.
  - Describe qualifications, expertise, and experience working with newborn screening stakeholders including families, medical professionals, state newborn screening programs, other federally funded newborn screening programs, disease specific advocacy groups, and the general public.

- Provide information on time allocation for all key staff on proposed project activities.
- A steering committee should help advise you on project activities. Include information on the project steering committee and what expertise will be represented within the steering committee:
  - Describe how the expertise and input of the members will guide the project.
- Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings.
- Describe how the organization has the capacity to meet the unique needs of states to provide technical assistance for this program.
- Provide assurances that you will use the amounts received under this program to implement the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary and support the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.

NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response, (4) Impact and (5) Resources/Capabilities
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative (below)	(6) Support Requested

iii. Budget

See Section 4.1.iv of HRSA's *SF-424 Application Guide.* Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions included in the Application Guide and, *if applicable*, the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for funding, you will have a well-organized plan and by carefully following the approved plan can avoid audit issues during the implementation phase.

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable. Costs for travel may not exceed amounts in the approved budget without prior approval from HRSA and must support the goals and purpose of the program.

The Consolidated Appropriations Act, 2018 (P.L. 115-141), Division H, § 202, states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." See Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in FY 2019, as required by law.

iv. Budget Narrative
See Section 4.1.v. of HRSA's *SF-424 Application Guide*.

Temporary Reassignment of State and Local Personnel during a Public Health Emergency

Section 201 of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), Public Law 113-5 amends section 319 of the Public Health Service (PHS) Act to provide the Secretary of the Department of Health and Human Services (HHS) with discretion to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency upon request by a state or tribal organization. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to be reassigned on a voluntary basis to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with section 319(e). This authority terminates September 30, 2018. Please reference detailed information available on the Assistant Secretary for Preparedness and Response (ASPR) website via
http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

v. Program-Specific Forms
Program-specific forms are not required for application.

vi. Attachments
Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. You must clearly label **each attachment**.

Attachment 1: Work Plan and Logic Model
Attach the work plan for the project that includes all information detailed in

Section IV. ii. Project Narrative. Also include the required logic model in this attachment. If funds will be sub-awarded or expended on contracts, describe how your organization will ensure the funds are properly documented.

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's [SF-424 Application Guide](#))
Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff. Also, please include a description of your organization's time keeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

Attachment 3: Biographical Sketches of Key Personnel
Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch.

Attachment 4: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific)
Provide any documents that describe working relationships between your organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverable. Letters of agreement must be signed and dated.

Attachment 5: Project Organizational Chart
Provide a one-page figure that depicts the organizational structure of the project.

Attachment 6: Tables, Charts, etc.
To give further details about the proposal (e.g., Gantt or PERT charts, flow charts, etc.).

Attachment 7: For Multi-Year Budgets--5th Year Budget (NOT counted in page limit), if applicable
After using columns (1) through (4) of the SF-424A Section B for a 5-year period of performance, you will need to submit the budget for the 5th year as an attachment. Use the SF-424A Section B. See Section 4.1.iv of HRSA's [SF-424 Application Guide](#)

Attachment 8: Progress Report
(FOR COMPETING CONTINUATIONS ONLY)

A well-documented progress report is a required and important source of material for HRSA in preparing annual reports, planning programs, and communicating program-specific accomplishments. The accomplishments of competing continuation applicants are carefully considered; therefore, you should include previously stated goals and objectives in your application and emphasize the

progress made in attaining these goals and objectives. HRSA program staff reviews the progress report after Objective Review Committee evaluates the competing continuation applications. See Section V.2 Review and Selection Process for a full explanation of funding priorities and priority points.

The progress report should be a brief presentation of the accomplishments, in relation to the objectives of the program during the current period of performance. The report should include:

(1) <u>The period covered (dates)</u>

(2) <u>Specific objectives</u> - Briefly summarize the specific objectives of the project.

(3) <u>Results</u> - Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.

Attachments 9 – 15: Other Relevant Documents
Include here any other documents that are relevant to the application, including letters of support. Letters of support must be dated and specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.).

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

The Grants.gov registration process requires information in three separate systems:
- Dun and Bradstreet (http://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

For further details, see Section 3.1 of HRSA's *SF-424 Application Guide*.

ALERT from SAM.gov: If you are registering a <u>new</u> entity in <u>SAM.gov,</u> you must now provide an original, signed <u>notarized letter</u> stating that you are the authorized Entity Administrator before your registration will be activated by SAM.gov. Please read <u>these</u> <u>FAQs</u> to learn more about this process change. Applicants registering as a new entity in SAM.gov should plan for additional time associated with submission and review of the notarized letter. This change is effective March 23, 2018. Entities already registered in SAM.gov are advised to log into SAM.gov and review their registration information, particularly their financial information.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

4. Submission Dates and Times

Application Due Date
The due date for applications under this NOFO is *May 22, 2018 at 11:59 p.m. Eastern Time.* HRSA suggests submitting applications to Grants.gov at least **3 days before the deadline** to allow for any unforeseen circumstances.

See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

The Newborn Screening Data Repository and Technical Assistance Program is not subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's *SF-424 Application Guide* for additional information.

6. Funding Restrictions

You may request funding for a period of performance of up to 5 years, at no more than $1,500,000 per year (inclusive of direct **and** indirect costs). The FY 2018 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds under this announcement may not be used for the following purposes:
1) Providing cash payments to or on behalf of affected individuals.
2) Providing inpatient services.

3) Purchasing land or making capital improvements to property.
4) Providing for proprietary research or training.

Per the PHS Act § 1109(g) SUPPLEMENT NOT SUPPLANT.— Funds appropriated under this section shall be used to supplement and not supplant other federal, state, and local public funds provided for activities of the type described in this NOFO.

The General Provisions in Division H of the Consolidated Appropriations Act, 2018 (P.L. 115-141) apply to this program. Please see Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in FY2019, as required by law.

You are required to have the necessary policies, procedures and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding, including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all other applicable grants requirements, the effectiveness of these policies, procedures and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at 45 CFR § 75.307.

Costs for travel may not exceed amounts in the approved budget without prior approval from HRSA and must support the goals and purpose of the program.

7. Other Submission Requirements

Per Public Health Service Act, § 1109:
(c) Approval factors

An application for a grant under this section shall not be approved by the Secretary unless the application contains assurances that the eligible entity has adopted and implemented, is in the process of adopting and implementing, or will use amounts received under such grant to adopt and implement the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.

V. Application Review Information

1. Review Criteria

HRSA has instituted procedures for assessing the technical merit of applications to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. HRSA has developed critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. See the review criteria outlined below with specific detail and scoring points.

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review, except for the competing continuations' progress report, which will be reviewed by HRSA program staff after the objective review process.

Review criteria are used to review and rank applications. The Newborn Screening Data Repository and Technical Assistance Program has six review criteria:

Criterion 1: NEED (5 points) – Corresponds to Section IV's Introduction and Needs Assessment

- The extent to which the application describes the purpose of the proposed project including the target populations and their needs.
- The extent to which the application uses and cites demographic data whenever possible to support the information provided and include any relevant barriers in the service area that the project hopes.
- The extent to which the application demonstrates an understanding of newborn screening, state processes related to newborn screening, assessment, data management, and public health genetics.

Criterion 2: RESPONSE (45 points) – Corresponds to Section IV's Methodology, Work plan and Resolution of Challenges

The extent to which the proposed project responds to the "Purpose" in Section I of this NOFO. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

The extent to which the applicant describes an effective national approach:

Data Management (15 points)
- Developing and maintaining newborn screening case definitions and quality indicators to measure the performance of newborn screening programs in partnership with state newborn screening programs and other newborn screening stakeholders.
- Developing a central web-based repository that includes:

- Information on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators.
- Aggregate data from state newborn screening programs on newborn screening quality indicators.
- State newborn screening program information, materials, best practices, policy initiatives, and resources on newborn screening for state newborn screening programs, public health officials, and primary and specialty care practitioners.
- Implementing data use agreements with state and territorial newborn screening programs to collect aggregated data on their newborn screening quality indicators.
- Collecting, standardizing and analyzing aggregate quantitative and qualitative data from state and territorial newborn screening programs.
- Monitoring and tracking annually, the challenges and barriers that states may encounter throughout the data collection process for entering data into the data repository.

Technical Assistance (20 points)
- Providing feedback, education, training and technical assistance to individual state and territorial newborn screening programs. This includes conducting onsite technical assistance at the request of states, providing a comprehensive report identifying areas of strengths and potential improvements, and assisting with quality improvement activities to strengthen the program.
- Providing technical assistance, education, and training to public health professionals, and primary and specialty care practitioners on newborn screening best practices (pre-analytic, analytic, and post analytic) and condition-specific issues.
- Developing and implementing a program to assist states in adding conditions that are on the RUSP.
- Developing HL7 or other health information technology guides to support efforts to incorporate electronic messaging and ease data transfer between states and hospitals/birthing centers.
- Developing a process to assess newborn screening in the United States through data collection and analysis, literature review, or other methods to identify best practices, areas in need of improvement, emerging issues, or emerging screening technologies (e.g. reaching high-risk populations or identifying gaps in evidence) and disseminate findings.

Collaboration and Dissemination (10 points)
- Creating a steering committee consisting of representatives of state newborn screening programs, public health, primary and specialty care practitioners, individuals or families with conditions detected by newborn screening, and other newborn screening stakeholders that will guide the project and identify best practices and areas of need within the newborn screening system.
- Supporting an annual in-person meeting of state newborn screening programs, family leaders, and other newborn screening stakeholders, including families, to discuss and disseminate information about current and emerging newborn screening topics/issues.

- Publishing a State of Newborn Screening Report in year 1, 3, and 5, of the project that includes aggregate data on conditions screened, number of out-of-range results, number of true positives and other quality indicators of newborn screening. The report should identify successes and challenges in newborn screening.
- Implementing activities that will strengthen the integration of child health information systems among newborn screening programs, public health, and clinical practice. Collaborating with other federally funded programs related to newborn screening such as HRSA-funded newborn screening programs including Quality Improvement in Newborn Screening Program (HRSA-18-070); NIH-funded Newborn Screening Translational Research Network; and CDC's Newborn Screening Quality Assurance Program.

Criterion 3: EVALUATIVE MEASURES (10 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity

The strength and effectiveness of the method proposed to monitor and evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project. The program performance evaluation should include monitoring of ongoing processes and the progress towards the goals, program requirements, objectives, and impact. The extent to which a data collection strategy is described that can collect, analyze and track data to measure process and impact/outcomes.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Work Plan

The feasibility and effectiveness of plans for dissemination of project results, and the extent to which project results may be national in scope, and the degree to which the project activities are replicable, and the program is sustainable beyond the federal funding.

Criterion 5: RESOURCES/CAPABILITIES (25 points) – Corresponds to Section IV's Work Plan, Evaluation and Technical Support Capacity and Organizational Information

The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

The extent to which the application describes:

Organizational Structure (15 points)
- The organization's current mission and structure, scope of current activities, including an organizational chart, and describes how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations.

- Support for provisions of culturally and linguistically competent and health literate services.
- Qualifications, expertise, and experience working with newborn screening stakeholders including families, medical professionals, state newborn screening programs, other federally funded newborn screening programs, disease specific advocacy groups, and the general public.
- Time allocation for all key staff on proposed project activities.
- Steering committee expertise and how input will be used to advise the project.
- The organization's capacity to lead a national program and meet the unique needs of states to provide technical assistance for this program.
- Assurances that the amounts received under this program will be used to implement the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary and support the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.

Technology Capacity (10 points)

The extent to which the application describes:

- The technology capacity in place to develop, implement, and host an online, interactive forum organized in a clear format for multiple audiences that promotes information sharing and dissemination of authoritative and/or evidence-based information.
- A description and/or diagrams explaining how information from various credible sources will be evaluated and made available in the Newborn Screening Data Repository and Technical Assistance Program. If applicable, diagrams that show the flow of data from disparate systems.
- Privacy and security measures that will be in place for the data repository.

Criterion 6: SUPPORT REQUESTED (5 points) – Corresponds to Section IV's Budget and Budget Narrative

The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.

The extent to which key personnel have adequate time devoted to the project to achieve project objectives.

The extent to which travel funds allocated supports the goals of the program and are reasonable given the scope of work.

2. Review and Selection Process

The independent review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. In addition to the ranking based on merit criteria, HRSA approving officials may also apply other factors in award

selection, (e.g., geographical distribution), if specified below in this NOFO. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

Please see Section 5.3 of HRSA's *SF-424 Application Guide* for more details.

Funding Priorities
This program includes a funding priority. A funding priority is the favorable adjustment of combined review scores of individually approved applications when applications meet specified criteria. An adjustment is made by a set, pre-determined number of points. HRSA staff will determine the funding factor. The Newborn Screening Data Repository and Technical Assistance Program has one funding priority:

Priority 1: (5 points)
HRSA will award 5 points if you are a competing continuation applicant applying to continue to maintain the Newborn Screening Data Repository and Technical Assistance Program and HRSA determines that you have successfully achieved the current project goals and objectives based on progress reports submitted during the period of performance and a detailed progress report (submitted with this application) describing how the objectives were implemented and achieved.

3. Assessment of Risk and Other Pre-Award Activities

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (45 CFR § 75.205).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of

performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

HRSA will report to FAPIIS a determination that an applicant is not qualified (45 CFR § 75.212).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of July 1, 2018.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of July 1, 2018. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's *SF-424 Application Guide*.

Human Subjects Protection:
Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

Requirements under Subawards and Contracts under Grants
The terms and conditions in the Notice of Award (NOA) apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients and contractors under grants, unless the NOA specifies an exception. See 45 CFR § 75.101 Applicability for more details.

3. Reporting

The new Discretionary Grant Information System (DGIS) reporting system will continue to be available through the Electronic Handbooks (EHBs). HRSA enhanced the DGIS and these improvements are available for recipient reporting as of October 1, 2017. HRSA will communicate with recipients and provide instructions on how to access the system for reporting. HRSA will also provide technical assistance via webinars, written guidance, and one-on-one sessions with an expert, if needed.

The updated and final reporting package incorporating all OMB accepted changes can be reviewed at:

https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection (OMB Number: 0915-0298 Expiration Date: 06/30/2019).

Award recipients must comply with Section 6 of HRSA's *SF-424 Application Guide* **and** the following reporting and review activities:

1) **Progress Report**(s). The recipient must submit a progress report to HRSA on an **annual** basis, which should address progress against program outcomes, including any expected outcomes in the first year of the program. Further information will be provided in the award notice.

2) **Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.

3) **Performance Reports.** HRSA has modified its reporting requirements for Special Projects of Regional and National Significance projects, Community Integrated Service Systems projects, and other grant/cooperative agreement programs to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). GPRA requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act.

   a) **Performance Measures and Program Data**

   To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are at https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/U22_7.HTML and below.

Administrative Forms
Form 1, Project Budget Details
Form 2, Project Funding Profile
Form 3, Budget Details by Types of Individuals Served
Form 4, Project Budget and Expenditures
Form 6, Maternal & Child Health Discretionary Grant
Form 7, Discretionary Grant Project
Technical Assistance/Collaboration Form
Products Publications and Submissions Data Collection Form

Updated DGIS Performance Measures, Numbering by Domain
(All Performance Measures are revised from the previous OMB package)

Performance Measure	New/Revised Measure	Prior PM Number (if applicable)	Topic
Core			
Core 1	New	N/A	Grant Impact
Core 2	New	N/A	Quality Improvement
Capacity Building			
CB 1	New	N/A	State Capacity for Advancing the Health of MCH Populations
CB 2	New	N/A	Technical Assistance
CB 4	Revised	5	Sustainability
CB 6			Products
CB 7			State capacity for accessing electronic health data
Perinatal Infant Health			
PIH 3	New	N/A	Newborn Screening
Children and Youth with Special Health Care Needs			
CSHCN 1	Revised	7	Family Engagement

b) Performance Reporting Timeline

Successful applicants receiving HRSA funds will be required, within 120 days of the period of performance start date, to register in HRSA's EHBs and electronically complete the program-specific data forms that are required for this award. This requirement entails the provision of budget breakdowns in the financial forms based on the award amount, the project abstract and other grant/cooperative agreement summary data as well as providing objectives for the performance measures.

Performance reporting is conducted for each year of the period of performance. Recipients will be required, within 120 days of the budget period start date, to enter HRSA's EHBs and complete the program-specific forms. This requirement includes providing expenditure data,

finalizing the abstract and grant/cooperative agreement summary data as well as finalizing indicators/scores for the performance measures.

c) Period of Performance End Performance Reporting

Successful applicants receiving HRSA funding will be required, within 90 days from the end of the period of performance, to electronically complete the program-specific data forms that appear for this program. The requirement includes providing expenditure data for the final year of the period of performance, the project abstract and grant/cooperative agreement summary data as well as final indicators/scores for the performance measures.

4) **Integrity and Performance Reporting.** The Notice of Award will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

VII. Agency Contacts

You may request additional information and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Marc Horner
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Room 11-103
Rockville, MD 20857
Phone: (301) 443-4888
Fax: (301) 443-6686
Email: mhorner@hrsa.gov

You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Andrea M. Matthews
Public Health Analyst
Attn: Newborn Screening Data Repository and Technical Assistance Program
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18W05-A
Rockville, MD 20857
Telephone: (301) 945-3062
Fax: (301) 594-0878
Email: amatthews@hrsa.gov

You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
Email: support@grants.gov
Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's EHBs. For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center
Telephone: (877) 464-4772
TTY: (877) 897-9910
Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Logic Models

You can find additional information on developing logic models at the following website: http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. You can find information on how to distinguish between a logic model and work plan at the following website: http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf.

Technical Assistance

HRSA has scheduled the following technical assistance webinar:

Webinar

Day and Date: Wednesday, April 18, 2018
Time: 2 p.m. – 3 p.m. ET
Call-In Number: 1-866-723-2075
Participant Code: 51349380
Weblink: https://hrsa.connectsolutions.com/hrsa18080nbsta/

Please provide questions to the HRSA project officer prior to the scheduled webinar.

To access the archived webinar recording, please visit the HRSA MCHB Funding Opportunities Webpage: https://mchb.hrsa.gov/fundingopportunities/Default.aspx.

Tips for Writing a Strong Application

See Section 4.7 of HRSA's *SF-424 Application Guide.*