

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Health Resources & Services Administration

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

***Long-term Follow-up for Severe Combined Immunodeficiency and
Other Newborn Screening Conditions***

Funding Opportunity Number: HRSA-21-079
Funding Opportunity Type(s): New
Assistance Listings (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: May 3, 2021

*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 3, 2021

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2021 Long-term Follow-up for Severe Combined Immunodeficiency and Other Newborn Screening Conditions program. The goal of this program is to ensure that newborns and children identified through newborn screening (NBS) achieve the best possible outcomes by expanding the ability of state public health agencies to provide screening, counseling and services to these newborns and children and to collaborate with clinicians, public health agencies and families to create a system of care that can assess and coordinate follow-up and treatment of newborn screening conditions. The purpose of this program is to support comprehensive models of long-term follow-up that demonstrate collaborations between clinicians, public health agencies, and families.

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| Funding Opportunity Title: | Long-term Follow-up for Severe Combined Immunodeficiency and Other Newborn Screening Conditions |
| Funding Opportunity Number: | HRSA-21-079 |
| Due Date for Applications: | May 3, 2021 |
| Anticipated Total Annual Available FY 2021 Funding: | \$3,000,000 |
| Estimated Number and Type of Award(s): | Up to six (6) cooperative agreements |
| Estimated Award Amount: | Up to \$500,000 per year |
| Cost Sharing/Match Required: | No |
| Period of Performance: | August 1, 2021 through July 31, 2023 (2 years) |
| Eligible Applicants: | <p>Eligible applicants include: (1) a state or a political subdivision of a state; (2) a consortium of two or more states or political subdivisions of states; (3) a territory; (4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or (5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.</p> <p>Per 42 U.S.C. § 201, the term “state” includes, in addition to the several states, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. Domestic faith-based and community-based</p> |

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| | <p>organizations, tribes, and tribal organizations are also eligible to apply.</p> <p>See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.</p> |
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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.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Thursday, March 25, 2021

Time: 2–3 p.m. ET

Call-In Number: 1-866-617-1525

Participant Code: 37637400

Weblink: <https://hrsa.connectsolutions.com/hrsa21079/>

HRSA will record the webinar and make it available at:

<https://mchb.hrsa.gov/fundingopportunities/default.aspx>.

Table of Contents

| | |
|--|-----------|
| I. PROGRAM FUNDING OPPORTUNITY DESCRIPTION | 1 |
| 1. PURPOSE | 1 |
| 2. BACKGROUND..... | 2 |
| II. AWARD INFORMATION..... | 3 |
| 1. TYPE OF APPLICATION AND AWARD | 3 |
| 2. SUMMARY OF FUNDING | 4 |
| III. ELIGIBILITY INFORMATION | 4 |
| 1. ELIGIBLE APPLICANTS | 4 |
| 2. COST SHARING/MATCHING..... | 4 |
| 3. OTHER | 4 |
| IV. APPLICATION AND SUBMISSION INFORMATION | 5 |
| 1. ADDRESS TO REQUEST APPLICATION PACKAGE | 5 |
| 2. CONTENT AND FORM OF APPLICATION SUBMISSION | 6 |
| <i>i. Project Abstract.....</i> | <i>8</i> |
| <i>ii. Project Narrative.....</i> | <i>8</i> |
| <i>iii. Budget.....</i> | <i>11</i> |
| <i>iv. Budget Narrative.....</i> | <i>12</i> |
| <i>v. Program-Specific Forms.....</i> | <i>12</i> |
| <i>vi. Attachments.....</i> | <i>12</i> |
| 3. DUN AND BRADSTREET DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER TRANSITION TO THE UNIQUE ENTITY IDENTIFIER (UEI) AND SYSTEM FOR AWARD MANAGEMENT (SAM) | 13 |
| 4. SUBMISSION DATES AND TIMES | 14 |
| 5. INTERGOVERNMENTAL REVIEW | 15 |
| 6. FUNDING RESTRICTIONS | 15 |
| V. APPLICATION REVIEW INFORMATION..... | 16 |
| 1. REVIEW CRITERIA | 16 |
| 2. REVIEW AND SELECTION PROCESS | 18 |
| 3. ASSESSMENT OF RISK | 18 |
| VI. AWARD ADMINISTRATION INFORMATION..... | 18 |
| 1. AWARD NOTICES..... | 19 |
| 2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS | 19 |
| 3. REPORTING | 20 |
| VII. AGENCY CONTACTS | 22 |
| VIII. OTHER INFORMATION..... | 23 |

I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Long-term Follow-up for Severe Combined Immunodeficiency and Other Newborn Screening Conditions program. The goal of this program is to ensure that newborns and children identified through newborn screening (NBS) achieve the best possible outcomes by expanding the ability of state public health agencies to provide screening, counseling and services to these newborns and children and to collaborate with clinicians, public health agencies and families to create a system of care that can assess and coordinate follow-up and treatment of newborn screening conditions.¹ This NOFO supports this goal by making available funding to support comprehensive models of long-term follow-up (LTFU) that demonstrate collaborations between clinicians, public health agencies, and families.

LTFU models supported under this program should:

- 1) Facilitate the collection and integration of data from public health and clinical information systems to assess, inform, and ultimately achieve comprehensive LTFU of individuals identified through NBS with severe combined immunodeficiency (SCID) or other NBS conditions on the [Recommended Uniform Screening Panel](#).
- 2) Implement and evaluate LTFU model systems building on the Advisory Committee on Heritable Disorders in Newborns and Children's framework that LTFU models assure the provision of quality chronic disease management, condition-specific treatment, and age-appropriate preventive care throughout the lifespan.^{2,3}

LTFU models supported under this program also should focus on:

- 1) Facilitating electronic data sharing among clinicians and public health databases to ensure no infant is lost to follow-up and infants, children, and their families have access to appropriate services.
- 2) Ensuring infants and children identified through NBS with SCID or other NBS conditions receive comprehensive, coordinated, family-centered care through a medical home throughout the lifespan.
- 3) Providing evidence-based/informed, condition-specific treatments and age-appropriate preventive care for infants and children with SCID or other NBS conditions, including using telehealth to link medically underserved populations to knowledgeable clinicians.
- 4) Equipping families with knowledge and ability to participate as equal partners in decision-making in all aspects of care.
- 5) Increasing partnerships and collaboration with primary and specialty clinicians, state NBS programs, state public health and maternal and child health programs,

¹ 42 U.S.C. § 300b-8(a)(1) and (a)(4) (§1109(a)(1) and (a)(4) of the Public Health Service Act)

² Kemper AR, Boyle CA, Aceves J, et al. Long-term follow-up after diagnosis resulting from newborn screening: statement of the US Secretary of Health and Human Services' Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. *Genet Med*. 2008;10(4):259-261

³ Kemper AR, Boyle CA, Brosco JP, Grosse SD. Ensuring the Life-Span Benefits of Newborn Screening. *Pediatrics*. 2019;144(6):e20190904.

parents/families, condition-specific organizations, laboratorians, researchers, education, and relevant community services.

- 6) Developing a set of LTFU quality measures at multiple levels and systems of care with associated data sources that can be used to conduct quality improvement projects to address LTFU gaps.
- 7) Collecting LTFU data from at least five different clinical sites to assess and evaluate LTFU activities. Data collected under this program must follow all institutional regulations and guidance as appropriate; data reported as part of the performance reporting must be in aggregate form and non-identifiable. Please see the [Data Rights](#) section of this NOFO for more information.

Program Objectives

- By July 2022, implement LTFU model protocols and data collection with at least five clinical sites.
- By July 2023, demonstrate integration of LTFU model data from clinical and public health systems.
- By July 2023, increase by 20 percent from baseline the number of infants, children, and families who receive coordinated LTFU care through a medical home consistent with the LTFU model, as documented through submissions to data systems.

Baseline data must be submitted at the time of application.

2. Background

This program is authorized by 42 U.S.C. § 300b-8(a)(1) and (a)(4).

Newborn screening (NBS) is an effective public health program that saves and improves the lives of thousands of newborns each year in the United States. Four million newborns each year are screened for conditions that require early diagnosis, intervention, and treatment to mitigate brain and organ damage, severe illness, cognitive and developmental delays, and life-threatening complications. Some of the conditions on NBS panels can be life threatening in the first week of life, so it is crucial that NBS is effective and efficient. NBS includes bloodspot screening for certain genetic, endocrine, and metabolic disorders, hearing screening, and screening for critical congenital heart disease.⁴

Most NBS conditions are chronic and require medical care throughout an individual's life. LTFU in NBS consists of providing quality chronic disease management, condition-specific treatment, and age-appropriate preventative care. In addition, LTFU care should include care coordination through a medical home, evidence-based treatment, continuous quality improvement, and new knowledge discovery.⁵

LTFU care is complex and often lacks coordination. Many of the NBS conditions may not have effective models of long-term treatment, and knowledgeable clinicians may not be easily accessible. Families must interact with a variety of clinicians, genetic

⁴ New born Screening Portal, Centers for Disease Control and Prevention, <https://www.cdc.gov/newbornscreening/index.html>, accessed November 1, 2020.

⁵ Kemper AR, Boyle CA, Brosco JP, Grosse SD. Ensuring the Life-Span Benefits of New born Screening. *Pediatrics*. 2019;144(6):e20190904.

counselors, public health nurses, laboratories, public and/or private payers, and pharmacists and lack support in navigating these interactions.⁴

This program supports models of LTFU that demonstrate collaborations between clinicians that provide LTFU services, state public health agencies, and families to create models that address all components of LTFU care. These models should include coordinated care that is condition-specific, evidence-informed, and family-centered. In addition, these models should incorporate electronic sharing/exchange of information between clinical sites and state public health departments to decrease loss to follow-up and ensure all infants and children identified with SCID or other NBS conditions are receiving optimal care and are connected to needed services.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where HRSA anticipates substantial involvement with the recipient during performance of the contemplated project.

HRSA program involvement will include:

- Participating in meetings conducted during the period of the cooperative agreement;
- Collaborating with recipients in developing activities and procedures to be established and implemented for accomplishing the goals and objectives of the project;
- Reviewing information on project activities, reports, and products prior to dissemination;
- Participating in dissemination of project information;
- Providing assistance in establishing and facilitating effective collaborative relationships with federal and state agencies, and especially HRSA MCHB award projects; and
- Providing technical assistance and support to recipients to ensure they are compliant with NOFO requirements and do not duplicate the work of other HRSA-funded projects.

The cooperative agreement recipient's responsibilities will include:

- Conducting all tasks as they relate to the goals, purpose, and required activities listed in the Purpose and Program-Specific sections;
- Reviewing, on a continuous basis, activities and procedures to be established and implemented for accomplishing the program's goals, objectives, and activities;
- Providing ongoing, timely communication and collaboration with the federal project officer;
- Working with the federal project officer to review information on program activities, reports, and products prior to dissemination;
- Establishing contacts that may be relevant to the project's mission;

- Facilitating partnerships with federal and non-federal entities and other HRSA-funded programs relevant to the program activities; and
- Meeting deadlines for information requests and reports as required by HRSA.

2. Summary of Funding

HRSA estimates approximately \$3,000,000 to be available annually to fund six (6) recipients. You may apply for a ceiling amount of up to \$500,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is August 1, 2021 through July 31, 2023 (2 years). Funding beyond the first year is subject to the availability of appropriated funds for the Long-term Follow-up for Severe Combined Immunodeficiency and Other Newborn Screening Conditions program 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

Per statute, eligible applicants include: (1) a state or a political subdivision of a state; (2) a consortium of two or more states or political subdivisions of states; (3) a territory; (4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or (5) any other entity with appropriate expertise in NBS, as determined by the Secretary.

Per 42 U.S.C. § 201, the term “state” includes, in addition to the several states, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

Domestic faith-based and community-based organizations, tribes, and tribal organizations are also eligible to apply.

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 notice.

HRSA will consider any application that exceeds the page limit referenced in [Section IV](#) non-responsive and will not consider it for funding under this notice.

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 notice.

NOTE: Multiple applications from an organization are not allowable.

HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

APPROVAL FACTORS

Per statute, an application for a grant under this section shall not be approved by the Secretary unless the application contains assurances (as *Attachment 7*) 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 on Heritable Disorders in Newborns and Children (ACHDNC) 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 ACHDNC and adopted by the Secretary.

SUPPLEMENT NOT SUPPLANT

Per statute, 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 section. Accordingly, recipients must ensure that they do use funds made available under this NOFO to supplement and not supplant other federal, state, and local public funds provided for activities of the type described in this NOFO.

VOLUNTARY PARTICIPATION

Per statute, the participation by any individual in any program or portion thereof established or operated with funds received under this section shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, another federal or state program.

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 notice of funding opportunity (NOFO) following the directions provided at <http://www.grants.gov/applicants/apply-for-grants.html>.

The NOFO is also known as “Instructions” on Grants.gov. You must select “Subscribe” and provide your email address for each NOFO you are reviewing or preparing in the workspace application package in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive

notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. *You are ultimately responsible for reviewing the [For Applicants](#) page for all information relevant to this NOFO.*

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 application 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 included in the page limit shall 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. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-079, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit. Any application exceeding the page limit of 80 will not be read, evaluated, or considered for funding.**

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are 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 you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 8: Other Relevant Documents*.

See Section 4.1 viii of HRSA's [SF-424 Application Guide](#) for additional information on all certifications.

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

Section 319(e) of the Public Health Service (PHS) Act provides the Secretary of the Department of Health and Human Services (HHS) with discretion upon request by a state or tribal organization to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency. 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 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 § 319(e). Please reference detailed information available on the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) website via <http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx>.

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), ensure details related to the following required activities are included:

Establish statewide collaborations to develop, implement, and evaluate models of LTFU. Collaborations should include:

- At least five clinical sites that provide LTFU care for SCID or other NBS conditions.
- State public health departments, including NBS programs.
- Other partners including condition-specific advocacy organizations, community based organizations, hospitals, and/or primary care providers.

Conduct LTFU care.

- Ensure infants identified with SCID or other NBS conditions receive coordinated care through a medical home.
- Provide evidence-based/informed, condition-specific treatments and age-appropriate preventive care for infants and children with SCID or other NBS conditions, including using telehealth to link medically underserved populations to knowledgeable clinicians.
- Ensure families are equal partners in decision-making and all aspects of their child's care.

Increase the knowledge base of LTFU care.

- Create and implement LTFU protocols that are condition-specific, evidence-informed, and family-centered.
- Collect LTFU data per institutional regulations as appropriate from at least five different clinical sites to assess and evaluate LTFU activities.
- Develop a set of LTFU quality measures at multiple levels and systems of care with associated data sources that can be used to conduct

Data collection and data sharing.

- Facilitate electronic data sharing/exchange among clinicians and public health databases to ensure no infant is lost to follow-up, and infants, children, and their families have access to appropriate services. Activities may include:
 - improving the collection, sharing and exchange of data across data systems
 - linking data across multiple settings, including health and educational systems, to conduct population-based analyses
- Contribute LTFU data as appropriate to a registry such as the Longitudinal Pediatric Data Resource housed at the Newborn Screening Translational Research Network funded by the National Institutes of Health, Eunice Kennedy Shriver National Institutes of Child Health and Human Development (NICHD).

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, consistent with forms and attachments, 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](#)
Briefly describe the purpose of the proposed project.
- ***NEEDS ASSESSMENT*** -- Corresponds to Section V's Review Criterion 1 [Need](#)
Outline the needs of the infants and children diagnosed with SCID or other NBS conditions for the target population and identify the geographic area that will be served. Describe and document the target populations and its unmet health needs. Use and cite demographic data whenever possible to support the information provided. Discuss any relevant barriers in the service area that the project hopes to overcome. Describe the long-term needs of infants and children diagnosed with SCID or other NBS conditions. Discuss the challenges and barriers these children and their families encounter after diagnosis as well as gaps within LTFU care. This section will help reviewers understand the communities that you will serve with the proposed project.
- ***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 and expectations in this NOFO under [Purpose](#) and [Program-Specific Instructions](#). As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination with efforts to involve patients, families, and communities. If applicable, include a plan to disseminate reports, products, and/or project outputs so key target audiences receive the project information.

Describe the LTFU model and protocol(s) you intend to implement and evaluate.

Describe the partners and collaborators that you will work with as documented through MOUs.

Describe the data systems that will be used to collect, analyze, and share LTFU data.

Describe how you will ensure families are equal partners in decision-making at all levels of implementing and evaluating the LTFU protocol and care and how families will be supported.

Describe a plan for conducting a quality improvement project to address gaps in LTFU activities.

Include a description of any innovative methods that you will use to address the stated needs.

Propose a plan for project sustainability after the period of federal funding ends. HRSA expects recipients to sustain key elements of their projects, e.g., strategies or services and interventions, which have been effective in improving practices and those that have led to improved outcomes for the target population.

- *WORK PLAN -- Corresponds to Section V's Review Criteria 2 [Response](#) and 4 [Impact](#)*

Work Plan (Attachment 1)

Describe the activities or steps that you will use to achieve each of the objectives proposed during the entire period of performance in the Methodology section. Use a time line that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities, including developing the application.

Logic Model (Attachment 1)

Submit a logic model for designing and managing the project. 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 notice, the logic model should summarize the connections between the:

- Goals of the project (e.g., reasons for proposing the intervention, if applicable);
- Assumptions (e.g., beliefs about how the program will work and support resources. Base assumptions on research, best practices, and experience.);
- Inputs (e.g., organizational profile, collaborative partners, key personnel, budget, other resources);
- Target population (e.g., the individuals to be served);
- Activities (e.g., approach, listing key intervention, if applicable);
- Outputs (i.e., the direct products of program activities); and

- Outcomes (i.e., the results of a program, typically describing a change in people or systems).

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 additional information on developing logic models at the following website:

https://www.acf.hhs.gov/sites/default/files/documents/prep-logic-model-ts_0.pdf.

- **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 address how you will overcome barriers in identifying infants and children with SCID or other NBS conditions and providing LTFU care.

- **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 that will contribute to continuous quality improvement. The program performance evaluation should 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 personnel, budget, and other resources), key processes, and expected outcomes of the funded activities. Be sure to include baseline data for the program objectives listed under the Purpose section.

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 software) in a way that allows for accurate and timely reporting of performance outcomes. Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. As appropriate, 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 for implementing the program performance evaluation and your plan to address those obstacles.

Describe how you will develop, collect, and share standardized data elements across participating sites. Provide a plan for you will obtain Internal Review Board (IRB) approvals so that data can be shared with relevant partners including state public health programs.

Within the proposed evaluation plan keep in mind that the following should also be tracked and reported in the annual progress report during the period of performance:

- Percent of families reporting they are currently receiving specialty care for the condition.
 - Percent of patients with a medical home.
 - Number of formal and informal partnerships developed with primary and specialty clinicians, state NBS programs, state public health and maternal and child health programs, parents/families, condition-specific organizations, laboratorians, researchers, education, and relevant community services.
 - Percent of families who report their needs are being met.
 - Percent of infants lost to follow-up.
- **ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion 5 [Resources/Capabilities](#)**
Succinctly describe your organization's current mission, structure, and scope of current activities, and how these elements all contribute to the organization's ability to implement the program requirements and meet program expectations. Include an organizational chart (*Attachment 5*). 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 you will routinely assess and improve the unique needs of target populations of the communities served.

iii. Budget

The directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's [SF-424 Application Guide](#) and 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, may 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) you incur to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by you to satisfy a matching or cost-sharing requirement, as applicable.

The Consolidated Appropriations Act, 2021 (P.L. 116-260), 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 the following fiscal years, as required by law.

iv. Budget Narrative

See Section 4.1.v. of HRSA's [SF-424 Application Guide](#).

| 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. Any attachments referenced in a narrative section may be considered during the objective review. | |
| <u>Narrative Section</u> | <u>Review Criteria</u> |
| Introduction | (1) Need |
| Needs Assessment | (1) Need |
| Methodology | (2) Response |
| Work Plan | (2) Response and (4) Impact |
| 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 | (6) Support Requested |

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. **Clearly label each attachment.**

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in [Section IV.2.ii. Project Narrative](#). Also include the required logic model in this attachment. If you will make subawards or expend funds on contracts, describe how your organization will ensure proper documentation of funds.

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 timekeeping 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 not yet hired, 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. Make sure any letters of agreement are 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).

Attachment 7: Assurances as detailed in the [APPROVAL FACTORS](#) section.

Briefly describe (not more than one page) how program activities support or will support the ACHDNC guidelines and recommendations.

Attachments 8–15: 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 Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. In April 2022, the *DUNS number will be replaced by the UEI, a “new, non-proprietary identifier” requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following pages: [Planned UEI Updates in Grant Application Forms](#) and [General Service Administration’s UEI Update](#).

You must also register with 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)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements and, if you have not fully complied with the requirements by the time HRSA is ready to make an award, you may be deemed 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.

*Currently, 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](#).

[SAM.GOV](#) ALERT: For your SAM.gov registration, you must submit a [notarized letter](#) appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages and the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at [SAM.gov](#).

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 3, 2021 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar 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 Long-term Follow-up for Severe Combined Immunodeficiency and Other Newborn Screening Conditions program is not a program 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 2 years, at no more than \$500,000 per year (inclusive of direct **and** indirect costs). 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.

The General Provisions in Division Hof the Consolidated Appropriations Act, 2021 (P.L.116-260) 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 following fiscal years, as required by law.

Per statute, you cannot use funds under this notice for the following purposes:

- 1) to provide cash payments to or on behalf of affected individuals;
- 2) to provide inpatient services;
- 3) to purchase land or make capital improvements to property; or
- 4) to provide for proprietary research or training.

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.

Be aware of the requirements for HRSA recipients and subrecipients at 2 CFR § 200.216 regarding prohibition on certain telecommunications and video surveillance services or equipment. For details, see the [HRSA Grants Policy Bulletin Number: 2021-01E](#).

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](#).

V. Application Review Information

1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has 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.

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.

Review criteria are used to review and rank applications. The Long-term Follow-up for Severe Combined Immunodeficiency and Other Newborn Screening Conditions program has six review criteria. See the review criteria outlined below with specific detail and scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's [Introduction](#) and [Needs Assessment](#)

The clarity with which the applicant describes the problem, associated contributing factors to the problem and supports the problem/need statement with data/statistics, references and expert views.

This includes the extent to which the application:

- Documents the long-term needs of infants and children diagnosed with SCID or other NBS conditions within the proposed geographic area.
- Documents the challenges and barriers children and their families encounter after diagnosis.
- Documents gaps within LTFU care.

Criterion 2: RESPONSE (40 points) – Corresponds to Section IV's [Methodology](#), [Work Plan](#), and [Resolution of Challenges](#)

The extent to which the proposed project responds to the “[Purpose](#)” included in the program description. 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.

Methodology (20 Points)

The strength, completeness, and feasibility of the applicant's approach to addressing the purpose, objectives, program requirements, and expectations in this NOFO and under [Purpose](#) and [Program-Specific](#) Instructions including:

- Developing, implementing, and evaluating LTFU protocols and model.
- Using innovative methods, such as implementing telehealth to address the stated needs.
- Developing a plan for project sustainability after the period of federal funding ends.

- Sustaining key elements of their projects, e.g., strategies or services and interventions, which have been effective in improving practices and those that have led to improved outcomes for the target population.

Work Plan and Logic Model (10 points)

- The coherence between and completeness of activities or steps that will be used to achieve each of the corresponding objectives proposed in the methodology section.
- The extent to which the application identifies meaningful support and collaboration with key stakeholders in planning, designing, and implementing activities.
- The clarity and completeness of the logic model, demonstrating a clear relationship among resources, activities, outputs, target population, short-term outcomes, and long-term outcomes.

Resolution of Challenges (10 points)

- The thoroughness with which the application discusses potential challenges and the feasibility of proposed approaches to resolve such challenges.

Criterion 3: EVALUATIVE MEASURES (15 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, 2) to what extent these can be attributed to the project, and 3) the capability of the applicant to collect and report on Program Objectives and data specified under the Evaluation and Technical Support Capacity section.

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

The extent to which the proposed project has a public health impact and the project will be effective, if funded. This may include: the effectiveness of plans for dissemination of project results, the impact results may have on the community or target population, the extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

Criterion 5: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV's [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.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's [Budget](#) and [Budget Narrative](#)

The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives, and the anticipated results.

- 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.

2. Review and Selection Process

The objective 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. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (e.g., geographical distribution) described below in selecting applications for award. See Section 5.3 of HRSA's [SF-424 Application Guide](#) for more details.

3. Assessment of Risk

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.

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 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](#)).

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of August 1, 2021. 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](#).

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Requirements of Subawards

The terms and conditions in the 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 under awards, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See [45 CFR § 75.101 Applicability](#) for more details.

Data Rights

All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, 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 award 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 others. If applicable, the specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

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 you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

- Please refer to instructions provided in HRSA's [SF-424 Application Guide](#), Appendix Supplemental Instructions for Preparing the Protection of Human

Subjects Section of the Research Plan and Human Subjects Research Policy for specific instructions on preparing the human subjects section of the application.

- Please refer to HRSA's [SF-424 Application Guide](#) to determine if you are required to hold a Federal Wide Assurance (FWA) of compliance from the Office of Human Research Protections (OHRP) prior to award. You must provide your Human Subject Assurance Number (from the FWA) in the application. If you do not have an assurance, you must indicate in the application that you will obtain one from OHRP prior to award.
- In addition, you must meet the requirements of the HHS regulations for the protection of human subjects from research risks, including the following: (1) discuss plans to seek IRB approval or exemption; (2) develop all required documentation for submission of research protocol to IRB; (3) communicate with IRB regarding the research protocol; (4) communicate about IRB's decision and any IRB subsequent issues with HRSA.
- IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the [Methods](#) portion of the Project Narrative section.

3. Reporting

Award recipients must comply with Section 6 of HRSA's [SF-424 Application Guide](#) and the following reporting and review activities:

- 1) **DGIS Performance Reports.** Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report **annually**, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at <https://grants4.hrsa.gov/DGISReview/FormAssignmentList/U1W.html>. The type of report required is determined by the project year of the award's period of performance.

| Type of Report | Reporting Period | Available Date | Report Due Date |
|---|---|---|----------------------------------|
| a) New Competing Performance Report | August 1, 2021 – July 31, 2023 <i>(administrative data and performance measure projections, as applicable)</i> | Period of performance start date | 120 days from the available date |
| b) Non-Competing Performance Report | August 1, 2021 – July 31, 2022 | Beginning of each budget period (Year 2, as applicable) | 120 days from the available date |
| c) Project Period End Performance Report | August 1, 2022 – July 31, 2023 | Period of performance end date | 90 days from the available date |

The full OMB-approved reporting package is accessible at <https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection> (OMB Number: 0915-0298 | Expiration Date: 06/30/2022).

- 2) **Progress Report(s)**. The recipient must submit a progress report narrative to HRSA **annually** via the Non-Competing Continuation Renewal in the EHBs, which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year). Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA.
- 3) **Integrity and Performance Reporting**. The NOA will contain a provision for integrity and performance reporting in [FAPIS](#), as required in [45 CFR part 75 Appendix XII](#).

Please note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at [2 CFR § 200.340 - Termination](#) apply to all federal awards effective August 13, 2020.

VII. Agency Contacts

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

Kaleema Ameen
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 442-7061
Email: KAmeen@hrsa.gov

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

Mabatemije Otubu, RN, MPH
Public Health Analyst, Genetic Services Branch
Attn: Long-term Follow-up for Severe Combined Immunodeficiency and Other
Newborn Screening Conditions
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 594-4462
Email: MOtubu@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 Electronic Handbooks \(EHBs\)](#). For assistance with submitting information in the 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

Technical Assistance

HRSA has scheduled following technical assistance:

Webinar

Day and Date: Thursday, March 25, 2021

Time: 2–3 p.m. ET

Call-In Number: 1-866-617-1525

Participant Code: 37637400

Weblink: <https://hrsa.connectsolutions.com/hrsa21079/>

HRSA will record the webinar and make it available at:

<https://mchb.hrsa.gov/fundingopportunities/default.aspx>.

Tips for Writing a Strong Application

See Section 4.7 of HRSA's [SF-424 Application Guide](#).