

U.S. Department of Health and Human Services



Health Resources & Services Administration

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2023

Maternal and Child Health Bureau

Division of Services for Children with Special Health Needs

State Newborn Screening System Priorities Program (NBS Propel)

Funding Opportunity Number: HRSA-23-065

and

National Center for Newborn Screening System Excellence (NBS Excel)

Funding Opportunity Number: HRSA-23-077

Funding Opportunity Type(s): New, Competing Continuation

Assistance Listings Number: 93.110

Application Due Date: February 13, 2023

Ensure your [SAM.gov](https://sam.gov) and [Grants.gov](https://grants.gov) registrations and passwords are current immediately!

HRSA will not approve deadline extensions for lack of registration.

Registration in all systems may take up to 1 month to complete.

Issuance Date: November 14, 2022

Modified on November 17, 2022, to correct bookmark errors on page 5.

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See [Section VII](#) for a complete list of agency contacts.

Authority: HRSA-23-065, NBS Propel: 42 U.S.C. § 300b-9 (Public Health Service Act §1110, as amended)

HRSA-23-077, NBS Excel: 42 U.S.C. § 300b-8 (Public Health Service Act §1109, as amended)

508 COMPLIANCE DISCLAIMER

Note: Persons using assistive technology may not be able to fully access information in this file. For assistance, email or call one of the HRSA staff listed in [Section VII. Agency Contacts](#).

EXECUTIVE SUMMARY

The [Health Resources and Services Administration \(HRSA\)](#) is accepting applications for its Newborn Screening (NBS) Program, which consists of two projects to be funded in fiscal year (FY) 2023 through this Notice of Funding Opportunity: HRSA-23-065: State Newborn Screening Priorities Program (NBS Propel) and HRSA-23-077: National Center for Newborn Screening System Excellence (NBS Excel). The overall purpose of the NBS Program is to strengthen the NBS system to provide screening, counseling, and health care services to newborns and children with, or at risk for, heritable disorders and help them achieve the best possible outcomes.

This announcement includes instructions for **two separate award competitions leading to two distinct sets of awards**:

HRSA-23-065: State Newborn Screening Priorities Program (NBS Propel) will support up to 25 state/territory NBS programs to 1) address state/territory-specific challenges and pursue priorities to enhance, improve, and expand their NBS System; 2) address timely collection and reporting of NBS specimens to improve early diagnosis and treatment for individuals with heritable conditions identified through NBS; and 3) support long-term follow-up (LTFU) for individuals with Severe Combined Immunodeficiency (SCID) and other NBS conditions that link public health agencies, clinicians, and meaningfully engages and partners with families. .

HRSA-23-077: National Center for Newborn Screening System Excellence (NBS Excel) will support one national organization to 1) provide leadership, technical assistance (TA), and quality improvement expertise to state NBS programs; 2) collect data to identify barriers to achieving health equity and equitable access to NBS services for all infants and families; 3) enhance state performance in NBS; and 4) provide subject matter expertise, TA and training, education, and other resources to youth and families in order to promote meaningful engagement of, active partnership with, and leadership by families and/or individuals with heritable disorders at all levels of the newborn screening system.

Funding Opportunity Titles/Numbers:	HRSA-23-065: State NBS System Priorities Program (NBS Propel) HRSA-23-077: National Center for NBS System Excellence (NBS Excel)
Due Date for Applications:	February 13, 2023
Anticipated FY 2023 Total Available Funding:	HRSA-23-065: \$8,600,000 HRSA-23-077: \$2,300,000
Estimated Number and Type of Award(s):	HRSA-23-065: 25 grants HRSA-23-077: One (1) cooperative agreement
Estimated Annual Award Amount:	HRSA-23-065: Up to \$345,000 per year subject to availability of appropriated funds HRSA-23-077: Up to \$2,300,000 per year subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	July 1, 2023 through June 30, 2028 (5 years)
Eligible Applicants:	HRSA-23-065 Eligible applicants include: a state or political subdivision of a state, or a consortium of two or more states or political subdivisions of states. HRSA-23-077 Eligible applicants include: (1) a state or a political subdivision of a state; (2) a consortium of 2 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. Domestic faith-based and community-based organizations, tribes, and tribal organizations are also eligible to apply. Per 42 U.S.C. § 201, the term “state” includes, in addition to the several states, only the District of

	<p>Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.</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 this NOFO and in [HRSA's SF-424 Application Guide](#). Visit [HRSA's How to Prepare Your Application page](#) for more information.

Technical Assistance

HRSA has scheduled the following webinars:

Project 1: State Newborn Screening Priorities Program (NBS Propel) Webinar:

Monday, December 12, 2022

2 p.m.— 3 p.m. ET

Weblink:

<https://hrsa.gov.zoomgov.com/j/1613070546?pwd=UjBZMENZdmJFQTE5bEwzUXIUNDdoZz09>

Attendees without computer access or computer audio can use the dial-in information below.

Call-In Number: 1-833-568-8864

Meeting ID: 23075779

Project 2: National Center for Newborn Screening Systems Excellence (NBS Excel) Webinar:

Thursday, December 8, 2022

10 a.m. — 11 a.m. ET

Weblink:

<https://hrsa.gov.zoomgov.com/j/1615211386?pwd=K2ZqWmVQQ1VSVzIQU25EM05nVDBXQT09>

Attendees without computer access or computer audio can use the dial-in information below.

Call-In Number: 1-833-568-8864

Meeting ID: 05643352

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding for the Newborn Screening (NBS) Program that consists of two separate projects to be awarded in fiscal year (FY) 2023 – HRSA-23-065: the State Newborn Screening Priorities Program (NBS Propel) and HRSA-23-077: the National Center for Newborn Screening System Excellence (NBS Excel). The purpose of the NBS Program is to strengthen the NBS system to provide screening, counseling, and health care services to newborns and children with, or at risk for, heritable disorders and help them achieve the best possible outcomes.

This announcement includes instructions for applying to **two separate awards**. You may only apply for HRSA-23-065 **or** HRSA-23-077, but not both projects.

Goal

The goal of the NBS program is to improve health outcomes by early screening, diagnosis, and treatment of newborns and children with heritable disorders identified by NBS.

HRSA-23-065: State Newborn Screening Priorities Program (NBS Propel)

The purpose of NBS Propel is to support state/territory NBS programs addressing state/territory-specific challenges; pursue priorities to enhance, improve, and expand the NBS System; improve on NBS timeliness; support implementation of new conditions added to the [Recommended Uniform Screening Panel](#); and increase access to treatment and follow-up activities for individuals and their families with conditions identified through NBS.

NBS Propel has two focus areas:

Focus Area 1 includes activities related to improving collection of specimens, testing of specimens, and reporting out results, including improving the [timeliness of these activities](#); and implementing screening for newly added RUSP conditions.

Focus Area 2 includes activities related to improving short-term follow-up¹ through long-term follow-up² and helping families understand and navigate the process from confirmation of a diagnosis to treatment, and through follow-up across the lifespan.

¹ For the purposes of this NOFO, short-term follow-up refers to the process of ensuring that all newborns are screened, that an appropriate follow-up caregiver is informed of results, that confirmatory testing has been completed, and that the infant has received a diagnosis and, if necessary, treatment. *Bellcross, Cecelia A. et al. "Infrastructure and Educational Needs of Newborn Screening Short-Term Follow-Up Programs Within the Southeast Regional Newborn Screening & Genetics Collaborative: A Pilot Survey." Healthcare (Basel) 3.4 (2015): 964–972. Web.*

² For the purposes of this NOFO, long-term follow-up comprises the assurance and provision of quality chronic disease management, condition-specific treatment, and age-appropriate preventive care throughout the lifespan of individuals identified with a condition included in newborn screening. *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;10:259–261*

These activities include expanding access to diagnosis and treatment resources for providers and families of infants with SCID and other NBS disorders with a focus on reaching underserved populations, and empowering families to actively engage at all levels of the newborn screening system.³

Up to 25 recipients will be awarded under NBS Propel to up to 25 different states. Up to three awards will be made to states in each of the 10 HHS/HRSA regions listed below.

- Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
- Region 2: New Jersey, New York, Puerto Rico, U.S. Virgin Islands
- Region 3: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia
- Region 4: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee
- Region 5: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin
- Region 6: Arkansas, Louisiana, New Mexico, Oklahoma, Texas
- Region 7: Iowa, Kansas, Missouri, Nebraska
- Region 8: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming
- Region 9: American Samoa, Arizona, California, Federated States of Micronesia, Guam, Hawaii, Marshall Islands, Nevada, Northern Mariana Islands, Palau,
- Region 10: Alaska, Idaho, Oregon, Washington

HRSA-23-077: National Center for Newborn Screening System Excellence (NBS Excel)

The purpose of HRSA-23-077 NBS Excel is to fund one (1) organization to support state NBS programs and stakeholders on a nationwide basis by: 1) providing leadership, technical assistance (TA), and quality improvement expertise; 2) collecting data to identify barriers to achieving health equity and equitable access to NBS services for all infants and families; 3) enhancing state performance in NBS; and 4) providing subject matter expertise, TA and training, education, and other resources to youth and families in order to promote meaningful engagement of, active participation with, and leadership by families and/or individuals with heritable disorders at all levels of the newborn screening system.

Program Objectives

HRSA-23-065: State Newborn Screening Priorities Program NBS Propel

³ Family engagement is defined as patients, families, their representatives, and health professionals working in active partnership at various levels across the health care system to improve health and health care."

- By June 2028, increase by five percent the number NBS specimens collected within 48 hours of birth.⁴ Data must be submitted to the recipient of NBS Excel.
- By June 2028, increase by 10 percent the presumptive positive results for time-critical conditions that are communicated immediately to the newborn's healthcare provider but no later than five days of birth. Data must be submitted to the recipient of NBS Excel.
- By June 2028, increase by five percent of all NBS results (normal and out-of-range) that are reported within seven days of birth, overall and for all races and ethnicities.⁴ Data must be submitted to the recipient of NBS Excel.

HRSA-23-077: National Center for Newborn Screening System Excellence (NBS Excel)

- By June 2028, establish data use agreements and receive data from 95 percent of state NBS programs.
- Provide TA to at least 30 states annually (July 2023-June 2028) on activities that improve their NBS system (e.g., timeliness, quality improvement support, implementation of new disorders, family and provider education, etc.).
- By June 2028, increase by 10 percent the number of states that report collecting 95 percent or more of specimens within 48 hours of birth.
- By June 2028, increase by 10 percent the number of states that report 95 percent or more of all newborn screening results (normal and out of range) within seven days of life.

If you are a competing continuation applicant for HRSA-23-077, baseline data for the last year of the current (i.e., immediately preceding) project will be used to establish the new benchmark for the objectives listed above. If you are a new applicant for either HRSA-23-065 or HRSA-23-077, you will collect and provide baseline data to HRSA to establish the benchmark for the objectives listed above by the end of year 1 of the award.

[For more details, see Program Requirements and Expectations.](#)

2. Background

Authority

HRSA-23-065, the State Newborn Screening Priorities Program (NBS Propel), is authorized by 42 U.S.C. § 300b-9 (Public Health Service Act §1110 as amended). HRSA-

⁴ In 2015, the Advisory Committee on Heritable Disorders in Newborns and Children (Committee) established [goals and timeframes](#) to achieve timely diagnosis and treatment of screened conditions and to avoid associated disability, morbidity and mortality. The Committee also suggested a target of 95% initial newborn screening specimens should be collected within 48 hours of birth. Grantees are expected to work towards achieving this target.

23-077, the National Center for Newborn Screening System Excellence (NBS Excel), is authorized by 42 U.S.C. § 300b-8 (Public Health Service Act §1109 as amended).

NBS is a successful public health program that saves lives and improves infants' health outcomes.⁵ Early identification and treatment can mitigate life-altering health impacts. The six (6) components of a successful NBS system are education, screening, short-term follow-up, diagnostic confirmation, management (long-term follow-up), and evaluation/continuous quality improvement. State NBS programs must coordinate across this complex system of multiple key stakeholders, including families, state public health agencies, public health laboratories, and health care providers. States and territories screen over 3.6 million babies⁶ and identify approximately 12,900⁷ infants with heritable conditions annually. Most states and territories screen for most of conditions on the [Recommended Uniform Screening Panel \(RUSP\)](#), as recommended by the Secretary of the Department of Health and Human Services. As of March 2022, 53 NBS programs screen for at least 30 out of 35 core RUSP conditions and 16 states screen for all 35 core RUSP conditions.⁸

In April 2015, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children ([ACHDNC](#)) established NBS timeliness goals⁹:

1. Presumptive positive results for time-critical conditions should be communicated immediately to the newborn's healthcare provider but no later than 5 days of life.
2. Presumptive positive results for all other conditions should be communicated to the newborn's healthcare provider as soon as possible but no later than 7 days of life.
3. All NBS tests should be completed within seven days of life with results reported to the healthcare provider as soon as possible.

While state NBS programs have made improvements with timeliness and improved the overall NBS system over the last decade, they continue to face challenges, specifically public health emergencies.^{10,11,12} For example, in the immediate period after Hurricane Katrina, The Office of Public Health Laboratories in Louisiana reviewed 2,828 newborns

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

⁶ Osterman MJK, Hamilton BE, Martin JA, Driscoll AK, Valenzuela CP. Births: Final data for 2020. *National Vital Statistics Reports*; vol 70 no 17. Hyattsville, MD: National Center for Health Statistics. 2022

⁷ Sontag MK, Yusuf C, Grosse SD, et al. Infants with Congenital Disorders Identified Through Newborn Screening — United States, 2015–2017. *MMWR Morb Mortal Wkly Rep* 2020;69:1265–1268. DOI: <http://dx.doi.org/10.15585/mmwr.mm6936a6>

⁸ For more information on what states screen for see the [HRSA Newborn Screening Information Center - Newborn Screening in Your State](#)

⁹ For more information on the ACHDNC NBS timeliness goals see the [HRSA ACHDNC Newborn Screening Timeliness Goals](#)

¹⁰ Singh S, Caggana M, Johnson C, Lee R, Zarbalian G, Gaviglio A, Keehn A, Morrison M, Becker SJ, Ojodu J. COVID-19 Pandemic-Related Impacts on Newborn Screening Public Health Surveillance. *International Journal of Neonatal Screening*. 2022; 8(2):28. <https://doi.org/10.3390/ijns8020028>

¹¹ Simon D, Broadbridge E, Baker M, Gaviglio A, Gruber D, Piper KN, Tavakoli NP, Sullivan J, Kennedy A. Common Challenges and Identified Solutions for State Newborn Screening Programs during COVID-19 Pandemic. *International Journal of Neonatal Screening*. 2022; 8(1):7. <https://doi.org/10.3390/ijns8010007>

¹² Lobato, M, Yanni E, Hagar A, Myers C, Rue A, Evans C, Lambert L, Olney R, for the Louisiana OPH-CDC Newborn Screening Assessment Team; Impact of Hurricane Katrina on Newborn Screening in Louisiana. *Pediatrics* October 2007; 120 (4): e749–e755. [10.1542/peds.2006-3616](https://doi.org/10.1542/peds.2006-3616)

and determined that no specimen was received within 14 days of collection for 631 newborns (22.3%).¹² During the COVID-19 pandemic, early discharge from hospitals impacted the time of specimen collection and many birth hospitals discharged healthy mothers before the newborn screening dried blood spot specimen collection timeframe of 24-48 hours after birth.¹⁰ Also, pervasive supply chain issues throughout the pandemic, including reagents, testing kits, and other laboratory supplies, represent an ongoing challenge for state NBS laboratories.

Additional challenges confronting state NBS programs include: shortages in a trained workforce,¹³ inequitable access to clinical care and services,^{14,15} and significant resource barriers. These challenges impact states' ability to add new conditions;¹⁶ implement quality improvement activities; develop continuity of operation plans in case of public health emergencies;⁴ achieve interoperability between NBS and other public health systems;⁴ and achieve equity in short and long-term follow-up activities for NBS conditions.^{17,18}

About MCHB and Strategic Plan

The HRSA Maternal and Child Health Bureau (MCHB) administers programs with focus areas in maternal and women's health, adolescent and young adult health, perinatal and infant health, child health, and children with special health care needs. To achieve its mission of improving the health and well-being of America's mothers, children, and families, MCHB is implementing a strategic plan that includes the following four goals:

Goal 1: Assure access to high quality and equitable health services to optimize health and well-being for all MCH populations

Goal 2: Achieve health equity for MCH populations

Goal 3: Strengthen public health capacity and workforce for MCH

Goal 4: Maximize impact through leadership, partnership, and stewardship

These programs address MCHB goals 1, 2, and 3. Specifically, NBS Propel and NBS Excel aim to (1) enhance, improve or expand the ability of state and local public health agencies to provide equitable access to screening, counseling, or health care services to newborns and children with, or at risk for, heritable disorders; (2) assist in providing health care professionals and NBS laboratory personnel with education in NBS and training in relevant and new technologies in NBS and heritable disorders; and (3)

¹³ Jenkins, B.D., Fischer, C.G., Polito, C.A. et al. The 2019 US medical genetics workforce: a focus on clinical genetics. *Genet Med* (2021). <https://doi.org/10.1038/s41436-021-01162-5>

¹⁴ Allen, D. (2021). *Newborn Screening and follow-up of children with endocrine disorders: current successes and challenges*. [Presentation slides]. [Allen ACHDNC NBS \(hrsa.gov\)](#)

¹⁵ Singh, R. (2021). *Genetic Metabolic Dietitians: Roles and workforce challenges*. [Presentation slides] [Singh Workforce Metabolic Dietitians \(hrsa.gov\)](#)

¹⁶ Association of Public Health Laboratories, 2020, NewSTEPS Annual Report, Sept 22, 2021, from APHL website, [NewSTEPS Annual Report 9 22 21.pdf](#)

¹⁷ Shone, S. (2021). *The Landscape of Newborn Screening Workforce: Public Health Professionals*. [Presentation slides] [Shone Workforce Lab and Follow Up \(hrsa.gov\)](#)

¹⁸ Fort, M. (2021) Workforce Issues in Early Hearing Detection and Intervention. [Presentation slides] [Fort EHDl Workforce Issues \(hrsa.gov\)](#)

establish, maintain, and operate a system to assess and coordinate equitable access to treatment relating to heritable disorders.

To learn more about MCHB and the bureau's strategic plan, visit [Mission, Vision, and Work | MCHB](#).

Approximately 14.1 million children, living in 1 in 5 households in the United States have a special health care need and include children diagnosed with a heritable disorder.¹⁹ HRSA defines children and youth with special health care needs (CYSHCN) as those who have or are at increased risk for chronic physical, developmental, behavioral, or emotional conditions and who also require health and related services of a type or amount beyond that required by children generally.

MCHB recently released [A Blueprint for Change: Guiding Principles for a System of Services for Children and Youth With Special Health Care Needs and Their Families](#) (*Blueprint for Change* or *Blueprint*), a national agenda guiding the field for research, programs, and policy in four priority areas: health equity, CYSHCN and family well-being and quality of life, access to services, and financing of services. The vision of the *Blueprint* is that "Children and youth with special health care needs (CYSHCN) enjoy a full life, from childhood to adulthood, and thrive in a system that supports their social, health, and emotional needs, ensuring dignity, autonomy, independence and active participation in their communities."

This NOFO is consistent with the principles of the Blueprint and the MCHB strategic plan with a specific focus on the following focus areas and principles in:

- *Health equity,*
- *Access to services, and*
- *Family well-being and quality of life.*

Equity

MCHB is committed to promoting equity in health programs for mothers, children, and families. As such, the definition of equity provides a foundation for the development of programs that intend to reach underserved communities and improve equity among all communities. The projects described in this NOFO support the use of NBS data to identify barriers to achieving health equity and equitable access to NBS services for all infants and families.

MCHB's working definition of Health Equity includes the following:

Health equity means that all people, including mothers, fathers, birthing people, children, and families achieve their full health potential. Achieving health equity is an active and ongoing process that requires commitment at the individual and

¹⁹ Child and Adolescent Health Measurement Initiative. 2019-2020 National Survey of Children's Health (NSCH) data query. Data Resource Center for Child and Adolescent Health supported by the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB). Retrieved [06/24/22] from www.childhealthdata.org.

organizational levels, and within communities and systems. Achieving health equity requires valuing everyone equally, eliminating systemic and structural barriers including poverty, racism, ableism, gender discrimination and other historical and contemporary injustices, and aligning resources to eliminate health and health care inequities.

COVID-19

In response to the Coronavirus disease (COVID-19) public health emergency, MCHB continues to prioritize meeting emerging needs, including routine childhood vaccinations and well-child visits; supporting the continued operations of existing public health programs, such as newborn screening, funding telehealth expansion; and supporting vaccination, testing, contact tracing, and slowing the spread of the coronavirus. MCHB is committed to supporting states, jurisdictions, and tribes to provide services safely to MCH populations, and encourages them to follow appropriate CDC, state, and local health department guidance. You can read more about MCHB's response to COVID-19 at <https://mchb.hrsa.gov/coronavirus-frequently-asked-questions>.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought:

HRSA-23-065 (NBS Propel): New

HRSA-23-077 (NBS Excel): New, Competing Continuation

HRSA-23-065 (NBS Propel) – HRSA will provide funding in the form of a grant.

HRSA-23-077 (NBS Excel) – 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.

In addition to the usual monitoring and technical assistance (TA) provided directly to award recipients, HRSA program involvement will include:

- Participating in the planning and development of project activities during the period of performance.
- Participating in at least monthly meetings and regular communication with the award recipient to assess progress in meeting the goals and objectives of this initiative.
- Reviewing policies and procedures, activities, emerging issues, and tools designed and implemented during the period of performance.

- Reviewing gaps identified and TA needs of state/territory NBS programs at the end of year 1 and reviewing actionable steps for implementation proposed by the recipient.
- Reviewing the data collection and evaluation plan, including progress to achieving proposed outcomes, data collected, and measures of success.
- Participating, when appropriate, in meetings, conference calls, and other sessions conducted during the period of performance, including but not limited to steering committee meetings, TA sessions, quality improvement meetings, etc.
- Reviewing and editing, as appropriate, all written documents and presentations developed by the recipient prior to submission for publication or public dissemination, including revisions to existing resources. Assisting in the establishment of partnerships that may be necessary for carrying out the project, including with other federal agencies or programs within HRSA or HHS.
- Providing substantial input on the composition of the project steering committee or other workgroups.

In addition to adhering to all applicable federal regulations and public policy requirements, the recipients' responsibilities will include:

- Meeting with the HRSA project officer at the start of the period of performance to review the current strategies and to ensure the project and goals align with HRSA priorities for this activity,
- Collaborating with HRSA personnel in the planning and development of project activities including, but not limited to: identifying emerging issues; developing strategies and tools for interoperability, TA and quality improvement activities, approaches for engaging and promoting leadership by families and individuals with heritable disorders in program activities and committees; offering NBS education support for families and parents; identifying topics for publications; and project evaluation,
- Producing and disseminating project findings through publishing articles, reports, and/or presentations and adhering to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA awards (see Acknowledgement of Federal Funding in Section 2.2 of HRSA's SF-424 Application Guide),
- Completing activities proposed in response to the project requirements and scope of work to meet the project goals and objectives,
- Collaborating with HRSA on ongoing review of activities, budget items, procedures, information/publications, and other documents prior to dissemination, contracts, and interagency agreements,

- Participating in meetings and conference calls with HRSA, conducted during the period of performance, to provide regular updates on progress in meeting goals and objectives; and provide quarterly updates on NBS data to HRSA leadership,
- Collaborating with other federal and non-federal NBS experts, grantees, families, contractors, and state NBS programs, as well as the recipients of the HRSA-23-078, Family Engagement and Leadership in Systems of Care award.

2. Summary of Funding

HRSA-23-065, NBS Propel

HRSA estimates approximately \$8,600,000 to be available annually to fund 25 recipients. The actual amount available will not be determined until enactment of the final FY 2023 federal appropriation. You may apply for a ceiling amount of up to \$345,000 annually (reflecting direct and indirect costs per year). 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 appropriately.

Additionally, applicants are expected to designate the following amounts for each focus area:

\$200,000 for Focus Area 1, which includes activities related to improving collection of specimens, testing specimens, and reporting out results; improving timeliness of NBS; and implementing screening for newly added RUSP conditions.

\$145,000 for Focus Area 2, which includes activities related to improving short-term follow-up through long-term follow-up and helping families understand and navigate the process, from confirmation of a diagnosis, to treatment, and through follow-up across the lifespan. These activities should include expanding access to diagnosis and treatment resources for providers and families of infants with SCID and other NBS disorders with a focus on reaching underserved populations, and empowering families to actively engage at all levels of the newborn screening system.

The period of performance is July 1, 2023 through June 30, 2028 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for HRSA-23-065 in subsequent fiscal years, satisfactory progress, and a decision that continued funding is in the best interest of the Federal Government.

HRSA-23-077, NBS Excel

HRSA estimates approximately \$2,300,000 to be available annually to fund 1 recipient. The actual amount available will not be determined until enactment of the final FY 2023 federal appropriation. You may apply for a ceiling amount of up to \$2,300,000 annually (reflecting direct and indirect, facilities and administrative costs) per year. 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 appropriately.

The period of performance is July 1, 2023 through June 30, 2028 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for HRSA-23-077 in subsequent fiscal years, satisfactory progress, 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

HRSA-23-065 (NBS Propel)

Eligible applicants include a state or political subdivision of a state, or a consortium of two or more states or political subdivisions of states.

HRSA-23-077 (NBS Excel)

Eligible applicants include: a state or a political subdivision of a state; a consortium of two or more states or political subdivision of states; a territory; a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Services; or any other entity with appropriate expertise in NBS as determined by the Secretary. 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 either HRSA-23-065 (NBS Propel), or HRSA-23-077 (NBS Excel).

3. Other

HRSA may not consider an application for funding if it contains any of the non-responsive criteria below:

- Exceeds the funding ceiling amount
- Fails to satisfy the deadline requirements referenced in [Section IV.4](#)

NOTE: Multiple applications from an organization are not allowed. HRSA will only accept and review your **last** validated electronic submission before the [Grants.gov application due date](#).

Applicants may only apply to one of the two announcements listed in this NOFO, HRSA-23-065 (NBS Propel) or HRSA-23-077 (NBS Excel). Please make sure you submit your

application to the correct announcement number. Applications submitted to the wrong competition may be deemed nonresponsive. HRSA will not consider funding applicants that apply to both announcements.

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](https://www.grants.gov) using the SF-424 workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at [Grants.gov: HOW TO APPLY FOR GRANTS](https://www.grants.gov). If you use an alternative electronic submission, see [Grants.gov: APPLICANT SYSTEM-TO-SYSTEM](https://www.grants.gov).

The NOFO is also known as “Instructions” on Grants.gov. You must select “Subscribe” and provide your email address for HRSA-23-065 or HRSA-23-077 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

Application Format Requirements

Section 4 of HRSA’s [SF-424 Application Guide](#) provides general instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, and certifications. You must submit the information outlined in HRSA *SF-424 Application Guide* in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in this NOFO and HRSA’s [SF-424 Application Guide](#). 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 HRSA *SF-424 Application Guide* for the Application Completeness Checklist to assist you in completing your application.

Application Page Limit

The total of uploaded attachment pages that count against the page limit shall be no more than the equivalent of **50 pages** when printed by HRSA.

Forms that DO NOT count in the Page Limit

- Standard OMB-approved forms included in the workspace application package **do not** count in the page limit. The abstract is the standard form (SF) "Project_Abstract Summary." It **does not** count in the page limit. The Indirect Cost Rate Agreement **does not** count in the page limit.

- The proof of non-profit status (if applicable) **does not** count in the page limit.

If there are other attachments that do not count against the page limit, this will be clearly denoted in Section IV.2.vi Attachments.

If you use an OMB-approved form that is not included in the workspace application package for HRSA-23-065 or HRSA-23-077, 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.

- HRSA will flag any application that exceeds the page limit and redact any pages considered over the page limit. The redacted copy of the application will move forward to the objective review committee.

It is important to take appropriate measures to ensure your application does not exceed the specified page limit.

Applications must be complete and validated by Grants.gov under HRSA-23-065 or HRSA-23-077 before 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. § 3354).
- 3) If you are unable to attest to the statements in this certification, you must include an explanation in *Attachment 9: 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), which sunsets /

terminates on September 30, 2023. Please reference detailed information available on the [HHS Office of the Assistant Secretary for Preparedness and Response \(ASPR\)](#) website.

Program Requirements and Expectations

In addition to addressing the goals, purpose, and objectives of the NBS program listed above, recipients are required to implement the following:

HRSA-23-065 (NBS Propel)

The NBS Propel recipients must use funds to support the enhancement, improvement and or expansion of any or all six (6) components of a successful NBS System: education, screening, short-term follow-up, diagnostic confirmation, management (long-term follow-up) and evaluation/continuous quality improvement. This includes ensuring NBS timeliness, supporting the implementation of new conditions added to the RUSP, and facilitating electronic data sharing/exchange among public health and clinical databases to decrease loss to follow-up and ensure infants, children, and their families have access to appropriate services. In addition, recipients are required to implement the following:

Collaboration with recipient of HRSA-23-077 NBS Excel

- Participate in HRSA-23-077-led quality improvement activities and attend all HRSA-23-077-led meetings.
- Execute a data use agreement with the HRSA-23-077 NBS Excel recipient and submit NBS data and information on all newborns screened from 2023-2028. Data collected from all state/territory NBS programs will be used to enhance NBS performance and identify barriers to achieving health equity and equitable access to NBS services for all infants and families.
 - Recipients must securely submit de-identified standardized NBS data annually to the NBS Excel recipient NBS data includes case definitions and other quantitative and qualitative NBS data. Data elements and definitions will be determined in consultation with the NBS Excel funding recipient within the first year of the period of performance. Baseline data will be established in Year 1. In addition, the following data must be submitted annually:
 - Number of days from birth to treatment²⁰ for individuals across all races and ethnicities identified with an NBS-screened condition in your state.

²⁰ Treatment is defined as “Medical Intervention: Any interaction by a medical professional with the infant’s family that changes the current care for the infant based on the newborn screening results and/or the presumptive diagnosis for a specific disorder. Intervention may occur in a medical setting or may include changes in care per phone conversations. Examples include advising parents to not let a newborn fast following an abnormal MCADD newborn screen, or initiating antibiotic therapy in the case of an abnormal sickle cell newborn screen. Medical intervention may precede a formal diagnosis and does not

- Percent of presumptive positive results for all other conditions that are communicated to the newborn’s healthcare provider as soon as possible, but no later than 7 days of birth.
- Collaborate with the HRSA-23-077 NBS Excel recipient on national level activities and workgroups.
- Participate in continuity of operations planning exercises led by the recipient for HRSA-23-077 NBS Excel.
- Engage and support families and individuals with heritable disorders in program advisory committees, working groups, program planning, and other related activities to ensure that they are included in the planning, implementation, and evaluation of activities funded under this program.

Other activities

- Ensure appropriate funding is allotted for both focus areas:
 - \$200,000 for Focus Area 1. This includes funding activities relating to improving collection of specimens, testing specimens, and reporting out results; improving timeliness of NBS; and implementing screening for newly added RUSP conditions.
 - \$145,000 for Focus Area 2. This includes activities ranging from short-term follow-up through long-term follow-up and helping families understand and navigate the process from confirmation of a diagnosis to treatment and through follow-up across the lifespan. These activities should expand access to resources for, and engagement and education of providers and families of infants with SCID and other NBS disorders with a focus on reaching underserved populations, and empowering families to actively engage at all levels of the newborn screening system.
- Address health equity and equitable access to treatment and follow-up services resulting from NBS.
- Collaborate, coordinate, and link to other systems and stakeholders that support the NBS system (such as dried blood spot screening, hearing screening, pulse oximetry screening), including NBS laboratories, NBS follow-up programs, Title V programs, birthing hospitals, clinicians, vital records, early intervention, etc., in order to assess the effectiveness of screening, treatment, counseling, testing, follow-up and specialty services for newborns and children at risk for heritable disorders.
- Address emerging issues in NBS and/or public health emergencies that impact NBS.

- Collaborate with other federally-funded programs in your state, such as the CDC, NIH, and the HRSA-23-078, Family Engagement and Leadership in Systems of Care recipient.

HRSA-23-077 (NBS Excel)

The NBS Excel program will be awarded to an entity that will work with all state/territory NBS programs, in addition to the recipients of the HRSA-23-065 NBS Propel program, to provide TA and collect data to measure, evaluate, and improve all state NBS systems within the U.S. In order to achieve the purpose, goals and objectives of the NBS Excel program, the recipient will establish a national NBS infrastructure by conducting the following activities:

Data Collection

In partnership with all state/territory NBS programs:

- Develop and/or confirm national NBS case definitions and quality measures.
- Initiate and implement data use agreements with state NBS programs to collect aggregated data on NBS measures.
- Establish, maintain, and operate an electronic data collection system where states can securely submit de-identified NBS data in order to collect, standardize and analyze state/territory NBS data, NBS case definitions and other quantitative and qualitative NBS data. Incorporate strategies that allow states and other NBS partners to track national NBS data.
 - Establish procedures that reduce burden on states to submit their data.
 - Data collected from all state/territory NBS programs will be used to enhance NBS performance and identify barriers to achieving health equity and equitable access to NBS services for all infants and families.
- Ensure that the aggregate data collected are maintained and shared on a central, web-based database that is publicly available (free of charge, for use, without restrictions, by the public).
- Ensure privacy and security measures for the data collection system.
- Provide, 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.
- Develop and pilot measures for long-term follow-up of conditions identified through NBS and quality of life²¹ that show impact of the NBS system and reflect

²¹ For examples of Quality of Life Measures, see: The Role of Quality Measures to Promote Long-Term Follow-Up of children Identified by Newborn Screening Programs. The Role of quality Measures Report. 2/8/18. Presented by the Follow-up and Treatment Workgroup to the Advisory Committee on Heritable Disorders in Newborns and Children. <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/reports-recommendations/role-quality-measures-nbs-sept2018-508c.pdf>; see also: Healthy People 2030 Objectives, <https://health.gov/healthypeople>

the goals of NBS in collaboration with a diverse group of NBS and long-term follow-up subject matter experts.

- Establish baselines for the following by June 30, 2024, to track and report on progress annually on the following process measures:
 - Number of states receiving TA on activities that improve their NBS system (e.g., quality improvement support, implementation of new disorders).
 - Number of state NBS programs with a data use agreement.
 - Number of states that reported collecting 95 percent or more of specimens within 48 hours of birth.
 - Number of state NBS programs that report the number of individuals that receive NBS results within 7 days of life, stratified by demographic characteristics, such as race/ethnicity, insurance type, rural/urban, etc.
 - Percent of states that reported 95 percent or more of all NBS results (normal and out-of-range) within 7 days of birth. Number of state NBS programs able to report the number of days from birth to intervention for individuals identified with a NBS condition by race and ethnicity.

Technical Assistance

- Provide leadership, TA, trainings, and resources to all states/territories and NBS partners/stakeholders critical to the NBS system on NBS- related topics including quality improvement, timeliness, implementation of new disorders added to the RUSP, short- and long-term follow-up, NBS interoperability, continuity of operation plans, family and provider education, and any emerging issues that arise during the period of performance.
- Provide onsite TA at state requests, and comprehensive reports identifying areas of strength and potential improvement.
- Lead quality improvement activities based on state/territory needs for at least 25 state/territory newborn screening programs.
- Convene a steering committee and relevant workgroups on NBS related issues including quality improvement, implementation of new disorders, short/long-term follow-up, and NBS interoperability, on an ongoing basis.
 - The steering committee should be established by January 2024 and consist of representation of state NBS programs and laboratories, public health professionals, follow-up program staff, primary and specialty care practitioners, individuals, and families with heritable disorders detected by NBS, experts in privacy rights, and other critical NBS partners to advise the project and identify best practices and areas of need within the NBS screening system.
- By the end of year 1, assess TA needs of states and NBS stakeholders and create a list of priorities to address during the 5 year period of performance. Every year, re-assess the list of priorities and review data with HRSA.
- Develop and implement resources and activities to strengthen the integration of child health information systems and NBS interoperability among NBS programs, public health, and clinical practice.

- Engage families and individuals with heritable disorders and maintain the meaningful involvement of families in all levels of the project, including: project planning and implementation; development of strategies, tools, and materials; and assisting states in recruiting family representatives to serve on advisory committees and working groups.

Education and Training

- Provide education and training to public health professionals and primary and specialty care practitioners on NBS best practices (pre-analytic, analytic, and post analytic) and condition specific issues.
- Provide NBS education to diverse families.
- Provide education and training to families and individuals with heritable disorders to serve as leaders within newborn screening system teams at local, state, and national levels.

Communications

- Develop a plan to disseminate reports, products, and/or project outputs to provide project information to key target audiences and the public.
- Publish a State of NBS Report annually in years 2 through 5 of the project to include aggregate data on conditions screened and all relevant NBS measures. The report should identify successes and challenges, best practices and emerging issues.
- Host an online, interactive forum organized in a clear format for multiple audiences that promotes information sharing and dissemination of TA and quality improvement resources developed under this program.
- Support an annual meeting of state NBS programs, family leaders, and other NBS partners to discuss and disseminate information about current and emerging NBS topics/issues.

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*

Use the Standard OMB-approved Project Abstract Summary Form that is included in the workspace application package. Do not upload the abstract as an attachment or it may count toward the page limit. For information required in the Project Abstract Summary Form, see Section 4.1.ix of HRSA's [SF-424 Application Guide](#).

NARRATIVE GUIDANCE

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

review criteria. Any forms or attachments referenced in a narrative section may be considered during the objective review.

Narrative Section	Review Criteria
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 Narrative	(6) Support Requested

ii. Project Narrative

This section provides a comprehensive description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and organized in alignment with the sections and format below 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](#)

For both HRSA-23-065 (NBS Propel) and HRSA-23-077 (NBS Excel)

State the project for which you are applying. Briefly describe the purpose of the proposed project.

- **NEEDS ASSESSMENT** -- Corresponds to Section V's Review Criterion [\(1\) Need](#)

For HRSA-23-065 (NBS Propel)

Outline the needs of the NBS system in your state. Describe and document the target population. Use and cite demographic data whenever possible to support the information provide. Discuss any relevant barriers or challenges within your state NBS system that the project hopes to overcome. This section will help reviewers understand who you will serve with the proposed project. In addition, describe your state's ability to address NBS timeliness, collection of NBS data, implementing new conditions, and any other emerging need.

HRSA-23-077 (NBS Excel)

Describe the current state of NBS across the U.S. and any ongoing challenges or barriers related to achieving an effective, timely, and equitable NBS system. Describe the parts of the NBS system that should be targeted to address any unmet educational, resource, or support needs. Use and cite demographic data whenever possible to support the information provided. Include information on NBS timeliness, implementing new conditions, and any other emerging need.

- *METHODOLOGY -- Corresponds to Section V's Review Criterion [\(2\) Response](#)*

HRSA-23-065 (NBS Propel) and HRSA-23-077 (NBS Excel)

Propose methods that you will use to address the stated needs and priorities while meeting each of the previously described objectives, and [Program Requirements and Expectations](#) in this NOFO. As appropriate, include development of effective tools and strategies for staff training, outreach, collaborations, clear communication, and information sharing/dissemination.

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.

In addition to the above, for HRSA-23-065 (NBS Propel), describe your plan to accomplish the following activities:

- Collaborating with the HRSA-23-077 NBS Excel recipient to implement a data use agreement and submit aggregate NBS data and information about your NBS program on an annual basis.
- Addressing health equity and equitable access to NBS services for infants and families.
- Addressing NBS timeliness goals and implementing new conditions.
- Engaging families and individuals with heritable disorders in program activities.

In addition to the above, for HRSA-23-077 (NBS Excel), describe your plans to accomplish the following activities:

- Establishing a national infrastructure that will address the data collection and TA activities described under the [Program Requirements and Expectations](#).
- Collaborating with all state/territory NBS programs and NBS stakeholders and experts.
- Providing TA and leading quality improvement activities with state/territory NBS programs.

- Supporting states in achieving health equity and equitable access to NBS services for all infants and families.
 - Recruiting and training diverse families to serve on and lead policy/systems-level groups in states and within NBS Excel.
 - Engaging and maintaining meaningful involvement of family leaders in all levels of the project.
 - Providing NBS education to diverse families.
- *WORK PLAN -- Corresponds to Section V's Review Criteria [\(2\) Response](#) and [\(4\) Impact](#)*

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, the extent to which these contributors reflect the cultural, racial, linguistic and geographic diversity of the population and communities served.

Logic Models

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 timeline used during program implementation; the work plan provides the “how to” steps. You can find additional information on developing logic models at [ACF HHS: Logic Model Tip Sheet](#).

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

HRSA-23-065 (NBS Propel) and HRSA-23-077 (NBS Excel)

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

In addition, for HRSA-23-077 (NBS Excel) –

Specifically, discuss the approaches of resolving challenges for the following:

- Establishing partnerships with different stakeholders.
 - Supporting states' data collection and reporting efforts.
 - Developing and piloting measures for NBS long-term follow-up and quality of life.
 - Engaging families in all levels of the project.
 - Training families and individuals with heritable disorders and developing a participation pathway in state level activities.
 - Providing NBS education to diverse families.
- **EVALUATION AND TECHNICAL SUPPORT CAPACITY** -- Corresponds to Section V's Review Criteria [\(3\) Evaluative Measures](#) and [\(5\) Resource/Capabilities](#)

For both HRSA-23-065 (NBS Propel) and HRSA-23-077 (NBS Excel) –

- Describe your plans and associated resources to carry out high-quality program monitoring, performance measurement, and evaluation functions for your program. Note that HRSA expects monitoring, performance measurement, and evaluation processes to be closely linked. Make sure to address the following:
 - **Monitoring:** Describe your plan for program monitoring, including how you will track project-related processes, activities, and milestones and use data to identify actual or potential challenges to implementation. Provide an initial list of indicators you will use to monitor progress toward each program and performance goal; this list may include required measures listed in the [Program Objectives and Requirement and Expectation Sections](#).
 - **Performance Measurement:** Describe your plan for measuring and tracking program performance, with a focus on the program goals and objectives outlined in the [Purpose](#) section. Include proposed measures and plans for the timely collection and reporting of measures, including the required measures listed in the [Reporting section](#).
 - **Evaluation:** Describe your plans for assessing progress toward your program and performance goals. Include when and how often you will examine your data for indications of progress or challenges. The

evaluation plan should focus primarily on outcomes over which the project has influence and for which you can produce data on an annual basis.

- Continuous Quality Improvement: Describe your plans for incorporating information learned in your ongoing evaluation and monitoring.
- Describe your capacity to collect and manage data in a way that allows for accurate and timely reporting of performance outcomes, including the required measures listed in the NOFO. This includes plans for establishing baseline data and targets. Include a description of the inputs (e.g., organizational profile, collaborative partners, staff skills and expertise, budget, and other resources), systems, and key processes you will use for performance monitoring and evaluation (e.g., data sources, data collection methods, frequency of collection, data management software).

In addition to the above, for HRSA-23-077 (NBS Excel) –

Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature.

Describe current and possible future collaborative efforts with federal and non-federal entities, as well as state NBS programs. You should provide documented evidence of collaborative relationships in Attachment 4 of letters of support, letters of agreement, memoranda of understanding, memoranda of agreement, and/or contracts. Agreements should provide details on the roles and responsibilities each entity will have in relation to project activities. Collaborative relationships should also be reflected in the budget plan and quantitative and qualitative work plan.

Describe the technological capacity to develop, implement, and host an interactive electronic data collection system for easy utility. Describe the system's ability to collect, validate, analyze and share data with relevant partners (as stipulated by HRSA). Describe all privacy and security measures that will be in place to safeguard states' data. If necessary, include diagrams that show the flow of data from disparate systems.

Describe how you will 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 this information available. Include a diagram that shows the flow of data from disparate state/territory data collection systems.

▪ **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. 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.

Describe qualifications, expertise, and experience working with NBS stakeholders including families, medical professionals, state NBS programs (if applicable), other federally funded NBS programs, disease specific advocacy groups, and the general public.

In addition to the above, for HRSA-23-065 (NBS Propel) –

Describe your state’s infrastructure to support short and long-term follow-up activities.

Describe your state’s plan for engaging and compensating families and/or individuals with heritable disorders in proposed activities.

In addition to the above, for HRSA-23-077 (NBS Excel) –

Include information on the project steering committee and what expertise will be represented within the steering committee. A steering committee should help advise you on project activities. Describe how the expertise and input of the members will guide the project.

Describe how the organization has the capacity to meet the unique needs of state and territory NBS programs to provide TA and lead quality improvement activities for this program.

Describe how your organization will engage and financially compensate families and/or individuals with heritable disorders to plan, implement, and evaluate the project.

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 your 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.

As required by the Consolidated Appropriations Act, 2022 (P.L. 117-103), Division H, § 202, “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](#).

In addition, HRSA-23-065 (NBS Propel), requires the following:

- The budget narrative must clearly show how each [focus area](#) will be funded. Please include separate budget narratives by focus area.

v. **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](#).** Your indirect cost rate agreement and proof of non-profit status (if applicable) will not count toward the page limit. **Clearly label each attachment.** You must upload attachments into the application. HRSA and the objective review committee will not open/review any *hyperlinked* attachments.

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in [Section IV.2.ii. Project Narrative](#). If applicable 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 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. If a biographical sketch is included for an identified individual not yet hired, include a letter of commitment from that person with the biographical sketch. Provide information on time allocation for all key staff on proposed project activities.

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. For purposes of the application, a table describing these letters/MOUs/Proposed Contracts (entity, brief description, type) is acceptable. Recipients will be expected to produce these items upon request.

Attachment 5: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of the project.

Attachment 6: Tables, Charts, etc.

This attachment should give more details about the proposal (e.g., Gantt or PERT charts, flow charts).

Attachment 7: For Multi-Year Budgets--5th Year Budget, if applicable as it only applies to 5-year periods of performance.

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, which does not count in the page limit; however, any related budget narrative does count. See Section 4.1.iv of HRSA's [SF-424 Application Guide](#).

Attachment 8: Proof of Non-profit Status (Does not count against the page limit)

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. Unique Entity Identifier (UEI) and System for Award Management (SAM)

Effective April 4, 2022:

- The UEI assigned by [SAM](#) has replaced the Data Universal Numbering System (DUNS) number.
- Register at [SAM.gov](#) and you will be assigned a UEI.

You must register with SAM and continue to maintain active SAM registration with current information at all times when you have an active federal award, an active application, or an active plan under consideration by an agency (unless you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or you have an exception approved by the agency under 2 CFR § 25.110(d)). For your SAM registration, you must submit a notarized letter appointing the authorized Entity Administrator.

If you are chosen as a recipient, HRSA will not make an award until you have complied with all applicable SAM requirements. 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 HRSA may 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 two separate systems:

- System for Award Management (SAM) (<https://sam.gov/content/home> | [SAM Knowledge Base](#))
- Grants.gov (<https://www.grants.gov/>)

For more details, see Section 3.1 of HRSA's [SF-424 Application Guide](#).

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 application due date under this NOFO is **February 13, 2023, at 11:59 p.m. ET**. HRSA suggests you submit your application 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 in HRSA's [SF-424 Application Guide](#) for additional information.

5. Intergovernmental Review

The State NBS System Priorities Program is not subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

The National Center for NBS System Excellence 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

For HRSA-23-065 (NBS Propel)

You may request funding for a period of performance of up to 5 years, at no more than \$345,000 per year (inclusive of direct **and** indirect costs). 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 appropriately. 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.

Applicants are expected to designate funding per the [focus areas](#) described under the Purpose and Budget sections of this NOFO.

The General Provisions in Division H of the Consolidated Appropriations Act, 2022 (P.L. 117-103) apply to this program. See Section 4.1 of HRSA's [SF-424 Application Guide](#) for additional information. Note that these and other restrictions will apply in following fiscal years, 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 specific uses of funding. It is imperative that you review and adhere to the list of statutory restrictions on the use of funds detailed in Section 4.1 of HRSA's [SF-424 Application Guide](#). Like 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](#).

For HRSA-23-077 (NBS Excel)

You may request funding for a period of performance of up to 5 years, at no more than \$2,300,000 per year (inclusive of direct **and** indirect costs). 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 appropriately. 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 H of the Consolidated Appropriations Act, 2022 (P.L. 117-103) apply to this program. See Section 4.1 of HRSA's [SF-424 Application Guide](#)

for additional information. Note that these and other restrictions will apply in following fiscal years, as required by law.

You cannot use funds under this notice 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 (i.e., made available to funding recipients) 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.

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 specific uses of funding. It is imperative that you review and adhere to the list of statutory restrictions on the use of funds detailed in Section 4.1 of HRSA's [SF-424 Application Guide](#). Like 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](#).

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 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.

Reviewers will evaluate and score the merit of your application based upon these criteria. However, if a progress report is submitted with a competing continuation application, HRSA program staff will review the report after the objective review process.

Six review criteria are used to review and rank both the HRSA-23-065, State NBS System Priorities Program and HRSA-23-077, National Center for NBS System Excellence applications. Below are descriptions of the review criteria and their scoring points.

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

For both projects:

The extent to which the application demonstrates the problem and associated contributing factors to the problem.

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV’s [Methodology](#), [Work Plan](#), [Logic Model](#), and [Resolution of Challenges](#)

The extent to which the proposed project responds to the “[Purpose](#),” objectives, and program requirements. 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.

HRSA-23-065 (NBS Propel)

Methodology (20 points)

The extent to which the proposed project describes the following:

- A plan to collaborate with the recipient of HRSA-23-077.
- How a data use agreement will be implemented in order to submit NBS data and information; and how data will be collected and aggregated in order to be submitted to the recipient of HRSA-23-077.
- How the timeliness goals and screening for new conditions will be implemented.
- How health equity and equitable access to NBS services for infants and families will be improved.
- How the project will include families and/or individuals with heritable disorders.

HRSA-23-077 (NBS Excel)

Methodology (20 points)

The extent to which the proposed project describes the following:

- A national infrastructure that will address the data collection and TA activities described under the Program Requirements and Expectations.
- How collaborations with all NBS programs and NBS stakeholders and experts will take place.
- How it will lead quality improvement activities with NBS programs.

- The approach to developing and piloting measures for long-term follow-up of conditions identified through NBS and quality of life.
- The methods that will support states in achieving health equity and equitable access to NBS services for all infants and families.
- How families and/or individuals with heritable disorders in the project are included.
- The methods to provide NBS education to diverse families.

For both projects:

Work Plan / Logic Model (10 points)

- The coherence and completeness outlined in the work plan activities to be used to achieve each of the objectives proposed within the methodology section.
- The clarity with which the application demonstrates in the logic model, a clear relationship among resources, activities, outputs, target population, short-term and long-term outcomes.

Resolution of Challenges (5 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](#)

For both projects:

The strength and effectiveness of the method proposed to monitor and evaluate the project results and submit data for the program objectives. 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.

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

For both projects:

- The extent to which the application work plan demonstrates the project has a public health impact and the project will be effective, if funded. This may include whether the activities are feasible to address the state/territory-specific priorities, the impact results may have on the NBS community or system at large, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

Criterion 5: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV’s [Evaluation and Technical Support Capacity](#) and [Organizational Information](#)

For both projects:

- 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 to fulfill the needs and requirements of the proposed project.
- The degree to which the applicant organization demonstrates readiness to meet the goal, purpose, objectives, and program requirements/expectations, including the annual reporting of performance outcomes and measures.

In addition, for HRSA-23-077 (NBS Excel):

- The strength and effectiveness of the technology proposed to develop, implement, and host an interactive, evidence-based, secure electronic data collection system for easy utility.

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

For both projects:

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

- The extent to which costs, as outlined in the budget(s) 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 of applications 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. See Section 5.3 of HRSA’s [SF-424 Application Guide for more details](#).

For HRSA-23-065, HRSA will use geographical dispersion as a factor to select recipients for this grant.

HRSA will award up to three (3) recipients from each of the [10 HHS/HRSA Regions](#) and located in three (3) different states within each region. The table below lists the states in each of the 10 HHS/HRSA Regions.

Region	State/Jurisdiction
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1	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
2	New Jersey, New York, Puerto Rico, U.S. Virgin Islands
3	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia
4	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee
5	Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin
6	Arkansas, Louisiana, New Mexico, Oklahoma, Texas
7	Iowa, Kansas, Missouri, Nebraska
8	Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming
9	American Samoa, Arizona, California, Federated States of Micronesia, Guam, Hawaii, Marshall Islands, Nevada, Northern Mariana Islands, Palau
10	Alaska, Idaho, Oregon, Washington

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.

For both HRSA-23-065 (NBS Propel) and HRSA-23-077 (NBS Excel)

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 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 release the Notice of Award (NOA) on or around the start date of July 1, 2023. 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 NOA, 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 federal regulations and HHS policies in effect at the time of the award or implemented during the period of award, and
- applicable statutory provisions.

Accessibility Provisions and Non-Discrimination Requirements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see <https://www.hhs.gov/civil-rights/for->

[individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html](https://www.hhs.gov/individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

Please contact the [HHS Office for Civil Rights](#) for more information about obligations and prohibitions under federal civil rights laws or call 1-800-368-1019 or TDD 1-800-537-7697.

The HRSA Office of Civil Rights, Diversity, and Inclusion (OCRDI) offers technical assistance, individual consultations, trainings, and plain language materials to supplement OCR guidance and assist HRSA recipients in meeting their civil rights obligations. Visit [OCRDI's website](#) to learn more about how federal civil rights laws and accessibility requirements apply to your programs, or contact OCRDI directly at HRSACivilRights@hrsa.gov.

Executive Order on Worker Organizing and Empowerment

Pursuant to the Executive Order on Worker Organizing and Empowerment (E.O. 14025), HRSA strongly encourages applicants to support worker organizing and collective bargaining and to promote equality of bargaining power between employers and employees. This may include the development of policies and practices that could be used to promote worker power. Applicants can describe their plans and specific activities to promote this activity in the application narrative.

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.

Health Information Technology (IT) Interoperability Requirements

Successful applicants under this NOFO agree that:

Where award funding involves:	Recipients and subrecipients are required to:
Implementing, acquiring, or upgrading health IT for activities by any funded entity	Utilize health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B to learn more.
Implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act	Utilize health IT certified under the ONC Health IT Certification Program, if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it to learn more.

If standards and implementation specifications adopted in [45 CFR part 170, Subpart B](#) cannot support the activity, recipients and subrecipients are encouraged to utilize health IT that meets non-proprietary standards and implementation specifications developed by consensus-based standards development organizations. This may include standards identified in the ONC Interoperability Standards Advisory, available at <https://www.healthit.gov/isa/>.

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.

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

For HRSA-23-077, the applicant must 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.

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. Please be advised the administrative forms and performance measures for MCHB discretionary grants will be updated on May 4, 2023. DGIS reports created on or after May 4, 2023 will contain the updated forms. To prepare successful applicants for their reporting requirements, the administrative forms and performance measures for the NBS Propel program are Form 1, Form 2, Form 3, Form 5, Form 6, Form 7, Products, Publications and Submissions Data Collection Form, Technical Assistance/Collaboration Form, Core 3, Capacity Building (CB 4), Capacity Building (CB 6), Capacity Building (CB 8), and Children and Youth with Special Health Care Needs and for the NBS Excel program are Form 1, Form 2, Form 3, Form 6, Form 7, Products, Publications and Submissions Data Collection Form, Technical Assistance/Collaboration Form, Core 3, Capacity Building (CB 1), Capacity Building (CB 4), Capacity Building (CB 6), Capacity Building (CB 8), and Children and Youth with Special Health Care needs . The type of report required is determined by the project year of the award's period of performance. 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: 08/31/2025).

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	July 1, 2023 – June 30, 2028 <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	July 1, 2023 – June 30, 2024 July 1, 2024 – June 30, 2025 July 1, 2025 – June 30, 2026 July 1, 2026 – June 30, 2027	Beginning of each budget period (Years 2–5, as applicable)	120 days from the available date
c) Project Period End Performance Report	July 1, 2027 – June 30, 2028	Period of performance end date	90 days from the available date

- 2) **Progress Report(s).** The recipient must submit a progress report to HRSA annually. More information will be available in the NOA.
- 3) **Final Project Period Narrative Report.** The recipient must submit a final narrative progress report to HRSA following the end of the period of performance. The report will be submitted in the EHBs and should include final outcomes related to the program goal and objectives, including accomplishments and barriers. Further information will be available in the NOA.
- 4) **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](#).

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. No additional termination provisions apply unless otherwise noted.

VII. Agency Contacts

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

Djuana Gibson
Grants Management Specialist
Division of Grants Management Operations, OFAM

Health Resources and Services Administration
Phone: (301) 443-3243
Email: dgibson@hrsa.gov

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

Kim Morrison, MS
Public Health Analyst, Division of Services for Children with Special Health Needs, Genetic Services Branch
Attn: State Newborn Screening System Priorities Program /or/ National Center for Newborn Screening System Excellence
Maternal and Child Health Bureau
Health Resources and Services Administration
Phone: (301) 443-6672
Email: KMorrison@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
Phone: 1-800-518-4726 (International callers dial 606-545-5035)
Email: support@grants.gov

[Self-Service Knowledge Base](#)

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through [HRSA's Electronic Handbooks \(EHBs\)](#). Always obtain a case number when calling for support. For assistance with submitting in the EHBs, contact the HRSA Contact Center, Monday–Friday, 7 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center
Phone: (877) 464-4772 / (877) Go4-HRSA
TTY: (877) 897-9910
Web: <http://www.hrsa.gov/about/contact/ehbhelp.aspx>

VIII. Other Information

Technical Assistance

See [TA details](#) in Executive Summary.

Tips for Writing a Strong Application

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