# U.S. Department of Health and Human Services


Maternal and Child Health Bureau

Division of Services for Children with Special Health Needs

**Hereditary Hemorrhagic Telangiectasia (HHT) Center**

**Funding Opportunity Number:** HRSA-22-145

**Funding Opportunity Type(s):** New

**Assistance Listings (AL/CFDA) Number:** 93.110

## NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2022

## Application Due Date: May 17, 2022

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!

HRSA will not approve deadline extensions for lack of registration.

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

**Issuance Date:** March 18, 2022

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See Section VII for a complete list of agency contacts.

Authority: 42 U.S.C. § 701(a)(2) (Title V, § 501(a)(2) of the Social Security Act)

## 508 COMPLIANCE DISCLAIMER

Note: Persons using assistive technology may not be able to fully access information in this file. For assistance, please 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 the fiscal year (FY) 2022 Hereditary Hemorrhagic Telangiectasia (HHT) Center. The purpose of this program is to reduce morbidity and mortality associated with hereditary hemorrhagic telangiectasia (HHT) by: 1) expanding access to and coordination of care for HHT patients; and 2) developing a de-identified, aggregate data collection registry to better understand this rare disease and treatment outcomes.

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|---|---|
| Funding Opportunity Title: | Hereditary Hemorrhagic Telangiectasia (HHT) Center |
| Funding Opportunity Number: | **HRSA-22-145** |
| Due Date for Applications: | May 17, 2022 |
| Anticipated Total Annual Available FY 2022 Funding: | Up to $2,000,000 |
| Estimated Number and Type of Award(s): | 1 cooperative agreement |
| Estimated Annual Award Amount: | Up to $2,000,000 per award |
| Cost Sharing/Match Required: | No |
| Period of Performance: | September 30, 2022 through September 29, 2025 (3 years) |
| Eligible Applicants: | Any domestic public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 25 U.S.C. 5304 (formerly cited as 25 U.S.C. 450b)) is eligible to apply. See 42 CFR § 51a.3(a)). Domestic faith-based |

| | |
|---|---|
| | and community-based organizations are eligible to apply<br><br>See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information. |

## Application Guide

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online, except where instructed in this NOFO to do otherwise.

## Technical Assistance

HRSA has scheduled the following technical assistance:

*Webinar*

Day and Date: Tuesday, April 5, 2022
Time: 2–3 p.m. ET
Call-In Number: 1-833-568-8864
Participant Code: 37251045
Weblink: https://hrsa-gov.zoomgov.com/j/1615874839?pwd=TVhzaTM2WTgwOU1DNUxHQ0dDYmpPdz09

HRSA will record the webinar and make it available at: https://mchb.hrsa.gov/fundingopportunities/default.aspx.

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# I. Program Funding Opportunity Description

## 1. Purpose

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2022 Hereditary Hemorrhagic Telangiectasia (HHT) Center. The purpose of the program is to reduce morbidity and mortality associated with hereditary hemorrhagic telangiectasia by funding a national center to: 1) expand access to and coordination of care for HHT patients; and 2) develop a de-identified, aggregate data collection registry to better understand this rare disease and treatment outcomes.

### Program Goal

The goal of this award is to improve the system of services for individuals with HHT, by establishing a national center supporting comprehensive HHT care.

The National HHT Center (NHHTC), awarded to one entity, will support the development and implementation of a data collection registry of HHT patients in at least 10 centers of excellence[1] ("partner centers"), with a focus on increasing understanding of this rare disease, accelerating the development of new diagnostic and treatment options, and working collaboratively with clinicians who care for individuals with HHT to identify and address gaps in the system of care, especially those from underserved populations.[2]

Data collected under this program must follow all applicable law and institutional guidance as appropriate; data reported to HRSA as part of the performance reporting must be in aggregate form and de-identified. Please see the Data Rights and Human Subjects Protection section of this NOFO for more information.

### Program Objectives

- By September 2025, increase by 15 percent the number of new patients seen by a multidisciplinary HHT team in each partner center.
- By August 2025, 100 percent of partner centers will be entering patient data into a data collection registry of HHT patients led by the NHHTC.
- Increase by 10 percent annually (October 2023 – August 2025) the number of medical providers reporting increased knowledge about HHT and its treatment.

For more details, see Program Requirements and Expectations.

[1] Definition of a Center: : A Hereditary Hemorrhagic Telangiectasia (HHT) Center is a center that demonstrates that it has the personnel, expertise, commitment, and resources to optimally provide comprehensive evaluation, treatment, and education to patients and families with HHT, OR is recognized by Cure HHT as a Center of Excellence. https://curehht.org/understanding-hht/get-support/hht-treatment-centers/

[2] "Underserved communities" refers to populations that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life. For additional information, see Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009, at § 2(b) (Jan. 20, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf

## 2. Background

Hereditary hemorrhagic telangiectasia (HHT) is a rare hereditary disorder[3] that results in the development of abnormal blood vessels. Rather than blood reaching the tissues by passing from arteries through smaller vessels called capillaries, gradually losing pressure along the way, the blood of HHT patients flows at high pressure from arteries directly into veins. This strains and enlarges vessels, causing irritation of surrounding tissues and severe bleeding.[4] Because blood vessel abnormalities can occur in individuals' lungs, brains, spinal cords, and gastrointestinal tracts,[5] HHT can severely impact multiple organ systems and require care from numerous specialists. Complications of HHT include stroke, pulmonary hypertension, gastrointestinal bleeds, and liver failure.[6] Ten percent of individuals with HHT die from complications.[7]

Treatment for HHT requires specialized provider knowledge about the condition and coordination of services across multiple specialties. Individuals receiving care in centers treating a high number of HHT patients—which typically corresponds with greater resources for, and staff experience and expertise with, HHT—have better outcomes, lower in-hospital mortality, and higher rates of discharge to their homes.[8,9,10] However, significant racial, economic, and age-related disparities exist in the types of centers in which individuals with HHT receive care; compared to patients seen in low-volume HHT centers, patients in high-volume centers are more likely to be white, older, and have higher incomes.[11] Cure HHT currently recognizes 25 of these high-volume centers in the United States as centers of excellence.[12]

HHT affects people of all genders, ages, and ethnic groups.[13] HHT occurs in an estimated 1 of every 5,000 individuals, or about 70,000 individuals in the United States.[14] However, diagnosis may be difficult, particularly among children,[15] suggesting

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[3] Farooqui, M. et al. (2021). "Cerebrovascular and Cardiovascular Disease Burden in Patients with Hereditary Hemorrhagic Telangiectasia." *Neurological sciences* 42.12: 5117–5122. Web.
[4] Medline Plus. "Hereditary hemorrhagic telangiectasia." Available at https://medlineplus.gov/genetics/condition/hereditary-hemorrhagic-telangiectasia/#references. Accessed 1/10/2022
[5] Chung, M.G. (2015). "Chapter 13 - Hereditary hemorrhagic telangiectasia." *Handbook of Clinical Neurology, Vol 132:* 185-197. Available at https://www.sciencedirect.com/science/article/abs/pii/B9780444627025000135?via%3Dihub.
[6] Ibid.
[7] Lessnau, K.-D. (2020). "Ossler-Weber-Rendu Disease (Hereditary Hemorrhagic Telangiectasia)." Medscape. Available at https://emedicine.medscape.com/article/2048472-overview#a7. Accessed 1/10/2022
[8] Iyer, V.N. et al. (2016)."Effect of Center Volume on Outcomes in Hospitalized Patients with Hereditary Hemorrhagic Telngiectasia." *Mayo Clinic Proceedings*(91) 12: 1753-1760. Available at https://www.mayoclinicproceedings.org/article/S0025-6196(16)30372-X/fulltext
[9] HHT Foundation International - Guidelines Working Group (2011). ; "International guidelines for the diagnosis and management of hereditary haemorrhagic telangiectasia." *J Med Genet.* 48(2):73-87. doi: 10.1136/jmg.2009.069013. Epub 2009 Jun 23. PMID: 19553198.
[10] de Gussem, E. M. et al. (2020). "Hereditary Hemorrhagic Telangiectasia (HHT) and Survival: The Importance of Systematic Screening and Treatment in HHT Centers of Excellence." *Journal of clinical medicine* 9.11: 3581–. Web.
[11] Ibid.
[12] Cure HHT. "North American HHT Centers of Excellence." Available at https://directory.curehht.org/hht-centers. Accessed 12/30/21. Patient volume and center capacity is one of Cure HHT's components for Center of Excellence certification. See "Criteria for North American Cure HHT Centers of Excellence." Available at https://directory.curehht.org/center-application. Accessed 1/10/2022.
[13] Cure HHT. "Frequently Asked Questions About HHT." Available at https://curehht.org/understanding-hht/what-is-hht/frequently-asked-questions/. Accessed 1/10/2022
[14] Cure HHT. "Medical Summary." Available at https://curehht.org/understanding-hht/what-is-hht/medical-summary/. Accessed 1/10/2022
[15] Chung, M.G. (2015). "Chapter 13 - Hereditary hemorrhagic telangiectasia."

this figure may underestimate the true prevalence. [16] Although some individuals may experience symptoms during infancy or early childhood—most commonly nosebleeds—many have few signs or symptoms until adulthood.[17] Currently, there is no comprehensive national registry to document and track HHT cases in the United States.[18] Farrooqui et. al. (2021) reflected that a large comprehensive prospective national registry would help identify co-morbidities such as anemia, cerebrovascular malformations, seizures, and congestive heart failure. Additionally, a registry would assist in developing preventive and management strategies.[19]

In response to Congressional Report language accompanying the FY 2022 appropriations and the aforementioned challenges, MCHB will fund the Hereditary Hemorrhagic (HHT) Telangiectasia Center to reduce morbidity and mortality associated with HHT and promote greater equity in these outcomes by funding a national center that partners with centers providing HHT care in order to expand patient care; facilitate partner centers' data collection and reporting efforts into the data collection registry; and works collaboratively with partner centers to identify and address gaps in the system of care and in clinical knowledge.

## Commitment to Equity

MCHB is committed to promoting equity in health programs for mothers, children, and families. Equity is defined as "the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality."[20]

The definition of equity provides a foundation for the development of programs that intend to reach underserved communities and improve equity among all communities. Addressing issues of equity should include an understanding of intersectionality and how multiple forms of discrimination impact individuals' lived experiences. Individuals and communities often belong to more than one group that has been historically underserved, marginalized, or adversely affected by persistent poverty and inequality. Individuals at the nexus of multiple identities often experience unique forms of

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[16] Kritharis, A., Al-Samkari, H., and Kuter D.J. (2018). "Hereditary hemorrhagic telangiectasia: Diagnosis and management from the hematologist's perspective." *Haematologica.*;103(9): 1433-1443. doi: 10.3324/haematol.2018.193003. Epub 2018 May 24. PMID: 29794143; PMCID: PMC6119150.

[17] National Organization for Rare Disorders, "Rare Disease Database: Hereditary Hemorrhagic Telangiectasia." Available at https://rarediseases.org/rare-diseases/hereditary-hemorrhagic-telangiectasia/. Accessed 1/10/2022

[18] Funded by Cure HHT, Dartmouth developed a HHT Outcomes Registry that conducted a pilot with two HHT centers in 2018. This registry sought to gather de-identified, clinical, radiographic, genetic, and treatment information on all HHT patients in North America who are evaluated in HHT COEs. However, few centers participate. See Cure HHT, "Development of a North American HHT Database." Available at https://curehht.org/research_project/development-north-american-hht-database/. Accessed 1/10/2022

[19] Farooqui, M. et al.(2021). "Cerebrovascular and Cardiovascular Disease Burden in Patients with Hereditary Hemorrhagic Telangiectasia."

[20] Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009, at § 2(a) (Jan. 20, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf.

discrimination or systemic disadvantages, including in their access to needed services.[21]

**About MCHB and Strategic Plan**

The 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 maternal and child health (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*

This program addresses MCHB's Goals 1 and 2 by improving access to high quality, coordinated services for all individuals with HHT, regardless of background, income, or geographic area.

To learn more about MCHB and the bureau's strategic plan, visit https://mchb.hrsa.gov/about.

**About The Hereditary Hemorrhagic Telangiectasia (HHT) Program**

The Hereditary Hemorrhagic Telangiectasia (HHT) Program is authorized by 42 U.S.C. § 701(a)(2) (Title V, § 501(a)(2) of the Social Security Act).

## II. Award Information

### 1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a cooperative agreement.

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.

[21] *See* Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, 86 FR 2023, at § 1 (Jan. 20, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01761.pdf Ibid.

**HRSA program involvement will include:**

- Participating in meetings conducted during the period of the cooperative agreement;
- Reviewing and approving activities and procedures to be established and implemented for accomplishing the scope of work;
- Reviewing project information prior to dissemination;
- Reviewing information on project activities;
- Providing assistance in establishing and facilitating effective collaborative relationships with federal and state agencies, MCHB award projects, other resource centers, and other entities that may be relevant to the project's mission;
- Participating in disseminating project information;
- Working with the recipient to ensure that they are compliant and not duplicating the work of other HRSA MCHB-funded projects; and
- Providing information resources.

**The cooperative agreement recipient's responsibilities will include:**

- Conducting all tasks as they relate to the goals and activities of the Hereditary Hemorrhagic Telangiectasia (HHT) Program listed in this NOFO;
- Adhering to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds (see Acknowledgement of Federal Funding in Section 2.2 of HRSA's SF-424 Application Guide);
- Meeting the deadlines for information and reports as required by the cooperative agreement;
- Facilitating partnerships with federal and non-federal entities and other HRSA-funded programs relevant to the program;
- Communicating and collaborating on an ongoing basis with HRSA;
- Providing the federal project officer the opportunity to review project information prior to dissemination; and
- Working with the federal project officer to review information on project activities as described within this award announcement.

## 2. Summary of Funding

HRSA estimates approximately $2,000,000 to be available annually to fund one (1) recipient. The actual amount available will not be determined until enactment of the final FY 2022 federal appropriation. You may apply for a ceiling amount of up to $2,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year.

The period of performance is September 30, 2022 through September 29, 2025 (3 years). Funding beyond the first year is subject to the availability of appropriated funds for the HHT Program in subsequent fiscal years, satisfactory progress, and a decision that continued funding is in the best interest of the Federal Government. HRSA may reduce or take other enforcement actions regarding recipient funding levels beyond the first year if they are unable to fully succeed in achieving the goals listed in application.

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

Any domestic public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 25 U.S.C. 5304 (formerly cited as 25 U.S.C. 450b)) is eligible to apply. See 42 CFR § 51a.3(a)). Domestic faith-based and community-based organizations are eligible to apply.

### 2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

### 3. Other

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

- Exceeds the ceiling amount
- Fails to satisfy the deadline requirements referenced in Section IV.4

NOTE: Multiple applications from an organization are not allowable.

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

# IV. Application and Submission Information

### 1. Address to Request Application Package

HRSA ***requires*** you to apply electronically. HRSA encourages you to apply through Grants.gov using the SF-424 workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at Grants.gov: HOW TO APPLY FOR GRANTS.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for HRSA-22-145 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, certifications, etc. You must submit the information outlined in the 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 HRSA's *SF-424 Application Guide* except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the HRSA *SF-424 Application Guide* for the Application Completeness Checklist.

### Application Page Limitation

The total size of all uploaded files included in the page limit shall be no more than the equivalent of **50 pages** when printed by HRSA. The page limit includes the project and budget narratives, and attachments required in the *Application Guide* and this NOFO.

Please note: Effective April 22, 2021, the abstract is no longer an attachment that counts in the page limit. The abstract is the standard form (SF) "Project_Abstract Summary." Standard OMB-approved forms included in the workspace application package do not count in the page limit. If you use an OMB-approved form that is not included in the workspace application package for HRSA-22-145, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit. Any application exceeding the page limit of 50 will not be read, evaluated, or considered for funding.**

**Applications must be complete, within the maximum specified page limit, and validated by Grants.gov under HRSA-22-145 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 7: Other Relevant Documents*.

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

**Program Requirements and Expectations**

The HHT program will be awarded to a national center that will work with the partner centers to collect data to measure and evaluate the impact and effectiveness of the different models of care, assist with national spread and sustainability of the promising models, and provide national leadership through training, technical assistance, and education. The national center is also expected to develop and implement educational tools and resources on HHT that will increase medical provider knowledge about HHT and be responsible for a national de-identified data collection registry for HHT patients.

As part of your application, you must identify and demonstrate formal partnerships (i.e., subawards) with at least 10 (ten) partner centers that provide patient-centered care to HHT patients. Partner centers are expected to provide patient-centered, comprehensive evaluation, treatment, and education directly to patients with HHT and their families. They are also expected to enter data into the proposed national data collection registry.

The recipient will be expected to perform the following activities:

- Identify and establish a network of at least 10 partner centers to provide patient-centered care to HHT patients.
- The HHT Program requires that the center provide sufficient support (i.e., subawards) to partner centers to expand their treatment and care of individuals with HHT along with data collection and entry into a registry.
- Lead the development and implementation of a national HHT data collection registry.
- Coordinate and facilitate uniform, consistent data collection and entry across partner centers into a data collection registry.
- Establish an advisory committee to provide direction on award activities, patient registry and data needs, input on the needs of individuals with HHT and their families, and gaps in care.
- Provide ongoing education and technical assistance to partner center staff and other providers to extend knowledge of latest HHT issues and treatment.
- Provide education (tools and resources) and outreach about HHT to non-HHT providers to improve recognition and referral.
- Establish communication and collaboration methods among the partner center network to support sharing of best practices.
- Develop and implement a mechanism to identify and address national challenges and gaps in patient-centered care and within participating partner centers.
- Annually report aggregate, de-identified data from the patient registry to HRSA that highlights health outcomes and best practices.

- Develop a report by September 2025 that describes the progress in HHT since the initiation of funding.

## 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 limitation. 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<br>(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
  Briefly describe the purpose of the proposed project and the proposed outcomes.

- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion (1) NEED
  Briefly outline the needs of the individuals with HHT, including the need for coordinated care, desired healthcare outcomes, and the challenges individuals from underserved populations face accessing care.

- METHODOLOGY -- Corresponds to Section V's Review Criterion (2) RESPONSE
  Briefly describe the methods that you will use to address the stated needs and meet each of the previously described program requirements and expectations in this NOFO.

  Include a description of any innovative methods that you will use to address the stated needs. Be sure to describe the following:

  - Plans for supporting and providing funding (i.e., subawards) to partner centers to support grant related activities including data collection and entry of patient data into a registry and plans for increasing the number of patients seen by partner centers.
  - Plans to develop an advisory committee that is representative of the field to provide input on activities and needs of the field.
  - Description of the data collection registry that will be used, or how one will be created.
  - Plans to support data entry into a patient registry, including methodology for establishing uniform, consistent data entry across supported partner centers.
  - Plans for providing ongoing education and technical assistance to partner center staff in order to improve staff knowledge of HHT issues and treatment.
  - Plans to provide education and outreach about HHT to non-HHT providers to improve recognition and referral.
  - Plans to support and strengthen the network of partner centers through communication, coordination, and collaborative activities.
  - Plans to collect information related to challenges, barriers to care, and knowledge gaps around care for individuals with HHT.

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

- WORK PLAN -- Corresponds to Section V's Review Criteria (2) RESPONSE and (4) IMPACT
  Briefly describe the activities or steps that you will use to achieve each of the objectives proposed during the entire period of performance in the Methodology section. Use a timeline that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key

stakeholders in planning, designing, and implementing all activities, including developing the application. Both the work plan and logic model should be submitted as Attachment 1.

**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 time line used during program implementation; the work plan provides the "how to" steps. You can find additional information on developing logic models at the following website: https://www.acf.hhs.gov/sites/default/files/documents/prep-logic-model-ts_0.pdf. The work plan and logic model should be submitted as Attachment 1.

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

  Briefly 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.

- EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria (3) EVALUATIVE MEASURES and (5) RESOURCES/CAPABILITIES

  Describe the plan for the program performance evaluation that will contribute to continuous quality improvement. The program performance evaluation should monitor ongoing processes and the progress towards the goals and objectives of the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key personnel, budget, and other resources), key processes, and expected outcomes of the funded activities.

Describe the systems and processes that will support your organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. As appropriate, describe the data collection strategy to collect, analyze, and track data to measure process and impact/outcomes, and explain how the data will be used to inform program development and service delivery. Describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.

As you develop the evaluation plan, keep in mind that the following will be tracked and reported in the annual progress report during the period of performance:

- Number of partner centers supported and location.
- Number of new and returning patients seen by each partner center. These should be disaggregated by relevant demographic characteristics—such as age, race/ethnicity, or insurance type--as determined in collaboration with HRSA.
- Number of medical providers (non-HHT providers as well as partner center staff) reporting increased knowledge about HHT and its treatment. These should be disaggregated by relevant characteristics—such as provider role or specialty--as determined in collaboration with HRSA.
- Number of partner centers entering patient data into the data collection registry.
- Number of new patients each partner center enters into the data collection registry.
- Number of returning patients with new data points entered into the data collection registry.

- 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 as Attachment 5. Include in Attachment 5, a list of the partner centers with whom you will work and a description of the roles and responsibilities of each partner center. Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings. Describe how you will routinely assess and improve the unique needs of target populations of the communities served.

### iii. *Budget*

The directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's *SF-424 Application Guide* and the additional budget instructions provided below. A budget that follows the *Application Guide* will ensure that, if HRSA selects 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, 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, the HHT Program requires you to demonstrate that you will provide sufficient financial support to the partner centers.

### 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 limitation.** Your indirect cost rate agreement and proof of non-profit status (if applicable) will not count toward the page limitation. **Clearly label each attachment**. You must upload attachments into the application. Any *hyperlinked* attachments will *not* be reviewed/opened by HRSA.

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in Section IV.2.ii. Project Narrative. Also include the required logic model in this attachment. If you will make subawards or expend funds on contracts, describe how your organization will assure that funds are used for appropriate purposes (e.g. through a subrecipient monitoring plan).

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. In the event that a biographical sketch is included for an identified individual not yet hired, include a letter of commitment from that person with the biographical sketch.

Attachment 4: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific)

Provide any documents that describe working relationships between your organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverable. Make sure any letters of agreement are signed and dated.

Attachment 5: Project Organizational Chart

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

Attachment 6: Tables, Charts, etc. (optional)

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

Attachments 7–15: 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)

The UEI, a "new, non-proprietary identifier" assigned by the System for Award Management (SAM.gov), will replace the *Data Universal Numbering System (DUNS) number.

From now until April 3, 2022, if you are not already registered in SAM.gov and wish to do business with the Federal Government, you need to obtain and/or use a UEI (DUNS) to register your entity in SAM.gov. Continue to use your UEI (DUNS) for registration and reporting until April 3, 2022.

Effective April 4, 2022:

- You can register in SAM.gov and you will be assigned your UEI (SAM) within SAM.gov.
- You will no longer use UEI (DUNS) and that number will not be maintained in any Integrated Award Environment (IAE) systems (SAM.gov, CPARS, FAPIIS, eSRS, FSRS, FPDS-NG). For more details, visit the following webpages: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update.

You must register with SAM and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless 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.gov 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.

*Currently, the Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (https://www.dnb.com/duns-number.html) *(through April 3, 2022)*
- System for Award Management (SAM) (https://sam.gov/content/home | SAM.gov Knowledge Base)
- Grants.gov (https://www.grants.gov/)

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

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

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

## 4. Submission Dates and Times

### Application Due Date

The due date for applications under this NOFO is *May 17, 2022 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 Application Guide* for additional information.

## 5. Intergovernmental Review

The Hereditary Hemorrhagic Telangiectasia (HHT) Program is not subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

## 6. Funding Restrictions

You may request funding for a period of performance of up to 3 years, at no more than $2,000,000 per year (inclusive of direct **and** indirect costs). Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division H of the Consolidated Appropriations Act, 2022 apply to this program. See Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in following fiscal years, as required by law.

You cannot use funds under this notice for the following purposes:

- Foreign travel: No foreign travel (using federal award dollars or federal program income) is allowed.

You are required to have the necessary policies, procedures, and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like 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 critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review.

Six review criteria are used to review and rank the HHT Program 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
The extent to which the application demonstrates an understanding of the problem and associated contributing factors to the problem. This includes the extent to which the application:

- Describes the target population and its unmet health needs in this section, and
- Discusses relevant barriers to service that this project will overcome.

Criterion 2: RESPONSE (40 points) – Corresponds to Section IV's Methodology, Work Plan and Resolution of Challenges
The extent to which the proposed project responds to the "Purpose" included in the program description and each of the Program Requirements and Expectations. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

*Methodology (20 points):* The strength, completeness, and feasibility of the applicant's approach to addressing the purpose, objectives, program requirements, and expectations in this NOFO.

*Work Plan and Logic Model (15 points)*

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

*Resolution of Challenges (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
The strength and effectiveness of the methods proposed to monitor and evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, 2) to what extent these can be attributed to the project and 3) the capability of the applicant to collect and report on Program Objectives and data specified under the Evaluation and Technical Support Capacity section.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Work Plan
The extent to which the proposed project has a public health impact and the project will be effective, if funded. This may include the effectiveness of plans for dissemination of project results, the impact results may have on the community or target population, the extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

Criterion 5: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information
The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The degree to which the applicant organization demonstrates readiness to provide the services and meet the award requirements, including its identification and documentation of partnership with at least 10 partner centers. The capabilities of the applicant organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's Budget and Budget Narrative
The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives, the complexity of the activities, and the anticipated results.

- The extent to which costs, as outlined in the budget and required resources sections are reasonable given the scope of work.
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.

**2. Review and Selection Process**

The objective review process provides an objective evaluation 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.

### 3. Assessment of Risk

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

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

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

HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk 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 September 30, 2022. 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 must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights (OCR) provides guidance on complying with civil rights laws enforced by HHS. See Providers of Health Care and Social Services and HHS Nondiscrimination Notice.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. 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 Fact Sheet on the Revised HHS LEP Guidance and Limited English Proficiency.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see Discrimination on the Basis of Disability.
- HHS-funded health and education programs must be administered in an environment free of sexual harassment. See Discrimination on the Basis of Sex.
- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see Conscience Protections for Health Care Providers and Religious Freedom.

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, 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.

### 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.

- Refer to instructions provided in HRSA's *SF-424 R&R 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.
- Refer to HRSA's *SF-424 R&R 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 any page limitation in the Methodology 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).

### 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 HRSA Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report **annually**, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at https://grants4.hrsa.gov/DGISReview/ProgramManual?NOFO=HRSA-22-145&ActivityCode=UP4. The type of report required is determined by the

project year of the award's period of performance.

| Type of Report | Reporting Period | Available Date | Report Due Date |
|---|---|---|---|
| **a) New Competing Performance Report** | September 30, 2022<br><br>*(administrative data and performance measure projections, as applicable)* | Period of performance start date | 120 days from the available date |
| **b) Non-Competing Performance Report** | September 30, 2023 | Beginning of each budget period (Years 2–3, as applicable) | 120 days from the available date |
| **c) Project Period End Performance Report** | September 29, 2025 | Period of performance end date | 90 days from the available date |

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

2) **Progress Report(s)**. The recipient must submit a progress report narrative to HRSA **annually** via the Non-Competing Continuation Renewal in the EHBs, which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year). Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA.

3) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in FAPIIS, 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:

Marc Horner
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-4888
Email: mhorner@hrsa.gov

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

Cristina Novoa, Ph.D.
Attn: HHT Program
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room
Rockville, MD 20857
Telephone: (301) 443-1463
Email: cnovoa@hrsa.gov

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

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International callers 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 the 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
Telephone: (877) 464-4772 / (877) Go4-HRSA
TTY: (877) 897-9910
Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

# VIII. Other Information

## Technical Assistance

HRSA has scheduled following technical assistance:

*Webinar*

Day and Date: Tuesday, April 5, 2022
Time: 2–3 p.m. ET
Call-In Number: 1-833-568-8864
Participant Code: 37251045
Weblink: https://hrsa-gov.zoomgov.com/j/1615874839?pwd=TVhzaTM2WTgwOU1DNUxHQ0dDYmpPdz09

HRSA will record the webinar and make it available at: https://mchb.hrsa.gov/fundingopportunities/default.aspx.

### Tips for Writing a Strong Application

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