U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA
Health Resources & Services Administration

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

Regional Genetics Networks

Funding Opportunity Number: HRSA-20-046
Funding Opportunity Type(s): Competing Continuation, New
Assistance Listings (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Application Due Date: January 14, 2020

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

Issuance Date: October 16, 2019

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2020 for the Regional Genetics Networks program. The purpose of this program is to develop and support a regional infrastructure system to provide health care professionals with education and to assess and coordinate follow-up and treatment relating to genetic disorders by linking patients to genetic services.

HRSA will fund one application per region, and recipients will undertake activities to support all of the states listed for the region. Seven Regional Genetics Networks will be funded, as follows:

1. **New England**: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
2. **Mid-Atlantic**: Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Puerto Rico, the Virgin Islands, Virginia, and West Virginia.
3. **Southeast**: Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee.
4. **Midwest**: Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin.
5. **Heartland**: Arkansas, Iowa, Kansas, Missouri, Nebraska, North Dakota, Oklahoma, and South Dakota.
6. **Mountain**: Arizona, Colorado, Montana, Nevada, New Mexico, Texas, Utah, and Wyoming.
7. **Western**: Alaska, California, Guam, Hawaii, Idaho, Oregon, and Washington.

The FY 2020 President's Budget does not request funding for this program. This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. You should note that this program may be cancelled prior to award.

Funding Opportunity Title:	Regional Genetics Networks
Funding Opportunity Number:	HRSA-20-046
Due Date for Applications:	January 14, 2020
Anticipated Total Annual Available FY 2020 Funding:	$4,200,000
Estimated Number and Type of Award(s):	Up to seven cooperative agreements
Estimated Award Amount:	Up to $600,000 per year, subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	June 1, 2020 through May 31, 2024 (4 years)

Eligible Applicants:	(1) a state or a political subdivision of a state; (2) a consortium of two or more states or political subdivisions of states; (3) a territory; (4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or (5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.
	See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

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

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Monday, November 18, 2019
Time: 3–4 p.m. ET
Call-In Number: 1-888-826-9572
Participant Code: 77014936
Weblink: https://hrsa.connectsolutions.com/hrsa20046/

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

This notice announces the opportunity to apply for funding under the Regional Genetics Networks (RGN) program. The purpose of this program is to develop and support a regional infrastructure system to provide health care professionals with education and to assess and coordinate follow-up and treatment relating to genetic disorders by linking patients to genetic services.[1] Each RGN will accomplish this by:

- developing and implementing mechanisms to identify individuals and their families with or at risk for such disorders, and to connect them to genetic services, with a focus on individuals who are underserved;
- coordinating with the Advances in Integrating Genetics into Clinical Care (AIGCC) (HRSA-20-050) program to provide health professionals with education, training, and other resources to improve their knowledge of genetic conditions and improve their ability to: identify individuals with or at risk for those conditions; refer for genetic services, apply genetic information in clinical management; and care for underserved population(s) in partnership with genetic services providers within the region;
- facilitating the implementation of telehealth and/or telemedicine to increase access to genetic services; and
- coordinating with the National Genetics Education and Family Support Program (HRSA- 20-049), and provide education to families, especially those who are underserved, about genetics and genetic services.

HRSA will fund one application per region, and recipients will undertake activities to support all of the states listed for the Region. Seven Regional Genetics Networks will be funded, as follows:

1. **New England**: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
2. **Mid-Atlantic**: Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Puerto Rico, the Virgin Islands, Virginia, and West Virginia.
3. **Southeast**: Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee.
4. **Midwest**: Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin.
5. **Heartland**: Arkansas, Iowa, Kansas, Missouri, Nebraska, North Dakota, Oklahoma, and South Dakota.
6. **Mountain**: Arizona, Colorado, Montana, Nevada, New Mexico, Texas, Utah, and Wyoming.
7. **Western**: Alaska, California, Guam, Hawaii, Idaho, Oregon, and Washington.

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[1] A genetic disorder is a disease caused in whole or in part by a change in the DNA sequence away from the normal sequence. For the purpose of this funding opportunity, genetic disorders include congenital disorders and metabolic disorders. National Institutes of Health, National Human Genome Research Institute, Accessed September 6, 2019, https://www.genome.gov/For-Patients-and-Families/Genetic-Disorders.

Goal

HRSA funds a portfolio of three coordinated programs to improve access to genetic services, especially for underserved, disadvantaged, geographically isolated, and special needs populations: the Regional Genetics Networks (HRSA-20-046); the Advances in Integrating Genetics into Clinical Care (AIGCC) (HRSA-20-050); and the National Genetics Education and Family Support Center (HRSA-20-049). The goal of the RGN program is to improve health equity and health outcomes in individuals with genetic conditions and to improve the quality of coordinated and comprehensive services to children with such conditions and their families by supporting an infrastructure to improve access to genetic services, providing training and education to health care professionals, and supporting families.

Objectives
1) By May 2024, each RGN will facilitate connections to genetic services for at least 2,000 individuals or families with or at risk for genetic conditions, within the geographic area served by the RGN.
2) By May 2024, increase to at least 33 percent of the individuals who are medically underserved[2] with or at risk for genetic conditions, served by each RGN.
3) By May 2024, increase by 20 percent the number of health care providers receiving education or training through the RGN.
4) By May 2024, increase by 20 percent the number of individuals with or at risk for genetic conditions, receiving genetic services through telemedicine visits.
5) By May 2024, increase by 20 percent the number of RGN resources accessed.

Competing continuation applicants should use baseline data for the last year of the current (i.e., immediately preceding) project to establish the new benchmark for the objectives listed above. For new applicants, baseline data will be collected and provided to HRSA for purposes of establishing the benchmark for the objectives listed above by the end of year 1 of the award.

Program Priorities
1) Support a regional infrastructure for the genetics health care delivery system.
2) Provide education-related activities for providers, families, individuals, and other stakeholders.
3) Facilitate the use of telehealth and telemedicine in the genetics health care delivery system.

2. Background

This program is authorized by the Public Health Service Act, Title XI, § 1109(a)(2) and (4) (42 U.S.C. 300b-8(a)(2) and (4)), as amended. The RGN program provides support

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[2] Medically Underserved Populations are specific sub-groups of people living in a defined geographic area with a shortage of primary care health services. These groups may face economic, cultural, or linguistic barriers to health care. Examples include, but are not limited to, those who are: homeless; low-income; Medicaid-eligible; Native American; or migrant farmworkers. Health Resources and Services Administration, "Medically Underserved Areas and Populations (MUA/Ps)," Accessed June 13, 2019, https://bhw.hrsa.gov/shortage-designation/muap.https://bhw.hrsa.gov/shortage-designation/muap.

for a regional infrastructure system to provide health care professionals with education and to assess and coordinate followup and treatment relating to genetic disorders.[3]

In 2017, approximately 3.5 percent of children ages 0–17 years were reported to have a genetic condition, representing approximately 2.6 million children.[2] Findings from the National Survey of Children's Health 2017 indicate that children with a genetic condition were more likely to also report a comorbid health condition, compared to children without a genetic condition. For example, 60 percent of children with a genetic condition also reported a behavioral, developmental, or intellectual condition, compared with only 14.4 percent of children without a genetic condition. Thirty percent of children with a genetic condition report having a mental health condition, compared to 6 percent of children without a genetic condition. Twelve percent of children with a genetic condition report missing 11 or more days of school due to illness or injury compared with 3.3 percent of children without a genetic condition. Children diagnosed with a genetic condition are less likely to have a medical home (39.5 percent compared with 49.1 percent for children without a genetic condition) and are more likely to have an unmet health need.[4]

Access to genetic and related services can be challenging for individuals and their families. Primary care providers, including pediatricians, often lack confidence in identifying children who have or are at risk of having a genetic condition and facilitating referrals to genetic services for individuals with or at risk for genetic conditions.[5,6,7] The genetic workforce is primarily concentrated in urban areas, further limiting access to genetic services for children and families who live in rural or geographically isolated areas across the United States.[8, 9] Once a diagnosis has been made, individuals may not know where to get condition-specific information, or how to access specialty care or other services related to their condition.

These findings indicate the need for genetic services and improved access to care for children and families with genetic conditions. Providers need additional training in identifying genetic conditions, providing clinical care and referrals for specialty care, and reaching underserved populations in need of genetic services. Telehealth can be an important tool for improving access to services and resources. Telehealth is defined as the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient, and professional health-related education, public health, and health administration. Technologies include video conferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless

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[3] A genetic disorder is a disease caused in whole or in part by a change in the DNA sequence away from the normal sequence. For the purpose of this funding opportunity, genetic disorders include congenital disorders and metabolic disorders. National Institutes of Health, National Human Genome Research Institute, Accessed September 6, 2019, https://www.genome.gov/For-Patients-and-Families/Genetic-Disorders.

[4] National Survey of Children's Health, Data Resource Center for Child and Adolescent Health, Accessed June 25, 2019, https://www.childhealthdata.org/.

[5] Hauser D, Obeng AO, Fei K, et al. Views of primary care providers on testing patients for genetic risks for common chronic diseases. Health Affairs 2018; 37:793–800.

[6] Klitzman R, Chung W, Marder K, Shanmugham A, Chin LJ, Stark M, et al. Attitudes and practices among internists concerning genetic testing. J Genetic Counseling 2013;22(1): 90–100.

[7] Saul RA, Trotter T, Sease K, Tarini B. Survey of family history taking and genetic testing in pediatric practice. J Community Genetics 2017;8(2):109–15.

[8] Cooksey, J., Forte, G., Benkendorf, J., & Blitzer, M. The state of the medical geneticist workforce: findings of the 2003 survey of American Board of Medical Genetics certified geneticists. Genetics in Medicine : Official Journal of the American College of Medical Genetics. 7(6), 439–443.

[9] Flannery, D. Challenges and opportunities for effective delivery of clinical genetic services in the US healthcare system. Current Opinion in Pediatrics 2018, 30(6): 740–745.

communications. Telehealth is especially critical in rural and other geographically isolated areas that lack sufficient health care services, including genetic services.

To address issues related to access to genetic services, HRSA made awards to seven regional recipients in FY 2017. The RGNs developed regional infrastructures to facilitate linking patients to genetic services, especially those that were underserved, facilitated the use of telehealth and telemedicine in the regions, and provided education and training to health care providers, families, and individuals on the use of genetic and genomic information. This funding opportunity will build upon the activities undertaken during the previous funding cycle.

II. Award Information

1. Type of Application and Award

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

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

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

The cooperative agreement recipient's responsibilities will include:
- Conducting all tasks as they relate to the goals of the RGNs listed under the "Purpose" section of this funding opportunity;
- Participating in HRSA-supported activities convened by the AIGCC;
- Ensuring the integral involvement of the RGNs with the National Genetics Education and Family Support Center Family Center;
- Reviewing, on a continuous basis, activities and procedures to be established and implemented for accomplishing the RGNs' goals, objectives, and activities;

- Providing ongoing, timely communication and collaboration with the federal project officer;
- Working with the federal project officer to review information on RGN activities, reports, and products prior to dissemination;
- Establishing contacts that may be relevant to the RGNs' project's mission;
- Facilitating partnerships with federal and non-federal entities and other HRSA-funded programs relevant to the RGN's cooperative agreement activities; and
- Meeting deadlines for RGN information and reports as required by HRSA.

2. Summary of Funding

HRSA estimates approximately $4,200,000 to be available annually to fund seven recipients. The actual amount available will not be determined until enactment of the final FY 2020 federal appropriation. You may apply for a ceiling amount of up to $600,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The FY 2020 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. The period of performance is June 1, 2020 through May 31, 2024 (4 years). Funding beyond the first year is subject to the availability of appropriated funds for the Regional Genetics Networks in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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

III. Eligibility Information

1. Eligible Applicants

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

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

SUPPLEMENT NOT SUPPLANT
Per legislation, funds appropriated under this section shall be used to supplement and not supplant other federal, state, and local public funds provided for activities of the type described in this section.

3. Other

An applicant may NOT apply for funding as a recipient under both this program and either the Advances in Integrating Genetics into Clinical Care program (HRSA-20-050) or the National Genetics Education and Family Support Program (HRSA-20-049). If an applicant applies for funding under this and either of these two other funding opportunities, its application will be considered non-responsive and both applications will be deemed nonresponsive and will not be considered for funding under this NOFO.

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

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

NOTE: Multiple applications from an organization are not allowable.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

APPROVAL FACTORS
Per legislation, an application for a grant under this section shall not be approved by the Secretary unless the application contains assurances (as *Attachment 8*) that the eligible entity has adopted and implemented, is in the process of adopting and implementing, or will use amounts received under such grant to adopt and implement the guidelines and recommendations of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the ACHDNC and adopted by the Secretary.

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

IV. Application and Submission Information

1. Address to Request Application Package

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

The NOFO is also known as "Instructions" on Grants.gov. You must provide your email address when reviewing or preparing the workspace application package in order to receive notifications including modifications and/or republications of the NOFO on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the For Applicants page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

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

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

Application Page Limit
The total size of all uploaded files may not exceed the equivalent of **50 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification
1) You, on behalf of the applicant organization certify, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.

2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
3) Where you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 9: Other Relevant Documents*.

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

Program-Specific Instructions

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

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

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

Successful applications will contain the information below. Please note that this is not a planning cooperative agreement. After award, recipients are required to conduct work on the project within the first 6 months of the period of performance. 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, the methods to be used, and the projected outcomes.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion (1) Need*
Outline the needs of the community. Describe and document the target population and its unmet needs in the region. Use and cite demographic data whenever possible to support the information provided. Discuss any relevant barriers that the project hopes to overcome. Address the needs of geneticists, primary and specialty care providers, and families. This section will help reviewers understand the population and health care system that you will serve with the proposed project.

- *METHODOLOGY -- Corresponds to Section V's Review Criterion (2) Response*
Propose methods that you will use to address the stated needs and meet each of the previously described program purpose, goal, and objectives in this NOFO. As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination with efforts to involve patients, families, and communities. If

applicable, include a plan to disseminate reports, products, and/or project outputs so key target audiences receive the project information.

Include a description of methods that you will use to address the following activities:

1. **Support a Regional Infrastructure**
   - Provide a draft of a region-specific strategic plan, tailored to one of the seven regions identified in this NOFO, that will address access to genetic services in each state/territory/district of the region, what particular populations will be targeted, and by what methods. The strategic plan will be reviewed by HRSA and finalized 6 months after the start date and reviewed and updated as appropriate at least once a year.
   - Establish an advisory committee that is reflective of the region and populations to be served. Be sure to include names and letters of agreement. Activities of the advisory committee may include, but are not limited to:
     - Providing expertise on the strategic plan for the region;
     - Identifying underserved populations, regional needs, and resources;
     - Reviewing resources developed (i.e., web-based resources, fact sheets, etc.);
     - Reviewing strategies for collecting performance measure data;
     - Reviewing final data prior to submission to the AIGCC.
   - Propose mechanisms to link patients to genetic services. Mechanisms may include, but are not limited to:
     - partnerships and/or contracts as appropriate with academic institutions, health systems, or public health professionals/entities to coordinate access to genetic services;
     - using telehealth or innovative outreach methods to reach patients and providers.
   - Propose mechanisms to identify and engage with underserved populations in the region that need access to genetic services.
   - Establish communication strategies to share information, successes, and barriers within the region and with the other regions.
   - Ensure that individuals or families with genetic conditions or that represent the populations to be served participate in all activities and planning in the region.
   - Establish data collection methods and work with the AIGCC on evaluation program activities, including the collection of RGN data and submitting to the AIGCC.
   - Partner with stakeholders in the region addressing genomic/genetic services including, but not limited to: HRSA-funded programs such as the Sickle Cell Treatment Demonstration Regional Collaboratives; the Sickle Cell Newborn Screening Program; the Regional Hemophilia Network Program; the Maternal and Child Environmental Health Network; HRSA-Supported Health Centers (funding recipients and lookalikes); the CARES National Interdisciplinary Training Resource

Center; Leadership, Education in Neurodevelopmental and Related Disabilities Program (LEND); the Catalyst Center, Improving Financing of Care for Youth and Children with Special Health Care Needs; the Association of Maternal and Child Health Programs (AMCHP); the Association of State and Territorial Health Officials (ASTHO).

2. **Provide Education-related Activities for Providers, Families and Individuals, and Other Stakeholders**
   - Develop, maintain, and update a regional web-based genetics resource for primary care providers, public health professionals, and individuals with or at risk for genetic conditions and their families.
   - Develop and expand educational resources for primary care providers, in coordination with the AIGCC. Educational resources may include, but are not limited to:
     - Project Echo-like projects or other e-consults to educate providers on genetic services.
     - Meetings, webinars, online courses.
   - Provide support to family leaders to participate in RGN activities, including attending annual meetings.
   - Develop educational resources for families in coordination with the National Genetics Education and Family Support Center.
   - Convene an annual regional meeting of partners, other stakeholders, and experts working within the region

3. **Facilitate the Use of Telehealth and Telemedicine in Genetics**
   - Provide technical assistance (TA) to geneticists, and primary and specialty care providers on various health information technology, such as telehealth/telemedicine, mobile health (mhealth), etc., to improve practice efficiencies and to link patients to services.
   - Facilitate the implementation of telehealth/telemedicine sites that provide services within the region. Provide documentation that shows which clinical sites will be implementing telehealth/telemedicine within the first 6 months of the project.

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

- *WORK PLAN -- Corresponds to Section V's Review Criteria (2) Response and (4) Impact*
  Submit a work plan *(Attachment 1)* that describes the activities or steps you will use to achieve each of the objectives proposed during the entire period of performance in the Methodology section. Use a time line that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities, including developing the application. This is not a planning

cooperative agreement; therefore, the work plan may not include planning activities that take the entire first year of the period of performance. Propose activities that you will implement within the first 6 months of the period of performance.

Logic Models

Submit **a logic model** *(Attachment 1)* **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., objectives, 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:
http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

- *RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion (2) Response*
  Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges.

- *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, 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.

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

- Number of providers, individuals, and families that received education or training on genetics from the RGN program
- Number of resources on genetics used/accessed from the RGN program
- Number of patients for whom the RGN program facilitated connections to a geneticist
- Number of providers trained in an RGN-supported event that focuses on telehealth modalities for genetics
- Number of RGN sites that use telehealth modalities
- Number of patients for whom telehealth modalities for genetics were used

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion (5) Resources/Capabilities*
  Succinctly describe your organization's current mission and structure, scope of current activities, and how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. Include an organizational chart *(Attachment 5)*. Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings. Describe how you will routinely assess and improve the unique needs of target populations of the communities served.

NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review.

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 and Budget Narrative	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

iii. Budget

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

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245), Division B, § 202 states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." See Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in the following FY, as required by law.

iv. Budget Narrative

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

In addition, the Regional Genetics Networks program requires funding for the following activities:

- Convening annual regional meeting
- Supporting travel for RGN key personnel including Co-Program Directors and Program Manager, to an annual meeting of RGN Program Directors/Managers conducted by AIGCC
- Supporting travel for family leaders to attend RGN regional annual meetings
- Implementing and/or supporting telehealth/telemedicine sites. Examples may include purchase of equipment and salary support. Please note that funds under this award may not be used to provide services to patients.

v. Program-Specific Forms

Program-specific forms are not required for this application.

vi. *Attachments*

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

Attachment 1: Work Plan

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

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's [SF-424 Application Guide]())

Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff. Also, please include a description of your organization's timekeeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

Attachment 3: Biographical Sketches of Key Personnel

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

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

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

Attachment 5: Project Organizational Chart

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

Attachment 6: Tables, Charts, etc.

To give further details about the proposal (e.g., Gantt or PERT charts, flow charts).

Attachment 7: Progress Report
(FOR COMPETING CONTINUATIONS ONLY)

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

progress made in attaining these goals and objectives. HRSA program staff reviews the progress report after the Objective Review Committee evaluates the competing continuation applications.

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

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

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

(3) <u>Results</u> - Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important. Competing Continuation applicants should include data collected during the current project.

Attachment 8: Assurances as detailed in the <u>*APPROVAL FACTORS*</u> *section. Briefly describe (not more than one page) how program activities support or will support the ACHDNC guidelines and recommendations.*

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

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

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

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

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

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

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

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

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at SAM.gov.

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

4. Submission Dates and Times

Application Due Date
The due date for applications under this NOFO is *January 14, 2020 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 Regional Genetics Networks program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

6. Funding Restrictions

You may request funding for a period of performance of up to 4 years, at no more than $600,000 per year (inclusive of direct **and** indirect costs). The FY 2020 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. Awards to support projects beyond the first budget year will be

contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division B of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245) are in effect at the time this NOFO is posted. Please see Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Awards will be made subsequent to enactment of the FY 2020 appropriation. The NOA will reference the FY 2020 appropriation act and any restrictions that may apply. Note that these or other restrictions may be updated, as required by law, upon enactment of a FY 2020 appropriations act.

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

- Foreign travel: Any foreign travel request (using federal award dollars or program income) must be submitted to HRSA for approval through the Electronic Handbooks (EHBs) under Prior Approval – Other.

Per legislation, an eligible entity may not use amounts received to—
1) provide cash payments to or on behalf of affected individuals;
2) provide inpatient services;
3) purchase land or make capital improvements to property; or
4) provide for proprietary research or training.

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

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

V. Application Review Information

1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

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

Review criteria are used to review and rank applications. The RGN program has six review criteria. See the review criteria outlined below with specific detail and scoring points.

For each review criterion, the reviewer will consider the thoroughness of the approach and methods, how effectively the proposal addresses the issues, and how the proposed activities are feasible and achievable.

Criterion 1: NEED (10 points) – Corresponds to Section IV's Needs Assessment
- The extent to which the application effectively demonstrates the problem and associated contributing factors to the problem.
- Sufficient demonstration of the needs of geneticists, primary and specialty care providers, and families.
- The quality of the description and documentation of the target population and its unmet needs.
- Sufficient demonstration of demographic data to support the information provided.
- Sufficient identification and discussion of relevant barriers that the project hopes to overcome.

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's Methodology, Work Plan, and Resolution of Challenges
The extent to which the proposed project effectively responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of effectively addressing the problem and attaining the project objectives.

Methodology (25 points)
The strength, completeness, and feasibility of the applicant's approach to:

1. **Supporting a Regional Infrastructure (10 points)**
   - Creating a region-specific strategic plan to be reviewed and updated as appropriate at least once a year. Was a draft of the strategic plan included in the application? How was it developed? Were stakeholders included? Is it achievable within the period of performance?
   - Establishing an advisory committee that is reflective of the region and populations to be served. Members should be identified and letters of agreement included in the application. Is it clear how the advisory committee will be used to guide regional goals and activities?
   - Developing mechanisms to identify and engage with underserved populations in the region that need access to genetic services. Will the proposal result in patients getting access to services?

- o Proposing mechanisms to link patients to genetic services. Are the mechanisms achievable and result in increase in patients receiving genetic services?
- o Establishing communication strategies to share information, successes, and barriers within the region and with the other regions.
- o Ensuring that individuals or families with genetic conditions or that represent the populations to be served participate in meaningfully ways in all activities and planning in the region.
- o Establishing feasible data collection methods and work with the AIGCC on evaluation program activities, including the collection and submission of RGN data to the AIGCC.
- o Partnering with stakeholders addressing genomic/genetic services. How will partners be incorporated into RGN activities?

2. **Providing Education-related Activities for Providers, Families, Individuals, and Other Stakeholders (5 points)**
    - o Developing, maintaining, and updating a regional web-based genetics resource for primary care providers, public health professionals, and individuals with or at risk for genetic conditions and their families. How will content be identified? How will the website be evaluated?
    - o Developing educational resources for primary care providers, in coordination with the AIGCC. How will decisions be made about what content to develop? How will it be evaluated?
    - o Providing support to family leaders to participate in RGN activities, including attending annual meetings.
    - o Developing educational resources for families in coordination with the National Genetics Education and Family Support program. How will decisions be made about what content to develop? How will the resources be evaluated?
    - o Convening an annual regional meeting of partners, other stakeholders, and experts working within the region.

3. **Facilitating the Use of Telehealth and Telemedicine in Genetics (5 points)**
    - o Providing technical assistance (TA) to primary care providers and other specialists on various health information technology, such as telehealth/telemedicine, mobile health (mhealth), etc., to improve practice efficiencies and to reach underserved populations.
    - o Identifying sites for the implementation of telehealth/telemedicine sites that provide services within the region.

4. **Sustainability (5 points)**
    - o Plans for project sustainability after the period of federal funding ends.
    - o Plans 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 (5 points)
- • The reasonableness, feasibility, and effectiveness of the proposed work plan, including the following:

- Describes the activities or steps that will be used to achieve each of the objectives proposed in the Methodology section.
- Describes activities that will be implemented within the first 6 months of the period of performance.
- Identifies meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities, including developing the application.

Resolution of Challenges (5 points)
- The extent to which the applicant effectively discusses potential challenges and approaches to resolve such challenges.

Criterion 3: EVALUATIVE MEASURES (25 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity
The strength and effectiveness of the method proposed to monitor and evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project.

The extent to which the applicant:
- Describes a comprehensive plan for the program performance evaluation that will contribute to continuous quality improvement.
- Plans to monitor ongoing processes and the progress towards the goals and objectives of the project.
- Describes feasible systems and processes that will support 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.
- Describes current experience, skills, knowledge, materials published, and previous work of a similar nature.
- Describes an effective and achievable data collection strategy to collect, analyze, and track data to measure process and impact/outcomes, and explains how data will be used to inform program development and service delivery.
- Thoroughly describes potential obstacles for implementing the program performance evaluation and plans to address those obstacles.

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 (10 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information
The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and

the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

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

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

2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. 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.

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

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

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

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of June 1, 2020. 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*.

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. 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 federally 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 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.

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 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://grants6.hrsa.gov/MchbExternal/DgisApp/formassignmentlist/UH7_1.html The type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	June 1, 2020 – May 31, 2024 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	June 1, 2020 – May 31, 2021 June 1, 2021 – May 31, 2022 June 1, 2022 – May 31, 2023	Beginning of each budget period (Years 2–4, as applicable)	120 days from the available date
c) Project Period End Performance Report	June 1, 2023 – May 31, 2024	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), and include annual data on performance measures identified in the Project Narrative, if not captured by DGIS. 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](#).

VII. Agency Contacts

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

Stanley Gordon
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10W10B
Rockville, MD 20857
Telephone: (301) 945-3935
Email: sgordon2@hrsa.gov

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

Ann Ferrero, MPH
Public Health Analyst
Genetic Services Branch
Division of Services for Children with Special Health Needs
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3999
Fax: (301) 594-0878
Email: aferrero@hrsa.gov

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

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

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

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

VIII. Other Information

Technical Assistance

HRSA has scheduled following technical assistance:

Webinar

Day and Date: Monday, November 18, 2019
Time: 3–4 p.m. ET
Call-In Number: 1-888-826-9572
Participant Code: 77014936
Weblink: https://hrsa.connectsolutions.com/hrsa20046/

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*.