

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Health Resources & Services Administration

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

Advances in Integrating Genetics into Clinical Care

Funding Opportunity Number: HRSA-20-050
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: SPRANS, Title V, § 501(a)(2) of the Social Security Act, as amended (42 U.S.C. 701(a)(2))

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2020 for the Advances in Integrating Genetics into Clinical Care program. The purpose of this program is to serve as a national resource on the use of genetic and genomic information in clinical practice for genetic service providers, primary and specialty health care providers, and families.

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:	Advances in Integrating Genetics into Clinical Care
Funding Opportunity Number:	HRSA-20-050
Due Date for Applications:	January 14, 2020
Anticipated Total Annual Available FY 2020 Funding:	\$800,000
Estimated Number and Type of Award(s):	Up to one cooperative agreement
Estimated Award Amount:	Up to \$800,000 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:	<p>Any domestic public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 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.</p> <p>See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.</p>

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: Wednesday, November 20, 2019

Time: 3:30–4:30 p.m. ET

Call-In Number: 1-888-826-9572

Participant Code: 77014936

Weblink: <https://hrsa.connectsolutions.com/hrsa20050/>

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 Advances in Integrating Genetics into Clinical Care (AIGCC) program. The purpose of this program is to serve as a national resource on the use of genetic and genomic information in clinical practice for genetic service providers, primary and specialty health care providers, and families.

The program will accomplish this by implementing the priorities below.

Program Priorities

- Serve as a national resource for developing and disseminating evidence-based practices, policies, tools, and resources related to the genetics care delivery system in the United States.
- Monitor, analyze, track, and report on national policy issues related to the genetics care service delivery system with a focus on finance and insurance coverage; genetics workforce; and emerging issues in the use of genetic testing and technologies.
- Develop and sustain partnerships with relevant national organizations and key stakeholders.
- Disseminate information on practices, policies, and resources related to the genetics care delivery system to states and stakeholders.
- Support the Regional Genetics Networks (RGNs) (HRSA-020-046) recipients through technical assistance, training, education, and evaluation.
- Coordinate with the Regional Genetics Networks on providing education and resources to primary and specialty health care providers on the use of genetic and genomic information in clinical care.
- Coordinate with the National Genetics Education and Family Support Program (NGEFSP) (HRSA-20-049) to provide education to medically underserved populations about genetic conditions and services to improve knowledge of genetic conditions among children and families.

Program Goals

HRSA funds a portfolio of three coordinated genetics programs to improve access to genetic services, especially those who are underserved, disadvantaged, geographically isolated, and special needs populations: the RGNs; the AIGCC; and the NGEFSP. The goals of the AIGCC program are 1) to improve access to genetic and genomic information for use in clinical practice by strengthening non-genetic provider ability to use genetic information to improve clinical care; 2) to improve the quality of genetic services; and 3) to support the activities of the RGNs to meet the needs of health care providers and individuals and families with, or at risk for, genetic conditions in their regions.

Program Objectives

- 1) By May 2024, increase by 25 percent from baseline the number of health care providers using AIGCC resources and materials.
- 2) By May 2024, increase by 80 percent from baseline the number of health care providers who report increased ability to use genomics in clinical practice as a result of AIGCC activities, resources, and materials.
- 3) By May 2024, increase by 25 percent from baseline the dissemination of information through multiple platforms on evidence-based/informed and innovative practices, tools, resources to improve genetic health care delivery systems.
- 4) By May 2024, 100 percent of RGN recipients report increased ability to meet program objectives due to the resources provided by the AIGCC.

Competing continuation applicants should use baseline data based on the last year of the current project. New applicants will provide baseline data to HRSA for purposes of establishing the benchmark for this program objective by the end of the first year of the award, May 31, 2021.

2. Background

This program is authorized by SPRANS, Title V, § 501(a)(2) of the Social Security Act, as amended (42 U.S.C. 701(a)(2)).

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.¹ Families with children who have, or who are at risk of having, a genetic condition need access to genetic services which include genetic testing, diagnosis, and treatment and genetic counseling to help families understand the implications of a genetic diagnosis in the family. Yet numerous challenges exist to obtaining access to quality genetic services in this country, especially for those who are underserved, disadvantaged, or geographically isolated. A recent assessment of the workforce estimated that there are only 1.78 genetic service providers² per 100,000 U.S. citizens.³ Additionally, genetic service providers tend to be located in urban academic settings, limiting access even more for those in rural areas. Issues related to health insurance coverage of genetic tests further complicates service delivery. Using innovative technologies to reach patients and their providers such as telemedicine and improving the efficiency of clinical genetic services can help address these issues to some degree, but it does not solve the overall workforce and coverage issue. One solution is to have primary and specialty care providers take a greater role in identifying patients who would benefit from genetic services, understanding what genetic tests to order, and how to use the information in the clinical management of patients. However, providers report low confidence in using

¹ National Survey of Children's Health, Data Resource Center for Child & Adolescent Health, Accessed June 25, 2019, <https://www.childhealthdata.org/>.

² Genetic service providers are defined as medical geneticist and genetic counselors.

³ 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.

genetic information.^{4,5,6} This is not surprising as a recent analysis estimated that there are approximately 75,000 genetic tests on the market, representing about 10,000 unique test types.⁷ One study demonstrated that as many as 25 percent of genetic tests were incorrectly ordered based on the patients clinical findings and/or family history.⁸

HRSA has funded this program since 2017 to address gaps in access to genetics care, especially for underserved populations and to provide support to the RGN program. In addition, the program advances the knowledge of primary and specialty health professionals and the genetics field by serving as a national driver for research and policy analysis on the use of genomic advances in clinical medicine and the delivery of genetic services. For example, in 2017 the program developed educational resources for providers to help provide quality genetic services. These resources describe systematic actions needed in determining the final diagnosis of an infant and information on communicating with the family and determining the appropriate steps in the follow-up of the infant with a rare genetic condition. From 2017 to 2019, the program also worked with maternal and child health policy experts to track legislative, insurance, and financing issues that impact the genetic service delivery system, as well as disseminate information about other organizations that work in health care access areas relevant to stakeholders working in genetics.

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, as appropriate, in meetings conducted by the AIGCC program during the period of the cooperative agreement, e.g., annual AIGCC/RGN meeting, and any workgroups created;
- Collaborating with AIGCC in developing activities and procedures to be established and implemented for accomplishing the scope of work;
- Reviewing AIGCC project information prior to dissemination;
- Participating in disseminating AIGCC project information;

⁴ Hauser D et al. Views of Primary Care Providers on Testing for Patients for Genetic Risks for Common Chronic Diseases. *Health Affairs*. 2018; 37(5): 793–800.

⁵ Klitzman R, Chung W, Marder K, Shanmugham A et al. Attitudes and practices among internists concerning genetic testing. *J Genetic Counseling*. 2013;22(1): 90–100.

⁶ Saul RA, Trotter T, Sease K, Tarinim B. Survey of family history taking and genetic testing in pediatric practice. *J. Community Genetics*. 2017; 8(2):109–15.

⁷ Phillips KA, Deverka PA, Hooker GW, and Douglas MP. Genetic Test Availability and Spending: Where are we now? Where are we going? *Health Affairs*. 2018; 37(5): 710–716.

⁸ Miller CE et al. Genetic counselor review of genetic test orders in a reference laboratory reduces unnecessary testing. *American Journal Medical Genetics Part A*. 164A:1094–1101.

- Providing assistance in establishing and facilitating effective collaborative relationships with federal and state agencies, and especially HRSA MCHB-funded projects;
- Working with AIGCC to ensure they are compliant with program requirements and do not duplicate the work of other HRSA MCHB-funded projects; and
- Providing AIGCC information resources to HRSA MCHB offices and recipients, and other Bureaus relevant to the program.

The cooperative agreement recipient's responsibilities will include:

- Conducting all tasks as they relate to the priorities, goals, and objectives listed in the "[Purpose](#)" section of this NOFO;
- Ensuring the integral involvement of the RGNs;
- Ensuring the involvement of the NGEFSP in AIGCC activities;
- Reviewing, on a continuous basis, activities and procedures to be established and implemented for accomplishing the AIGCC scope of work;
- Providing ongoing, timely communication and collaboration with the federal project officer;
- Working with the federal project officer to review information and reports prior to dissemination on AIGCC project activities and products;
- Establishing contacts that may be relevant to the AIGCC project's mission;
- Facilitating partnerships with federal and non-federal entities, including other HRSA-funded programs relative to the AIGCC cooperative agreement activities; and
- Meeting deadlines for AIGCC information and reports as required by the cooperative agreement and requested by HRSA.

2. Summary of Funding

HRSA estimates approximately \$800,000 to be available annually to fund one recipient. 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 \$800,000 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 AIGCC program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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

III. Eligibility Information

1. Eligible Applicants

Any domestic public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 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 for these funds.

An applicant may NOT apply for concurrent funding as the lead award recipient for this program and either the National Genetics Education and Family Support Program (HRSA-20-049) or the National Genetics Education and Family Support Program and a Regional Genetics Network (HRSA-20-046). If an applicant does apply for any two of these funding opportunities for fiscal year 2020, it will be considered non-responsive and both applications will be disqualified.

Foreign entities are not eligible for HRSA awards, unless the authorizing legislation specifically authorizes awards to foreign entities or the award is for research. This exception does not extend to research training awards or construction of research facilities.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

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

HRSA will consider any application that 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.

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 **60 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 8: 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 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 expected outcomes.
- ***NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion [\(1\) Need](#)***
Outline the needs of the community and/or organization. Describe and document the target population and its unmet health needs. Discuss the needs of geneticists, primary and specialty health care providers, and families. Use and cite demographic data whenever possible to support the information provided. Discuss any relevant barriers to the use of genetic and genomic information in clinical practice that the project hopes to overcome. This section will help reviewers understand the communities, organizations, and health care systems 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 priorities and expectations in this NOFO. As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination 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 accomplish the following priorities and activities:

1. Provide National Policy Analysis and Research on the Genetics Care Delivery System

- Identify and examine policy and program initiatives at the national and state level in the following areas:
 - Finance and insurance coverage
 - Genetic workforce
 - Emerging issues in the use of genetic testing and technologies
- Identify evidence-based and evidence-informed practices, innovations, validated measures, and cost analysis studies related to improving access to and the quality of genetic services.
- Monitor, analyze, evaluate, and report on emerging national and state trends, policies, and issues related to the utilization of genetic services and workforce and accessing services.

2. Disseminate Information on Practices, Policies, and Resources Related to the Genetics Care Delivery System

- Develop a plan for dissemination of evidence-based practices, policies, tools, and resources to states and stakeholders.
- Link and disseminate products with existing websites to share best practices.
- Interface with external partners (e.g., Catalyst Center, National Society of Genetic Counselors, etc.) to ensure that resources, tools, and trainings are disseminated through multiple and diverse channels.

3. Support a Resource Infrastructure for the RGN Recipients

- Provide technical assistance, training, education, expertise and evaluation to the RGN recipients on the following issues:
 - evidence-based and evidence-informed practices for individuals with, or at risk for, genetic conditions,
 - access to quality coordinated care in a family-centered medical home,
 - other issues identified by the recipients.
- Develop infrastructure and implement a comprehensive plan for communication, coordination, and data sharing between the RGN recipients including information sharing and learning opportunities to support recipients' ability to meet the objectives of the program.
- Convene workgroups and annual meetings for the RGN recipients, NGEFSP recipient, and other experts and stakeholders to share best practices and collaborate on challenges.
- Collaborate with the RGNs to develop, implement, and report on an evaluation plan for the RGN program that includes a core set of performance measures.
- Disseminate evaluation findings to stakeholder groups.
- Apply evaluation findings to inform program and stakeholder decisions, policies, procedures, and processes.

4. Sustainability

- 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](#)*

Submit a work plan (*Attachment 1*) that describe 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.

Logic Model

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.

You should use the following measures to assess performance and progress towards the objectives outlined in the "[Purpose](#)" section. Document your plans and ability to collect and report data on those performance measures as part of your annual progress report. This includes plans for establishing baseline data and targets.

1. Number of educational resources (e.g., issue briefs, tools, toolkits, fact sheets, webinars, and publications, as needed) developed and offered
2. Number of webinars, conferences, and educational opportunities conducted for RGNs
3. Number of genetic specialists and stakeholders participating on workgroups
4. Number of partnership activities with relevant national organizations and key stakeholders
5. Number of evidence-based/informed practices, innovations, measures, and cost analysis studies disseminated
6. Number and type of technical services provided to each region served by the RGNs
7. Number and type of technical services provided nationally
8. Number of individuals with, or at risk for, genetic conditions, engaged in AIGCC work groups or committees

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.

- **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.	
<u>Narrative Section</u>	<u>Review Criteria</u>
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan and Logic Model	(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.

In addition, the AIGCC program requires that funds be budgeted to convene an annual meeting for the RGN recipients and National Genetics Education and Family Support Program.

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 AIGCC program requires that funds be budgeted to convene an annual meeting for the RGN recipients and National Genetics Education and Family Support Program.

v. Program-Specific Forms

Program-specific forms are not required for application.

vi. Attachments

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

Attachment 1: Work Plan and Logic Model

Attach the work plan for the project that includes all information detailed in [Section IV.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) The period covered (dates).
- (2) Specific objectives - Briefly summarize the specific objectives of the project.
- (3) Results - Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.

Attachments 8–15: Other Relevant Documents

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

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number 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 AIGCC 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 \$800,000 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.

Funds under this announcement may not be used for the following purposes:

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

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 AIGCC 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 [Introduction](#) and [Needs Assessment](#)

- The strength of the application in demonstrating the problem and associated contributing factors to the problem.
- The extent to which the application describes and documents the target population and its unmet needs.
- The extent to which the application provides sufficient description of data to support the information provided.
- The reasonableness of the application’s discussion of relevant barriers that the project hopes to overcome.

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

The extent to which the proposed project responds to the “[Purpose](#)” included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities described in the application are capable of addressing the problem and attaining the project objectives.

Methodology (30 points)

The strength, completeness, and feasibility of the applicant's approach to

1. Providing National Policy Analysis and Research on the Genetics Care Delivery System (10 points)
 - Identifying and examining policy and program initiatives at the national and state level in the following areas:
 - Finance and insurance coverage
 - Genetic workforce
 - Emerging issues in the use of genetic testing and technologies
 - Identifying evidence-based and evidence-informed practices, innovations, validated measures, and cost analysis studies related to improving access to and the quality of genetic services, including how the content will be assessed.
 - Monitoring, analyzing, evaluating, and reporting on emerging national and state trends, policies, and issues related to the utilization of genetic services and workforce and accessing services.
2. Disseminating Information Related to the Genetics Care Delivery System (5 points)
 - Developing a plan for dissemination of successful innovations, trainings, and reports to states and stakeholders, including how the plan will be developed and how stakeholders will be involved.
 - Linking and disseminating products with existing websites to share best practices.
 - Interfacing with external partners to ensure that resources, tools, and trainings are disseminated through multiple and diverse channels.
3. Supporting a Resource Infrastructure for the RGN Recipients (10 points)
 - Providing technical assistance, training, education, expertise and evaluation to the RGN recipients on the following issues:
 - evidence-based and evidence-informed practices for individuals with, or at risk for, genetic conditions,
 - access to quality coordinated care in a family-centered medical home,
 - other issues identified by the recipients.
 - Developing infrastructure and implementing a comprehensive plan for communication, coordination, and data sharing between the RGN recipients, including information sharing and learning opportunities to support recipients' ability to meet the objectives of the program, including how the plan will be developed and how stakeholders will be involved.
 - Convening an annual meeting and workgroups for RGN recipients, the National Genetics Education and Family Support Program, and other experts and stakeholders to share best practices and collaborate on challenges, including how experts will be identified.
 - Collaborating with the RGNs to develop, implement, and report on an evaluation plan for the RGN program that includes a core set of performance measures, including how measures will be developed. Disseminating evaluation findings to stakeholder groups.

- Applying evaluation findings to inform program and stakeholder decisions, policies, procedures, and processes.
4. Sustainability (5 points)
- Plans for project sustainability after the period of federal funding ends.
 - Plans to sustain key elements of the project, e.g., strategies and interventions, which have been effective in improving practices and those that have led to improved outcomes.

Work Plan (5 points)

- The extent to which the application describes activities or steps that will be used to achieve each of the 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.

Resolution of Challenges (5 points)

- The extent to which the application discusses potential challenges and approaches to resolve such challenges.

Criterion 3: EVALUATIVE MEASURES (20 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.

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

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 scope of work.
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.

2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. 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/UH9_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 <i>(administrative data and performance measure projections, as applicable)</i>	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	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 [FAPIS](#), 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:

Devon Cumberbatch
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10N176A
Rockville, MD 20857
Telephone: (301) 443-7532
Email: DCumberbatch@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: Wednesday, November 20, 2019

Time: 3:30–4:30 p.m. ET

Call-In Number: 1-888-826-9572

Participant Code: 77014936

Weblink: <https://hrsa.connectsolutions.com/hrsa20050/>

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](#).