U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Evaluating Genetic and Genomic Medicine Implementation and Outcomes in the Regional Genetics Networks (EGGMIO-RGN)

Funding Opportunity Number: HRSA-21-110
Funding Opportunity Type(s): Competing Supplement
Assistance Listings (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: June 7, 2021

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

Issuance Date: April 22, 2021

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2021 for the Evaluating Genetic and Genomic Medicine Implementation and Outcomes in the Regional Genetics Networks (EGGMIO-RGN) project. The purpose of this project is to evaluate and report upon the implementation and outcomes of Regional Genetics Networks (RGN) program activities aimed to improve access to genetic and genomic services to study their utility, applicability, and effectiveness.

Funding Opportunity Title:	Evaluating Genetic and Genomic Medicine Implementation and Outcomes in the Regional Genetics Networks
Funding Opportunity Number	HRSA-21-110
Due Date for Applications:	June 7, 2021
Anticipated Total Annual Available FY 2021 Funding:	$495,000
Estimated Number and Type of Award(s):	Up to 3 cooperative agreements
Estimated Award Amount:	Up to $165,000 per year, subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	June 1, 2021 through May 31, 2024 (3 years)
Eligible Applicants:	Eligible applicants are current recipients funded under HRSA-20-046 Regional Genetics Networks program. 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, May 10, 2021
Time: 3-4 p.m. ET
Call-In Number: 1-833-568-8864
Meeting ID: 160 078 8761
Participant Code: 49694989
Weblink: https://hrsa-gov.zoomgov.com/j/1600788761?pwd=WndNdS9rdHFyMlZzUUMxVHY0YVhhZz09

The recording will be posted on the MCHB website 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 supplemental funding under the Regional Genetics Networks (RGN) program (HRSA-20-046). The purpose of this Evaluating Genetic and Genomic Medicine Implementation and Outcomes in the Regional Genetics Network (EGGMIO-RGN) project is to evaluate the implementation and outcomes of selected RGN program activities aimed to improve access to services for individuals with, or at risk for, genetic or genomic conditions[1] and their families, especially those among underserved populations. This evaluation will be used to inform the RGN recipients and the field of genetic and genomic medicine with best practices and strategies to implement genetic and genomic advances into clinical and public health.

HRSA will fund up to three awards, and each RGN recipient will plan and conduct a focused, rigorous evaluation of implementation and/or outcomes of one or more of their program activities to study their utility, applicability, and effectiveness. The evaluation should focus on one or more strategies the RGN is implementing to meet the goals of the RGN program and not a new activity. Example topics of interest include, but are not limited to, evaluating:

- Strategies to outreach and engage primary care providers and non-geneticists to provide additional resources, education, or training to improve their ability to use genomics for the care of their patients.
- Perceived clinical utility by providers or individuals and families of RGN-developed genetic or genomic resource(s) throughout the lifecycle of diagnosis, treatment, and management.
- Implementation and clinical outcomes of RGN-supported genetic or genomic services offered through nontraditional modalities, such as telehealth.[2]
- Applicability of RGN developed resources or strategies across regions and subsequent dissemination of lessons learned across the regions. Examples include adaptation of a strategy through multi-RGN collaboration to address unmet needs common across regions or expanding implementation of the strategy to multiple regions.

[1] A genetic condition is a condition caused in whole or in part by a change in the DNA sequence away from the normal sequence (typically at a single gene, genomic location or region) and, as relevant to the RGN program, include congenital and metabolic disorders. National Institutes of Health, National Human Genomic Research Institute, Accessed March 12, 2021, https://www.genome.gov/For-Patients-and-Families/Genetic-Disorders.
In contrast to genetics, which refers to the study of genes and the way that certain traits or conditions are passed down from one generation to another, genomics describes the study of all of a person's genes (the genome). A genomic condition is a condition caused by multiple genes potentially interacting with environmental factors. Genomics takes into account the impact of multiple genes and variants or even the entire genome of an individual, whereas genetics refers to the study of a particular gene. In addition, genomic conditions are not limited to congenital or metabolic disorders and may often become manifest much later in life. National Institutes of Health, National Human Genomic Research Institute, Accessed March 14, 2021, https://www.genome.gov/about-genomics/fact-sheets/Genetics-vs-Genomics.

[2] 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 communications. Health Resources and Services Administration, “Telehealth Programs,” Accessed March 11, 2021, https://www.hrsa.gov/rural-health/telehealth.

- Impact of integrating the latest scientific evidence relevant to the genetic or genomic condition to improve the utility, applicability and/or effectiveness of the RGN program activity.

2. Background

This program is authorized by the Public Health Service Act, Title VI, § 1109(a)(2) and (4) (42 U.S.C. 300b-8(a)(2) and (4)).

The RGN program funds seven regions 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. Each RGN dedicates the annual $600,000 base award to: 1) support a regional infrastructure for the genetics health care delivery system; 2) provide education-related activities for providers, families, individuals, and other stakeholders; and, 3) facilitate the use of telehealth and telemedicine in the genetics health care delivery system, based on the unique needs of the region. The goal is to improve health equity and health outcomes in individuals with genetic and genomic conditions and to improve the quality of coordinated and comprehensive services to children with such condition and their families.

While the RGNs have developed and implemented diverse approaches to address the need for improved access to genetic and genomic services, the knowledge and evidence base for identification of best practices and strategies to effectively advance genetic and genomic services delivery systems, especially for underserved populations, remains limited. Through the EGGMIO-RGN project, HRSA is collaborating with the National Human Genome Research Institute (NHGRI) at the National Institutes of Health (NIH) to build this evidence base. NHGRI advances the application of genomics to medical science and clinical care and supports research in the evaluation and implementation of educational and clinical practice efforts that are based within the existing regional infrastructures connecting patients with genetic or genomic conditions to health care professionals and to genetic services. This HRSA-NHGRI collaboration reflects NHGRI's commitment to maximize the usability of genomics for all members of the public, including the ability to access genomics in health care.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: Competing Supplement

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

HRSA program involvement will include:

- Participating in EGGMIO-RGN-supported meetings conducted during the period of the cooperative agreement;

- Collaborating with EGGMIO-RGN recipients in developing activities and procedures to be established and implemented for accomplishing the goals and objectives of the project;
- Reviewing information on EGGMIO-RGN recipients' project activities, reports, and products prior to dissemination;
- Participating in dissemination of EGGMIO-RGN recipients' project information;
- Providing assistance in establishing and facilitating effective collaborative relationships with NHGRI, other federal and state agencies, and HRSA- and NHGRI-funded programs;
- Providing technical assistance and support to EGGMIO-RGN recipients to ensure they are compliant with NOFO requirements and do not duplicate the work of other HRSA-funded or NHGRI-funded projects; and
- Collaborating with NHGRI to participate in EGGMIO-RGN meetings, develop relevant project activities, and review and disseminate information.

The cooperative agreement recipient's responsibilities will include:

- Conducting all tasks as they relate to the goals of the EGGMIO-RGN listed under the "Purpose" section of this funding opportunity;
- Ensuring collaboration with the Advances in Integrating Genetics into Clinical Care (HRSA-20-050) and the National Genetics Education and Family Support Center Family Center (HRSA-20-049) in the EGGMIO-RGN activities;
- Reviewing, on a continuous basis, activities and procedures to be established and implemented for accomplishing the EGGMIO-RGN's goals, objectives, and activities;
- Providing ongoing, timely communication and collaboration with the HRSA Project Officer;
- Working with the HRSA Project Officer to review information on EGGMIO-RGN activities, reports, and products prior to dissemination;
- Establishing contacts that may be relevant to the EGGMIO-RGN project's mission;
- Establishing partnerships with NHGRI, other federal and non-federal entities, and HRSA-and NHGRI-funded programs relevant to the EGGMIO-RGN cooperative agreement activities; and
- Meeting deadlines for EGGMIO-RGN information and reports as required by HRSA.

2. Summary of Funding

HRSA estimates approximately $495,000 to be available annually to fund up to three recipients. You may apply for a ceiling amount of up to $165,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is June 1, 2021 through May 31, 2024 (three years). Funding beyond the first year is subject to the availability of appropriated funds for EGGMIO-RGN 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 are current recipients who are currently receiving funding under HRSA-20-046 Regional Genetics Network program.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

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

HRSA will consider any application that exceeds the page limit referenced in Section_IV non-responsive and will not consider it for funding under this notice.

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

NOTE: Multiple applications from an organization are not allowable.

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

IV. Application and Submission Information

1. Address to Request Application Package

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

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

reviewing the For Applicants page for all information relevant to this NOFO.

2. Content and Form of Application Submission

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

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

Application Page Limit
The total size of all uploaded files included in the page limit may not exceed the equivalent of **20 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-110, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit. Any application exceeding the page limit of 20 will not be read, evaluated, or considered for funding.**

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3321).
3) Where you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 5-15: 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*.

The project abstract is optional.

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 Criteria (1) Need and (4) Impact)*
  Briefly describe the current RGN program activity or activities on which the implementation and/or outcomes evaluation will focus. Succinctly describe the scope of the proposed evaluation project and the relevancy of the information generated from the project to increasing our knowledge of implementing genetic and genomic advances into clinical and public health.

- *NEEDS ASSESSMENT (Corresponds to Section V's Review Criteria (1) Need and (4) Impact)*
  This section should help reviewers understand how the proposed evaluation of the selected RGN activity will address a genetics and genomics services delivery knowledge gap and how the target population(s) will benefit.

  Discuss the genetics and genomics services delivery knowledge gap that this evaluation project proposes to address. Explain how the proposed project will improve scientific knowledge, technical capability, methodological innovation, and/or clinical practice in individuals with, or at risk for, genetic- or genomic-related conditions and their families, especially those among underserved populations.

  Describe the target population(s) of the RGN program activity being evaluated and its unmet needs. If the evaluation involves implementing the activity in a different setting or population, discuss their unmet needs. Briefly discuss how the expected outcome(s) will address the unmet needs of the targeted population(s). If the RGN already started implementing the activity being evaluated, include any relevant, available quantitative or qualitative data.

- *METHODOLOGY (Corresponds to Section V's Review Criteria (2) Response, (3) Evaluative Measures, and (4) Impact)*

Propose methods that you will use to address the stated needs and meet each of the previously described program requirements and expectations in this NOFO.

1. **Project Goals and Objectives**
   Clearly and succinctly state the specific goals and objectives of the particular evaluation proposed. Objectives should be specific, measurable, realistic, and achievable within the project period.

2. **Project/Evaluation Design**
   Describe the approach to the proposed EGGMIO-RGN project. As relevant, describe the overall evaluation design, methodology, and analyses you will use to accomplish the specific aims of the proposed project. Include the following:
   - Discussion of how the data will be collected, analyzed, and interpreted and any resource sharing plans as appropriate.
   - Description of the procedures for data collection and instrumentation, including information/citations regarding the established validity of the instruments used if applicable.
   - Description of specific measures that you will use for the proposed evaluation project. If the proposed project is an outcome evaluation, integrate consensus measures and protocols, such as those recently released by the PhenX program (https://www.phenxtoolkit.org/domains/view/310000), as appropriate.
   - If the proposed project involves a multi-RGN collaboration, describe the structure for collaboration and the roles of each involved RGN.

   Distinguish between the work that is being done as part of the RGN program and the additional work to be done as part of the EGGMIO-RGN project. The described approach should provide assurance of cultural competence as well as discussion of how individuals or families with genetic conditions or that represent the target population would be engaged as appropriate in the planning and implementation of the proposed evaluation project.

3. **Dissemination Plan**
   Describe a plan to advance the transfer of findings into practice or research by disseminating findings, reports, and/or other deliverables to key stakeholders, including but not limited to researchers, providers, State Title V and children with special health care needs programs, other program(s) serving populations with genetic or genomic conditions, policymakers, families and the general public.

- *WORK PLAN (Corresponds to Section V's Review Criterion (2) Response)*
  The work plan provides a succinct overview of the cooperative agreement's goals, objectives, activities, and timeline of projected outcomes in a table format as *Attachment 1*. The work plan table should provide details for all activities proposed in year 1 of the period of performance, as well as all multi-year activities that start in year 1. The work plan should not be a narrative, but instead refer to the Methodology and other narrative sections to explain the relationship between needs, activities, objectives, and goals.

The work plan should clearly identify steps or activities to achieve the goals and objectives of the project and depict how project activities will achieve outcomes. The work plan should include each activity, the timeframe for completing the activity, who on the staff is responsible for that activity, progress or process measures, and the intended outcome. As needed, describe which activities or steps are based on already existing processes or infrastructure, and which are new to the proposed EGGMIO-RGN project. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing, implementing, and disseminating results related to all activities, including developing the application.

- *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)*
  Briefly describe the plan for tracking project performance to monitor ongoing processes and the progress towards the project's specific objectives outlined in the Methodology section.

  Describe organization's technical capacity in evaluation to successfully implement the proposed work plan as well as monitoring project progress. Describe experience, skills, and knowledge of assigned staff and organization's previous evaluation work of a similar nature.

iii. Budget

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

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

The Consolidated Appropriations Act, 2021 (P.L. 116-260), Division H, § 202 states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." See Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

iv. Budget Narrative

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

NARRATIVE GUIDANCE To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review.	
Narrative Section	**Review Criteria**
Introduction	(1) Need and (4) Impact
Needs Assessment	(1) Need and (4) Impact
Methodology	(2) Response,(3) Evaluative Measures, and (4) Impact
Work Plan	(2) Response
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested

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. **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. If you will make subawards or expend funds on contracts, describe how your organization will ensure proper documentation of funds.

Attachment 2: Project Organizational Chart and Biographical Sketches of Key Personnel (see Section 4.1. of HRSA's *SF-424 Application Guide)*

Provide a one-page figure that depicts the organizational structure of the project. Include biographical sketches for persons occupying the key positions, ONLY for the staff that are new to EGGMIO-RGN and not already a part of the RGN staffing plan.

Attachment 3: 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 4: Tables, Charts, etc.

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

Attachments 5 –15: Other Relevant Documents

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

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)

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

You must also register with SAM and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d))**.**

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

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

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

- Dun and Bradstreet (http://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

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

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

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

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

4. Submission Dates and Times

Application Due Date
The due date for applications under this NOFO is *June 7, 2021 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

The EGGMIO-RGN 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 three years, at no more than $165,000 per year (inclusive of direct **and** indirect costs). Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division A of the Further Consolidated Appropriations Act, 2021 (P.L. 116-260) apply to this program. Please see Section 4.1 of HRSA's *SF-424*

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

Funding restrictions placed under HRSA-20-046 apply. 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.

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

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at 45 CFR § 75.3 07.

V. Application Review Information

1. Review Criteria

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

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

Review criteria are used to review and rank applications. The Evaluating Genetic and Genomic Medicine Implementation and Outcomes in the Regional Genetics Networks program has six review criteria. See the review criteria outlined below with specific detail and scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's Introduction and Needs Assessment
The extent to which:

- The applicant effectively demonstrates the need for the proposed EGGMIO-RGN project.
- The applicant clearly outlines the target population of the proposed evaluation project and its unmet needs.
- The applicant clearly describes the genetics and genomics services delivery knowledge gap that this evaluation project proposes to address.
- The applicant clearly describes the relevance to individuals with, or at risk for, genetic or genomic conditions and their families, especially those among underserved populations.

Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's Methodology, Work Plan, and Resolution of Challenges
The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities described in the application are capable of addressing the problem and attaining the project objectives.

Goals and Objectives (5 points)
The extent to which:

- Stated project objectives are specific, measurable, realistic, and achievable within the project period.

Project Design (10 points)
The extent to which:

- The applicant clearly outlines the evaluation design, methodology, and planned analyses.
- The overall design, methodology, and analyses are well reasoned and appropriate to accomplish the specific goals and objectives of the proposed EGGMIO-RGN project.
- The proposed EGGMIO-RGN design and methodology build and leverage on but not duplicate the existing RGN-funded work.

Work Plan (10 points)
The extent to which:

- The applicant clearly outlines the activities or steps that will be used to achieve each of the objectives proposed during the period of performance.
- The work plan provides a reasonable and feasible timeline that includes each activity and identifies responsible staff.
- Meaningful support and collaboration with key stakeholders are identified in planning, designing and implementing all activities.

Resolution of Challenges (5 points)
The extent to which:

- The applicant describes the challenges likely to be encountered in designing and implementing the work plan and approaches that will be used to resolve such challenges.

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's Methodology and Evaluation and Technical Support Capacity

Evaluation Design (10 points)
The extent to which:

- The applicant clearly proposes measures that have been selected or developed for the EGGMIO-RGN project.
- The proposed measures are adequate and appropriate.
- If the proposed EGGMIO-RGN project is an outcome evaluation, the proposed evaluation measures integrate consensus measures and protocols as appropriate.
- The applicant describes an effective and achievable data collection strategy to collect, analyze, and track data for the proposed measures for the EGGMIO-RGN project.
- Adequacy, appropriateness, and established validity are described for any procedures for data collection and/or instruments included in the application.

Evaluation and Technical Support Capacity (10 points)
The extent to which:

- The applicant describes a feasible and reasonable plan to assess and track project progress.
- The proposed project performance evaluative measures will be able to assess to what extent the project objectives have been met.

Criterion 4: IMPACT (20 points) – Corresponds to Section IV's Introduction, Needs Assessment, and Methodology

Impact (15 points)
The extent to which:

- The expected outcomes are likely to address the unmet needs of the targeted population.
- The expected outcomes are likely to help improve the genetics and genomics services delivery system and/or the health and well-being of individuals with genetic or genomic conditions in underserved populations.
- The proposed project will improve scientific knowledge, technical capability, and/or clinical practice in individuals with, or at risk for, genetic- or genomic-related conditions and their families, especially those among underserved populations.
- The findings will be generalizable and are of regional or national significance and scope.

- The proposed project advances the application of genetics or genomics to medical science or clinical care; the likely impact of the project on maximizing the usability of genomics for all members of the public, including the ability to access genomics in health care.

Dissemination Plan (5 points)
The extent to which:

- The applicant provides a clear plan to advance the transfer of findings into practice or research by disseminating findings, reports, and/or award project outputs to key target audiences, including but not limited to researchers, providers, State Title V and children with special health care needs programs, other program(s) serving populations with genetic or genomic conditions, policymakers, families and the general public.

Criterion 5: RESOURCES/CAPABILITIES (10 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity
The extent to which:

- The applicant clearly describes project personnel, including proposed partners, demonstrating that they have sufficient training, qualifications, expertise, and experience to carry out the proposed project.
- The applicant demonstrates the capabilities of the 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 project 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 budget line items are well described and justified in the budget justification.
- Key personnel have adequate time devoted to the project to achieve project objectives.

2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (e.g., program balance) described below in selecting applications for award. See Section 5.3 of HRSA's *SF-424 Application Guide* for more details.

Funding Special Considerations
In making final award decisions, HRSA, in consultation with NHGRI, will take into consideration the program balance of proposed projects with existing NHGRI programs,

per 45 CFR part 75, Appendix 1 (E)(2).

PLEASE NOTE: In order to achieve the distribution of awards as stated above, HRSA may need to fund out of rank order.

3. Assessment of Risk

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

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

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

HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

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

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to September 30, 2021. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

Accessibility Provisions and Non-Discrimination Requirements
Federal funding recipients must comply with applicable federal civil rights laws. HRSA supports its recipients in preventing discrimination, reducing barriers to care, and promoting health equity. For more information on recipient civil rights obligations, visit the HRSA Office of Civil Rights, Diversity, and Inclusion website.

See Section 2.1 of HRSA's *SF-424 Application Guide*.

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

Requirements of Subawards
The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See 45 CFR § 75.101 Applicability for more details.

Data Rights
All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by others. If applicable, the specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

Human Subjects Protection
Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

- Please refer to instructions provided in HRSA's *SF-424 R&R Application Guide*, Appendix Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy

for specific instructions on preparing the human subjects section of the application.

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

3. Reporting

Award recipients must comply with Section 6 of HRSA's *SF-424 Application Guide* **and** the following reporting and review activities:

1) **Progress Report(s)**. The recipient must submit a progress report narrative to HRSA annually. This progress report will be a separate submission from the Non-Competing Continuation Renewal for the RGN program. The report will address project accomplishments, barriers, significant changes, and plans for the upcoming budget year. Submission and HRSA approval of the progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA.

2) **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.

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

VII. Agency Contacts

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

Stanley Gordon
Grants Management Specialist
Division of Grants Management Operations, OFAM

Health Resources and Services Administration
5600 Fishers Lane, 10W10BRockville, 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:

Soohyun Kim, MPH
Public Health Analyst, Genetic Services Branch
Division of Services of Children with Special Health Needs
Attn: Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, 18N38A
Rockville, MD 20857
Telephone: (301) 594-4202
Email: skim@hrsa.gov

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

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

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

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

VIII. Other Information

Technical Assistance

HRSA has scheduled following technical assistance:

Webinar

Day and Date: Monday, May 10, 2021
Time: 3-4 p.m. ET
Call-In Number: 1-833-568-8864
Meeting ID: 160 078 8761
Participant Code: 49694989
Weblink: https://hrsa-gov.zoomgov.com/j/1600788761?pwd=WndNdS9rdHFyMlZzUUMxVHY0YVhhZz09

Tips for Writing a Strong Application

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

508 Compliance Disclaimer

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