U.S. Department of Health and Human Services

Maternal and Child Health Bureau

Division of Services for Children with Special Health Needs

Genetic Services Branch

Maternal and Child Environmental Health Network (MCEHN)

Funding Opportunity Number: HRSA-22-083

Funding Opportunity Type(s): New and Competing Continuation

Assistance Listings (AL/CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2022

Application Due Date: March 28, 2022

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

HRSA will not approve deadline extensions for lack of registration.

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

Issuance Date: January 27, 2022

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See Section VII for a complete list of agency contacts.

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

508 COMPLIANCE DISCLAIMER

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2022 Maternal and Child Environmental Health Network (MCEHN). The purpose of this program is to decrease maternal and child morbidity and mortality associated with pre-and post-natal environmental exposures. One cooperative agreement will be funded to implement and support a national network of state and/or regional teratogen[1] information service (TIS) counseling centers. This program is intended to be a resource for individuals of reproductive age, their partners, and health care providers, with an emphasis on underserved populations.

Funding Opportunity Title:	Maternal and Child Environmental Health Network (MCEHN)
Funding Opportunity Number:	HRSA-22-083
Due Date for Applications:	March 28, 2022
Anticipated Total Annual Available FY 2022 Funding:	**$**1,200,000 per year
Estimated Number and Type of Award(s):	One (1) cooperative agreement
Estimated Annual Award Amount:	Up to $1,200,000 subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2022 through August 31, 2027 (5 years)
Eligible Applicants:	Any domestic public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 25 U.S.C. § 450b) is eligible to apply.

[1] Teratogen, as used in this notice of funding opportunity, refers to agents that may induce abnormal embryo or fetal development.

	See 42 CFR § 51a.3(a). Domestic faith-based and community-based organizations are also eligible to apply. See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

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

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Wednesday, February 16, 2022
Time: 2 p.m. – 3 p.m. ET
Call-In Number: 1-833-568-8864
Participant Code: 57045078
Weblink: https://hrsa-gov.zoomgov.com/j/1600985003?pwd=VVVqMHhybFpkSlkxOGhOUHdRY2pMUT09
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 Maternal and Child Environmental Health Network (MCEHN). The purpose of this program is to decrease maternal and child morbidity and mortality associated with pre-and post-natal environmental exposures. One cooperative agreement will be funded to implement and support a national network of state and/or regional teratogen information service (TIS) counseling centers. This program is intended to be a national resource for individuals of reproductive age, their partners, and health care providers, with an emphasis on underserved populations.

This program will provide resources (including web-based resources), information, and individual risk assessment and counseling to pregnant or breastfeeding individuals, individuals planning to become pregnant, their partners, and providers, in order to ensure informed decision-making to support maternal and fetal/infant health, and ultimately prevent adverse pregnancy and infant health outcomes. The network ("TIS network") of teratogen information service counseling centers ("TIS centers") should be able to respond to inquiries in a variety of formats (e.g., text messages, phone calls, emails) and serve all ten regions identified as such by the U.S. Department of Health and Human Services (HHS) and served by HHS regional offices. [2] The TIS network must be able to disseminate objective, current, and easy-to-understand information about the impact of environmental and medical exposures, targeting underserved populations, defined as people living in medically underserved areas,[3] or who share particular characteristics that have been systematically denied a full opportunity to participate in aspects of economic, social and civic life.[4]

Program Goal

The goal of MCEHN is to improve access to accurate, comprehensible information related to teratogen and environmental exposures that facilitate evidence-based health care decision-making.

Program Objectives

- By August 2027, increase by 10 percent from baseline the average number of responses per month to one-on-one counseling inquiries from pregnant or breastfeeding individuals, individuals planning to become pregnant, partners, and/or health providers.

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[2] For more information on the HHS Regions, please visit http://www.hhs.gov/about/agencies/regional- offices/index.html.

[3] See HRSA definition for Medically Underserved Areas/Populations: https://data.hrsa.gov/tools/shortage-area/mua-find

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

- By August 2027, increase by 30 percent from baseline the number of responses to counseling inquiries from individuals who are from underserved populations.
- By August 2027, increase by 20 percent from baseline the number of individuals receiving information materials through various vehicles (e.g., fact sheets, podcasts, social media).

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

2. Background

About MCHB and Strategic Plan

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

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

Goal 2: *Achieve health equity for MCH populations*

Goal 3: *Strengthen public health capacity and workforce for MCH*

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

The MCEHN addresses MCHB's Goals 1 and 2 by:

- Improving access to accurate, comprehensible information on teratogen exposures for all individuals of reproductive age, their providers, and partners.
- Prioritizing outreach and education to underserved populations, with the goal of improving health outcomes and promoting health equity.

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

About MCEHN

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

Individuals of child-bearing age are exposed to substances ranging from medications[5]

[5] Studies show over 90% of women use at least one medication during pregnancy. See Hass, D.M. et al (2019), "Prescription and Other Medication Use in Pregnancy," *Obstet Gynecol.* 131(5); 789-798, available at https://pubmed.ncbi.nlm.nih.gov/21514558/ and Mitchell, AA et al. (2011). "Medication Use

and illicit substances[6] to environmental toxins[7] that may adversely affect reproductive outcomes. During pregnancy, exposure to teratogens—agents that may induce abnormal embryo or fetal development[8]—may increase the risk of negative health outcomes including birth defects, preterm delivery, and poor fetal growth. These in turn greatly contribute to infant mortality and morbidity in the U.S.[9] Infants can also be exposed through breast milk to substances that negatively influence early brain development and may contribute to cognitive delay, poor behavior regulation, shortened attention span, and other conditions.[10]

Research indicates limited knowledge among parents and health care providers about potentially harmful effects of specific perinatal exposures.[11] Providing risk assessment information requires synthesizing complicated or contradictory data, translating findings from population-based studies into individualized information about maternal and infant health,[12] and conveying this information through different formats.[13] Moreover, given the development of new medications[14] and emerging public health threats like infectious diseases, specialists must interpret limited data within a rapidly-evolving research landscape in order to counsel parents and providers. Finally, individuals from some underserved backgrounds may have greater exposure to specific environmental teratogens,[15] even as they have less access to certain communication technologies that

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during pregnancy, with particular focus on prescription drugs: 1976-2008." *AmJ Obstet and Gynecol, 205*, 51.e1-8. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3793635/

[6] For example, opioid use disorder quadrupled among pregnant and breastfeeding women between 1999 and 2014. See Haight SC et al (2018), "Opioid use disorder documented at delivery hospitalization—United States, 1999-2014," *MMWR Morb Mortal Wkly Rep,* 67(31), 845-849 https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1.htm?s_cid=mm6731a1_w).

[7] An estimated 23 percent of U.S. women of reproductive age in 2007-2012 had detectable levels of pollutants. See Shim, Y.K et al, (2017) "Prevalence and associated demographic characteristics of exposure to multiple metals and their species in human populations: The United States NHANES, 2007-2012," *J. Toxicol Environ Health A.* 80)9): 502-512, available at https://pubmed.ncbi.nlm.nih.gov/28703686/

[8] Alwan, S. & Friedman, J.M. (2019), "Clinical Teratology," *Emery and Rimoin's Principles and Practice of Medical Genetics and Genomics: Clinical Principles and Applications, 7th Edition,* pg 15-60 https://doi.org/10.1016/B978-0-12-812536-6.00002-X

[9] Ibid.

[10] U.S. Environmental Protection Agency (2017). NIEHS/EPA Children's Environmental Health and Disease Prevention Research Centers Impact Report: Protecting children's health where they live, learn, and play. EPA Publication No. EPA/600/R-17/407. Retrieved from https://www.epa.gov/sites/production/files/2017-10/documents/niehs_epa_childrens_centers_impact_report_2017_0.pdf

[11] Widnes, S.F., Schjott, J. (2017), "Risk perception regarding drug use in pregnancy," *AmJ Obstet and Gynecol, 216* (4) 375-378. Available at https://www.sciencedirect.com/science/article/pii/S0002937816331751

[12] Cannover, E.A., Polifka, J.A. (2011), "The art and science of teratogen risk communication," *Am J. Med Genet Part C. Semin Med Genet 157*: 2270233

[13] Ibid.

[14] Batta, A., Kalra, B.S., and Khirasaria, R. (2020), "Trends in FDA drug approvals over last 2 decades: An observational study," *J. Family Med Prim Care,* 9(1) 105-114 available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7014862/

[15] Shim, Y.K et al,. (2017) "Prevalence and associated demographic characteristics of exposure to multiple metals and their species in human populations: The United States NHANES, 2007-2012"

would connect them to critical information about the impact of different exposures on their health.[16]

In response to these challenges, MCHB funds a Maternal and Child Environmental Health Network to decrease maternal and child morbidity and mortality associated with perinatal environmental exposures, and promote equity in these outcomes. The U.S. Department of Health and Human Services defines equity as the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.[17]

MCHB is committed to promoting equity in health programs for mothers, children, and families. As such, the definition of equity provides a foundation for the development of programs that intend to reach underserved communities and improve equity among all communities. Addressing issues of equity should include an understanding of intersectionality and how multiple forms of discrimination impact individuals' lived experiences. Individuals and communities often belong to more than one group that has been historically underserved, marginalized, or adversely affected by persistent poverty and inequality. Individuals at the nexus of multiple identities often experience unique forms of discrimination or systemic disadvantages, including in their access to needed services.[18]

In response to the COVID-19 public health emergency, MCHB continues to prioritize meeting emerging needs, including vaccination of pregnant, recently-pregnant, and lactating people.[19]. MCHB is committed to supporting states, jurisdictions, and tribes to provide services safely to MCH populations, and encourages them to follow appropriate CDC, state, and local health department guidance. Read more about MCHB's response to COVID-19 at https://mchb.hrsa.gov/coronavirus-frequently-asked-questions.

Burris, H.H. and Hacker, M.R (2017) "Birth outcomes and racial disparities: a result of intersecting social and environmental factors," *Semin. Perinatol.*41(6): 360-366 available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5657505/

[16] Benda, N.C et al (2020), "Broadband Internet Access Is a Social Determinant of Health!" Am J Public Health, 110(8): 1123-1125

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

[18] Ibid.

[19] Compared to non-pregnant people, pregnant and recently-pregnant people, which may include people who are lactating, are more likely to become severely ill with COVID-19. See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New and Competing Continuation

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

The cooperative agreement recipient's responsibilities will include:

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

2. Summary of Funding

HRSA estimates approximately $1,200,000 to be available annually to fund one recipient. The actual amount available will not be determined until enactment of the final FY 2022 federal appropriation. You may apply for a ceiling amount of up to $1,200,000 total cost (includes both direct and indirect, facilities and administrative costs) per year.

The period of performance is September 1, 2022 through August 31, 2027 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for the Maternal and Child Health Environmental Network in subsequent fiscal years, satisfactory progress, and a decision that continued funding is in the best interest of the Federal Government. HRSA may reduce or take other enforcement actions regarding recipient funding levels beyond the first year if they are unable to fully succeed in achieving the goals listed in application.

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

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include 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.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

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

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

NOTE: Multiple applications from an organization are not allowable.

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

IV. Application and Submission Information

1. Address to Request Application Package

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

The NOFO is also known as “Instructions” on Grants.gov. You must select “Subscribe” and provide your email address for HRSA-22-083 in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. *You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.*

2. Content and Form of Application Submission

Application Format Requirements

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

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

Application Page Limitation

Please note: Effective April 22, 2021, the abstract is no longer an attachment that counts in the page limit. The abstract is the standard form (SF) "Project Abstract Summary.” Standard OMB-approved forms included in the workspace application package do not count in the page limit. If you use an OMB-approved form that is not included in the workspace application package for HRSA-22-083, 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 60 will not be read, evaluated, or considered for funding.**

Applications must be complete, within the maximum specified page limit, and validated by Grants.gov under HRSA-22-083 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. §3354).

3) If you are unable to attest to the statements in this certification, you must include an explanation in *Attachment 10: 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*

Use the Standard OMB-approved Project Abstract Summary Form 2.0 that is included in the workspace application package. Do not upload the abstract as an attachment or it will count toward the page limitation. For information required in the Project Abstract Summary Form, see Section 4.1.ix of HRSA's *SF-424 Application Guide.*

Provide a summary of the application in the Project Abstract box using 4,000 characters or less.

- Address
- Project Director Name
- Contact Phone Numbers (Voice, Fax)
- Email Address
- Website Address, if applicable
- List all grant program funds requested in the application, if applicable
- If requesting a funding preference, priority, or special consideration as outlined in Section V. 2. of the program-specific NOFO, indicate here.

Because the abstract is often distributed to provide information to the public and Congress, prepare this so that it is clear, accurate, concise, and without reference to other parts of the application. It must include a brief description of the proposed project including the needs to be addressed, the proposed services, and the population group(s) to be served. If the application is funded, your project abstract information (as submitted) will be made available to public websites and/or databases including USAspending.gov.

NARRATIVE GUIDANCE

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

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need

Narrative Section	Review Criteria
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget Narrative	(6) Support Requested

ii. *Project Narrative*

This section provides a comprehensive description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and organized in alignment with the sections and format below so that reviewers can understand the proposed project.

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 used, and projected outcomes.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion (1) NEED
  This section will help reviewers understand the populations that will be served by the proposed project and the national landscape regarding maternal and child environmental health as well as pre-and post-natal environmental exposures. Describe the target population and its unmet health needs in this section, considering disparities based on relevant social determinants of health.[20] Use and cite demographic data whenever possible to support the information provided. Discuss any relevant barriers to service that the project hopes to overcome.
- 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 requirements 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.

[20] HHS defines social determinants of health as the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

Include a description of any innovative methods that you will use to address the stated needs. Be sure to describe your plans in each of the following subject areas of the proposed project:

Support TIS network infrastructure

- Support a national network of state and/or regional TIS centers to respond to teratogen-related inquiries in a variety of formats (e.g., phone calls, texts, emails) from individuals located in all ten (10) regions served by HHS regional offices.
- Develop or maintain a system that allocates inquiries from any location in the U.S. to the TIS center most appropriate to provide an individualized risk assessment.
- Facilitate and support communication, coordination, and collaboration among all TIS centers, provide access to common database information on teratogen and environmental exposures, and otherwise support the work of the TIS network.
- Provide ongoing professional education to all TIS network staff, including education on emerging or potential environmental risks to reproduction.
- Conduct annual meetings for TIS network staff.

Provide Education, Consultation, and Individual Risk Assessment

- Use the HRSA definition of medically underserved areas/population, Executive Order 13985 on Advancing Racial Equity and support for Underserved Communities,[21] and/or other sources to report medically underserved areas and populations reached by the project. Applicants do not need to include all groups enumerated in these sources as their target population; however, the definition must clearly delineate which groups the applicant will prioritize for outreach, education, and risk assessment, and why.
- Develop or maintain an online resource of evidence-based information on teratogen and environmental exposures for parents, providers, and the general population that is accurate, current, culturally-sensitive, and at the appropriate literacy level for the target audience.
- Provide accurate information about common teratogens and environmental exposures tailored to a variety of stakeholders (e.g., pregnant and/or breast-feeding people and their partners, health professionals, child care providers, home visitors, policymakers) in concise and understandable ways. Products may include, but are not limited to, background papers and briefs, fact sheets, podcasts and other media, etc. Explain how you will address the needs of underserved population(s) through this activity.
- Provide individualized risk assessment and TIS counseling through various formats (e.g., phone calls, online chat, text messaging). Explain how you will address the needs of underserved population(s) through this activity.

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

Improve Quality of Educational Resources

- Form a multidisciplinary advisory committee that meets at least twice a year to review educational materials, advise on messaging and relevance to target population(s), and otherwise advise the program's activities. The committee should be composed of community members—including those from the program's target population—past service recipients, and/or communication experts.
- Monitor emerging environmental public health issues nationally, regionally, and locally in order to develop timely educational resources.
- Develop measure(s) to capture TIS recipients' change in knowledge and/or ratings of resource quality. The final measure will be developed in collaboration with HRSA after award. See also Evaluation and Technical Resource Capacity.

Strategic Partnerships

- Partner with other stakeholders to promote the use of teratology information services and otherwise advance program goals and objectives. Potential partners include other entities receiving HRSA funding, such as Maternal and Child Health (MCH) Title V agencies, Family to Family Health Information Centers, Poison Control Centers, Community Health Centers, Healthy Start, and the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) grant programs. Other partners may include, but are not limited to, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), Pediatric Environmental Health Specialty Units (PEHSUs).[22]

Resource Dissemination

- Increase the visibility of teratology information services. Include dissemination plans, strategies and tools to reach underserved populations.

Facilitate Research

- Identify and refer eligible pregnant and breastfeeding individuals to participate in research studies to advance the knowledge in the field.
- Increase diversity of research participant pool.

You must also propose a plan for project sustainability after the period of federal funding ends. HRSA encourages 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.

[22] Pediatric Environmental Health Specialty Units are a source of medical information and advice on environmental conditions that influence children's health. They respond to requests for information throughout North America and offer advice on prevention, diagnosis, management, and treatment of environmentally-related health effects in children. For more information please visit http://www.pehsu.net/.

- WORK PLAN -- Corresponds to Section V's Review Criteria (2) RESPONSE and (4) IMPACT

  Describe the activities or steps that you will use to achieve each of the 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 Models

  Submit a logic model for designing and managing the project. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this notice, the logic model should summarize the connections between the:

  - Goals of the project (e.g., reasons for proposing the intervention, if applicable);
  - Assumptions (e.g., beliefs about how the program will work and support resources. Base assumptions on research, best practices, and experience.);
  - Inputs (e.g., organizational profile, collaborative partners, key personnel, budget, other resources);
  - Target population (e.g., the individuals to be served);
  - Activities (e.g., approach, listing key intervention, if applicable);
  - Outputs (i.e., the direct products of program activities); and
  - Outcomes (i.e., the results of a program, typically describing a change in people or systems).

  Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. You can find additional information on developing logic models at the following website: https://www.acf.hhs.gov/sites/default/files/documents/prep-logic-model-ts_0.pdf.

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

  Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges.

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

  Describe the plan for the program performance evaluation that will contribute to continuous quality improvement. The program performance evaluation should monitor ongoing processes and the progress towards the goals and objectives of

the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key personnel, budget, and other resources), key processes, and expected outcomes of the funded activities.

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

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

- Number of TIS centers in operation serving the ten (10) HHS-defined regions and total number of individualized counseling inquiries per year addressed by each.
- Number of individualized counseling inquiries per month. This should be disaggregated in a way that allows the awardee to calculate the total number of inquiries from individuals from underserved populations, as defined by the program. When feasible and appropriate, these should be disaggregated as follows:
    - Caller type (e.g., individuals who are pregnant/breastfeeding/planning for pregnancy, partners, health providers, other)
    - Type of information requested (e.g., information on medication, environmental exposures, infectious diseases, other)
    - Age
    - Race/ethnicity
    - Other relevant demographic characteristics, as determined in collaboration with HRSA.
- Total number of individuals that have received information through various means. When feasible, this should be disaggregated by mechanism (e.g., social media engagement, website traffic, webinar attendance) and audience type (e.g., individuals who are pregnant/breastfeeding/planning for pregnancy, partners, health providers, other).

- Total number of pregnant and breastfeeding individuals referred to participate in research studies on perinatal exposures in order to expand the knowledge base. When feasible and appropriate, this should be disaggregated by race/ethnicity and other relevant demographic characteristics.
- Data pertaining to teratogen information service recipients' change in knowledge as a result of services, and/or ratings of resource quality. Applicants will be expected to propose a measure, and the award recipient will finalize in collaboration with HRSA during award period.

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

Provide information on the program's resources and capabilities to support provision of culturally and linguistically appropriate and health literate services across all ten (10) HHS regions. Describe your expertise providing teratogen information services nationwide, and partnering with a variety of stakeholders to: provide resources and education to individuals of reproductive age, their partners and health providers, and other audiences; identify individuals with or at-risk for environmental teratogen exposure; refer eligible pregnant and breastfeeding individuals for research studies and medical services when appropriate; and develop strategies and tools to reach underserved populations.

iii. *Budget*

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

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

As required by the Consolidated Appropriations Act, 2021 (P.L. 116-260), Division H, § 202 and Act Division A of the Further Extending Government Funding Act (P.L. 117-70), "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. Effective January 2022, the Executive Level II salary increased from $199,300 to **$203,700**. 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*.

v. *Program-Specific Forms*

Program specific forms are not required for this program.

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

Attachment 1: Work Plan

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

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

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

Attachment 3: Biographical Sketches of Key Personnel

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

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

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

Attachment 5: Project Organizational Chart

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

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

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

Attachment 7: For Multi-Year Budgets--5th Year Budget

After using columns (1) through (4) of the SF-424A Section B for a 5-year period of performance, you will need to submit the budget for the 5th year as an attachment. Use the SF-424A Section B, which does not count in the page limitation; however, any related budget narrative does count. See Section 4.1.iv of HRSA's *SF-424 Application Guide*.

Attachment 8: Request for Funding Preference or Priority

To receive a funding preference, include a statement that you are eligible for a funding preference and identify the preference. Include documentation of this qualification. See Section V.2.

Attachment 9: 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. See Section V.2 Review and Selection Process for a full explanation of funding priorities and priority points.

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 10–15: 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 webpages: Planned UEI Updates in Grant Application Forms and General Service Administration’s UEI Update.

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

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

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

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

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

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

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

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

4. Submission Dates and Times

Application Due Date

The due date for applications under this NOFO is *March 28, 2022 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

The Maternal and Child Environmental Health Network is not subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

6. Funding Restrictions

You may request funding for a period of performance of up to five years, at no more than $1,200,000 per year (inclusive of direct **and** indirect costs). Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division H of the Consolidated Appropriations Act, 2021 (P.L. 116-260) and Division A of the Further Extending Government Funding Act (P.L. 117-70) apply to this program. See Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in following fiscal years, as required by law. Effective January 2022, the Executive Level II salary increased from $199,300 to **$203,700**.

45 C.F.R. part 75 and the HHS Grants Policy Statement (HHS GPS) include information about allowable expenses. Note that funds under this notice may not be used for travel outside the U. S.

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

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

V. Application Review Information

1. Review Criteria

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

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

Six review criteria are used to review and rank Maternal and Child Environmental Health Network applications. Below are descriptions of the review criteria and their scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's Introduction and Needs Assessment
The extent to which the application demonstrates the problem and associated contributing factors to the problem. This includes the extent to which the application:

- Describes the target population and its unmet health needs in this section, including a clear description of the underserved population(s) of interest to this project.
- Discusses relevant barriers to service that this project will overcome.

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

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

- Supporting a national network of state and/or regional TIS centers to respond to teratogen inquiries in a variety of formats by facilitating coordination across the network, providing ongoing professional education, and otherwise supporting the work of the TIS network.
- Providing teratology information, education, and individual risk assessment for a broad array of stakeholders—including those from underserved populations—in a concise, understandable, and culturally sensitive way.
- Improving quality, timeliness, and/or relevance of educational resources, including resources related to emerging environmental public health issues.

- Developing or enhancing partnerships to expand the reach of the TIS network, and engaging partners in activities that may be relevant to the project's mission.
- Developing a dissemination plan to increase visibility of teratology information services and reach underserved populations.
- Advancing research about teratogens by implementing a plan to identify and refer eligible pregnant and breastfeeding individuals to participate in research studies.

Work Plan and Logic Model (10 points)

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

Resolution of Challenges (10 points)

- The thoroughness with which the application discusses potential challenges and the feasibility of proposed approaches to resolve such challenges.

Criterion 3: EVALUATIVE MEASURES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity The strength and effectiveness of the 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, 2) to what extent these can be attributed to the project, and 3) the capability of the applicant to collect and report on Program Objectives and data specified under the Evaluation and Technical Support Capacity section

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

Criterion 5: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information
The extent to which project personnel are qualified by training and/or experience to implement and carry out the project, including staff's expertise on environmental exposures and communication skills. The degree to which the applicant organization demonstrates readiness to provide the services and meet the award requirements, including its ability to provide comprehensive, high quality teratology services and information nationwide, adapt services and resources to address emerging public health needs. The quality and availability of facilities and personnel to serve the nation and otherwise 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 of applications to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. See Section 5.3 of HRSA's *SF-424 Application Guide* for more details.

Funding Priorities
This program includes a funding priority. A funding priority is the favorable adjustment of combined review scores of individually approved applications when applications meet specified criteria. HRSA staff adjusts the score by a set, pre-determined number of points. The Maternal and Child Environmental Health Network has one funding priority/priorities:

Priority 1: Program Compliance (5 Points)
You will be granted a funding priority if:

1.) You are a competing continuation applicant applying to continue serving the ten (10) HHS regions by supporting a national network of state and/or regional teratogen information service (TIS) counseling centers and;

2.) You have successfully achieved the previous award goals and objectives based on progress reports submitted during the project period and a progress report describing how the objectives were implemented and achieved. See *Attachment 9: Progress Report* under Section IV.2.vi.

3. Assessment of Risk

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

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable; cost analysis of the project/program budget; assessment of your management systems, ensuring continued applicant eligibility; and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional

programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

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

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

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

VI. Award Administration Information

1. Award Notices

HRSA will release the Notice of Award (NOA) on or around the start date of September 1, 2022. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

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

If you are successful and receive a NOA, in accepting the award, you agree that the award and any activities thereunder are subject to:

- all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award,
- other federal regulations and HHS policies in effect at the time of the award or implemented during the period of award, and
- applicable statutory provisions.

Accessibility Provisions and Non-Discrimination Requirements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights

laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights (OCR) provides guidance on complying with civil rights laws enforced by HHS. See Providers of Health Care and Social Services and HHS Nondiscrimination Notice.

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

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

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

Executive Order on Worker Organizing and Empowerment

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

Requirements of Subawards

The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the

appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See 45 CFR § 75.101 Applicability for more details.

Data Rights

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

Human Subjects Protection

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

- Refer to instructions provided in HRSA's *SF-424 R&R Application Guide*, Appendix Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy for specific instructions on preparing the human subjects section of the application.
- Refer to HRSA's *SF-424 R&R Application Guide* to determine if you are required to hold a Federal Wide Assurance (FWA) of compliance from the Office of Human Research Protections (OHRP) prior to award. You must provide your Human Subject Assurance Number (from the FWA) in the application. If you do not have an assurance, you must indicate in the application that you will obtain one from OHRP prior to award.
- In addition, you must meet the requirements of the HHS regulations for the protection of human subjects from research risks, including the following: (1) discuss plans to seek IRB approval or exemption; (2) develop all required documentation for submission of research protocol to IRB; (3) communicate with IRB regarding the research protocol; (4) communicate about IRB's decision and any IRB subsequent issues with HRSA.

- IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent any page limitation in the Methodology portion of the Project Narrative section.

3. Reporting

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

1) **DGIS Performance Reports.** Available through the HRSA Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report **annually**, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at https://grants4.hrsa.gov/DGISReview/ProgramManual?NOFO=HRSA-22-083&ActivityCode=UG4.The type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	September 1, 2022-August 31, 2027 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	September 1, 2022 – August 31, 2023 September 1, 2023-August 31, 2024 September 1, 2024-August 31, 2025 September 1, 2025-August 31, 2026	Beginning of each budget period (Years 2–5, as applicable)	120 days from the available date
c) Project Period End Performance Report	September 1, 2026-August 31, 2027	Period of performance end date	90 days from the available date

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

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

3) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

Note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at 2 CFR § 200.340 - Termination apply to all federal awards effective August 13, 2020. No additional termination provisions apply unless otherwise noted.

VII. Agency Contacts

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

Djuana Gibson
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-3243
Email: dgibson@hrsa.gov

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

Cristina Novoa, Ph.D.
Public Health Analyst
Genetic Services Branch
Division of Services for Children with Special Health Needs
Attn: Maternal and Child Environmental Health Network
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18W09A
Rockville, MD 20857
Telephone: (301) 443-1463
Email: cnovoa@hrsa.gov

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

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International callers dial 606-545-5035)
Email: support@grants.gov
Self-Service Knowledge Base

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

HRSA Contact Center
Telephone: (877) 464-4772 / (877) Go4-HRSA
TTY: (877) 897-9910

Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Technical Assistance

HRSA has scheduled following technical assistance:
Webinar

Day and Date: Wednesday, February 16, 2022
Time: 2 p.m. – 3 p.m. ET
Call-In Number: 1-833-568-8864
Participant Code: 57045078
Weblink: https://hrsa-gov.zoomgov.com/j/1600985003?pwd=VVVqMHhybFpkSlkxOGhOUHdRY2pMUT09
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*.