U.S. Department of Health and Human Services

Health Resources & Services Administration

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2023

Maternal and Child Health Bureau

Office of Epidemiology and Research

Maternal and Child Health Field-Initiated Innovative Research Studies (MCH FIRST)

Funding Opportunity Number: HRSA-23-067

Funding Opportunity Type(s): New

Assistance Listings Number: 93.110

Application Due Date: February 7, 2023

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: November 9, 2022

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See Section VII for a complete list of agency contacts.

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

508 COMPLIANCE DISCLAIMER

Note: Persons using assistive technology may not be able to fully access information in this file. For assistance, 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) 2023 Maternal and Child Health Field-Initiated Innovative Research Studies (MCH FIRST) Program. The purpose of this program is to advance the health and well-being of MCH populations by supporting innovative, applied, and translational intervention research studies on critical issues affecting MCH populations. There is a significant gap in the body of rigorous evidence on effective interventions[1] available to the MCH field.[2] The MCH FIRST Program aims to improve health equity[3] by supporting groundbreaking intervention research to influence clinical practice, health care services, and early interventions for populations from underserved communities.[4] This Program provides an opportunity for researchers to explore diverse MCH topics of regional and national significance.

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[1] An intervention is defined as a manipulation of the subject or subject's environment to modify one or more health-related biomedical or behavioral processes and/or endpoints or outcomes for children and adolescents. Examples include, but are not limited to, delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior(s); treatment strategies; prevention strategies; and diagnostic strategies. A manipulation or task would be regarded as an intervention if it is used to modify a health-related biomedical or behavioral outcome. A manipulation or task used expressly for measurement, and not modification, would not be considered as an intervention. Source: National Institutes of Health, Office of Extramural Research. Frequently Asked Questions: NIH Clinical Trial Definition. Available at: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5226.

[2] Sosa S, Kogan MD, Garcia S, Strobino DM, Minkovitz CS. Strengthening the Evidence for Maternal and Child Health: Implementing the New Performance Measurement Framework for the Title V Maternal and Child Health Block Grant. Matern Child Health J. 2021 Feb;25(2):221-229. doi: 10.1007/s10995-020-03018-x. Epub 2021 Jan 4. PMID: 33392933

[3] Health equity means that all people, including mothers, fathers, birthing people, children, and families achieve their full health potential. Achieving health equity is an active and ongoing process that requires commitment at the individual and organizational levels, and within communities and systems. Achieving health equity requires valuing everyone equally, eliminating systemic and structural barriers including poverty, racism, ableism, gender discrimination and other historical and contemporary injustices, and aligning resources to eliminate health and health care inequities. The Maternal and Child Health Bureau created this definition of health equity. It is a working definition that encompasses concepts of equity as reflected in the 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.

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

This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. You should note that this program may be cancelled before award.

Funding Opportunity Title:	Maternal and Child Health Field-Initiated Innovative Research Studies (MCH FIRST)
Funding Opportunity Number:	HRSA-23-067
Due Date for Applications:	February 7, 2023
Anticipated FY 2023 Total Available Funding:	$600,000
Estimated Number and Type of Award(s):	Up to 2 grants
Estimated Annual Award Amount:	Up to $300,000 per award subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	July 1, 2023 through June 30, 2026 (3 years)
Eligible Applicants:	Eligibility is limited to public or nonprofit institutions of higher learning and public or private nonprofit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs. See 42 CFR § 51a.3(b). Faith-based and community-based organizations, tribes, and tribal organizations are 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 this NOFO and in HRSA's *SF-424 R&R Application Guide*. Visit HRSA's How to Prepare Your Application page for more information.

Technical Assistance

HRSA has scheduled the following webinar:

Thursday, November 17, 2022

2–3 p.m. ET

Weblink: https://hrsa-gov.zoomgov.com/j/1604352004?pwd=NXo5ajluanVhRVRvS3ZlZjV6WDByZz09

Attendees without computer access or computer audio can use the dial-in information below:

Call-In Number: 1-833-568-8864
Meeting ID: 160 435 2004
Passcode: 71141036

In an attempt to more effectively utilize our TA webinar time, if you have questions about the NOFO, please send them prior to the webinar via email to MCHFIRST@hrsa.gov. We will compile and address these questions during the TA webinar.

HRSA will record the webinar and make it available approximately 2 weeks after the webinar at: https://mchb.hrsa.gov/research/pre-app-ta-webinars.asp

Table of Contents

I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the FY 2023 Maternal and Child Health Field-Initiated Innovative Research Studies (MCH FIRST) Program. The purpose of the MCH FIRST Program is to advance the health and well-being of MCH populations by supporting innovative, applied, and translational intervention research studies on critical issues affecting MCH populations. There is a significant gap in the body of rigorous evidence on effective interventions available to the MCH field. The MCH FIRST Program aims to improve health equity[5] by supporting groundbreaking intervention research to influence clinical practice, health care services, and early interventions for underserved communities.[6] The MCH FIRST Program provides an opportunity for researchers to explore diverse MCH topics of regional and national significance.

The MCH FIRST program goals are to:

- Strengthen and expand the evidence base on topics addressed by the Title V Maternal and Child Health Services Block Grant National Performance Measures (see Appendix A), HRSA MCHB's Strategic Research Issues, Strategic Plan Goals, OR Healthy People 2030 objectives;
- Enhance the evidence and strategies for improving health equity for all MCH populations; and
- Address existing and new research topics of regional and national significance that highlight new data, knowledge, evidence, and strategies for addressing the burden of diseases that affect MCH populations. For more details, see Program Requirements and Expectations.

By the end of the period of performance, the recipient will have:

- Implemented an innovative applied or translational intervention research study in the field of MCH.

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[5] Health equity means that all people, including mothers, fathers, birthing people, children, and families achieve their full health potential. Achieving health equity is an active and ongoing process that requires commitment at the individual and organizational levels, and within communities and systems. Achieving health equity requires valuing everyone equally, eliminating systemic and structural barriers including poverty, racism, ableism, gender discrimination and other historical and contemporary injustices, and aligning resources to eliminate health and health care inequities. The Maternal and Child Health Bureau created this definition of health equity. It is a working definition that encompasses concepts of equity as reflected in the 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.

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

- Submitted or published at least three manuscripts in peer-reviewed journals.
- Partnered with at least one program or institution that works with underserved populations to ensure cultural competency and recruit study participants representing underserved populations.
- Disseminated results of the study to diverse stakeholders, including the study participants, outside the vehicle of peer-reviewed journals, such as blogs, reports, social media, guidelines, etc.

2. Background

This program is authorized by 42 U.S.C. § 701(a)(2) (Title V, § 501(a)(2) of the Social Security Act) and is a component of the Special Projects of Regional and National Significance (SPRANS). The MCH FIRST program is administered by the Division of Research in MCHB's Office of Epidemiology and Research.

The MCH FIRST program has significantly influenced clinical practice and preventive care for the MCH population by funding intervention research that can be used by practitioners. The MCH FIRST program has resulted in over 227 publications in peer-reviewed journals since 2011. Studies have shaped new knowledge for example by integrating behavioral risk assessment into well-child visits;[7] exploring the role of teen mothers' supportive relationships in maintenance of contraceptive use,[8] and leveraging telemedicine to improve equity in access to acute care.[9] For FY 2023, the Maternal and Child Health Bureau will solicit studies addressing HHS/HRSA's priorities and the MCHB strategic plan goals, as well as studies that align with the Title V Block Grant National Performance and Outcome Measures, and focus on underserved populations.

About MCHB and its Strategic Plan

The HRSA Maternal and Child Health Bureau (MCHB) administers programs that focus on 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 MCH populations*

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[7] Bailey-Davis L, Kling SMR, Wood GC, et al. Feasibility of enhancing well-child visits with family nutrition and physical activity risk assessment on body mass index. Obes Sci Pract. 2019;5(3):220-230. doi:10.1002/osp4.339.

[8] Quinn DA, Mitchell SJ, Lewin A. The Role of Teen Mothers' Support Relationships in Maintenance of Contraceptive Use. J Pediatr Adolesc Gynecol. 2017 Feb;30(1):35-40.

[9] Ronis SD, McConnochie KM, Wang H, Wood NE. Urban Telemedicine enables equity in access to acute illness care. Telemed J E Health. 2017;23(2):105-112.

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*

To learn more about MCHB and the Bureau's strategic plan, visit Mission, Vision, and Work | MCHB.

The MCH FIRST Program addresses MCHB's Goal 1 and Goal 2 to assure access to high quality and equitable health services to optimize health and well-being for all MCH populations and achieve health equity for MCH populations. This program advances Goal 3 by supporting innovative interventions that build the evidence base in MCH. Goal 4 is addressed through the broad dissemination of research findings to health care providers, other practitioners, researchers, policy makers, public health systems, Title V Block Grant programs, and the MCH community.

Promoting Health Equity

MCHB is committed to promoting equity in health programs for mothers, children, and families. As such, MCHB's working definition of health equity provides a foundation for the development of programs that aim to improve equity within and among communities. The definition is as follows: Health equity means that all people, including mothers, fathers, birthing people, children, and families achieve their full health potential. Achieving health equity is an active and ongoing process that requires commitment at the individual and organizational levels, and within communities and systems. Achieving health equity requires valuing everyone equally, eliminating systemic and structural barriers including poverty, racism, ableism, gender discrimination and other historical and contemporary injustices, and aligning resources to eliminate health and health care inequities.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a grant.

2. Summary of Funding

HRSA expects approximately $600,000 to be available annually to fund two recipients. The actual amount available will not be determined until enactment of the final FY 2023 federal appropriation. You may apply for a ceiling amount of up to $300,000 total cost (includes both direct and indirect costs) per year. The actual amount available will not be determined until enactment of the final FY 2023 federal appropriation. This program notice is subject to the appropriation of funds, and is a contingency action taken to

ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately.

The period of performance is July 1, 2023 through June 30, 2026 (3 years). Funding beyond the first year is subject to the availability of appropriated funds for MCH FIRST 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

Eligibility is limited to public or nonprofit institutions of higher learning and public or private nonprofit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs. See 42 CFR § 51a.3(b). Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

You are required to submit proof of non-profit status as Attachment 5. A foreign applicant will need to be affiliated with, and a sub-awardee, of a U.S. entity (e.g., university, institution) with a U.S. EIN established and recognized by HRSA to be considered a public or nonprofit institution of higher learning or a public or private nonprofit agency.

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

NOTE: Multiple applications from an organization with the same Unique Entity Identifier (UEI) are allowable if the applications propose separate and distinct projects. For example, different investigators (or research teams) from the same institution can apply for the same funding opportunity.

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.

Please make sure you submit your application to the correct NOFO number: HRSA-23-067, the MCH FIRST Program competition. Applications submitted to the wrong competition will be deemed nonresponsive and will not be considered for funding under this notice.

Due to funding limitations and in order to diversify the MCHB research portfolio the following are additional application responsiveness criteria. All applications that do not comply with these criteria will be deemed nonresponsive and will not be considered for funding under this notice.

- An individual cannot be named as the project director (PD) or principal investigator (PI)[10] **on more than one** application for the MCH FIRST;
- The current PD/PI of an active HRSA/MCHB/Office of Epidemiology and Research (OER)/Division of Research (DOR) award can serve for **no more than 10 percent time** on a new proposal;
- A PD/PI cannot have two (2) active HRSA/MCHB/OER/DOR awards at the same time. An award in a no-cost extension year is considered active and the PD/PI is not allowed to receive another award;
- Longitudinal follow-up studies for previously funded MCH or Autism FIRST studies will **NOT** be considered for funding;
- Projects that focus primarily on secondary data analysis will **not** be considered for funding under this award as there are separate competitions that focus on secondary data analyses, the MCH and Autism Secondary Data Analysis Research competitions;
- Projects addressing autism spectrum disorder (ASD) will **not** be considered for this award competition (a separate competition for Autism Field-Initiated Innovative Research Studies Program may be held, if funds are available); and,
- Projects which include the collection of biological specimens will **not** be considered for the award competition as this program funds translational intervention research on MCH populations.

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 Research and Related (R&R) workspace application

[10] HRSA allows one PD/PI to be named on the face page of the SF-424 R&R application, who will serve as the key point of contact, yet multiple co-PI/co-PDs are allowed. This application responsiveness criterion only applies to current MCHB PI/PDs, not co-PI/PDs.

package associated with this notice of funding opportunity (NOFO) following the directions provided at Grants.gov: HOW TO APPLY FOR GRANTS. If you use an alternative electronic submission, see Grants.gov: APPLICANT SYSTEM-TO-SYSTEM.

Form Alert: For the Project Abstract Summary, applicants using the SF-424 R&R Application Package are encountering a "Cross-Form Error" associated with the Project Summary/Abstract field in the "Research and Related Other Project Information" form, Box 7. To avoid the "Cross-Form Error," you must attach a blank document in Box 7 of the "Research and Related Other Project Information" form and use the Project Abstract Summary Form in workspace to complete the Project Abstract Summary. See Section IV.2.i Project Abstract for content information.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for HRSA-23-067 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 R&R Application Guide* provides general instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, and certifications. You must submit the information outlined in HRSA *SF-424 R&R Application Guide* in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in this NOFO and HRSA's *SF-424 R&R Application Guide*. 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 R&R Application Guide* for the Application Completeness Checklist to assist you in completing your application. In addition, please refer to the Research Program Application Completeness Checklist (Appendix C) and Frequently Asked Questions (Appendix D) for additional guidance on completing your application.

Application Page Limit

The total of uploaded attachment pages that count against the page limit shall be no more than the equivalent of **80 pages** when printed by HRSA. All sections combined count towards the 80-page total limit, including the project and budget narratives, attachments including biographical sketches (biosketches), works cited, and letters of commitment and support required in HRSA's SF-424 R&R Application Guide and this NOFO.

Forms that DO NOT count in the Page Limit

- Standard OMB-approved forms included in the workspace application package **do not** count in the page limit. The abstract is the standard form (SF) "Project_Abstract Summary." It **does not** count in the page limit.
- The Indirect Cost Rate Agreement **does not** count in the page limit.
- The proof of non-profit status (if applicable) **does not** count in the page limit.

If there are other attachments that do not count against the page limit, this will be clearly denoted in Section IV.2.v Attachments.

If you use an OMB-approved form that is not included in the workspace application package for HRSA-23-067, 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.

- HRSA will flag any application that exceeds the page limit and delete any pages considered over the page limit. The altered copy of the application will move forward to the objective review committee

It is important to take appropriate measures to ensure your application does not exceed the specified page limit.

Applications must be complete and validated by Grants.gov under HRSA-23-067 before the deadline.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3354).
3) If you are unable to attest to the statements in this certification, you must include an explanation in *Attachment: Other Relevant Documents*.

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

Program Requirements and Expectations

HRSA expects each MCH FIRST award recipient to complete the following major activities:

- Conduct and complete the innovative applied or translational intervention research studies using rigorous scientific methodology as you described in your application;
- Recruit, track, and report study participants from diverse backgrounds to include diversity with regards to race/ethnicity, gender/sex, disability, geographic location, and socioeconomic status;
- Submit a dissemination plan for the distribution of research findings and products to study participants, scientific, professional, and lay audiences; including a timeline for implementation. Dissemination activities include, but are not limited to, peer-reviewed articles, manuscripts, conference presentations, newsletter articles, webcasts, fact sheets, infographics, policy briefs, websites, and social media posts, as appropriate;
- Produce at least **three** peer-reviewed publications; and
- Present findings at the End of Project Presentation (Research Festival) to MCHB staff.

Program-Specific Instructions

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

i. *Project Abstract*

Use the Standard OMB-approved Project Abstract Summary Form that is included in the workspace application package. Do not upload the abstract as an attachment or it may count toward the page limit. See **Form Alert** in Section IV.1 Application Package. For information required in the Project Abstract Summary Form, see Section 4.1.ix of HRSA's *SF-424 R&R Application Guide*.

Include the information requested at the top of the abstract. Because the abstract is often distributed to provide information to the public and Congress, be clear, accurate, concise, and do not refer to other parts of the application. Briefly state the principal needs and problem, goals, proposed data sets including study population(s), planned coordination, anticipated products, and plans for evaluation.

Provide the information below in the Project Abstract field:

- PROBLEM: Briefly state the needs and problems that are addressed by the project, including the project's relationship to *MCHB Strategic Research Issues*.
- GOAL(S) AND OBJECTIVES: Identify the major goal(s) and objectives for the period of performance. Typically, the goal is stated in a sentence or paragraph, and the objectives are presented in a numbered list.
- PROPOSED DATA SETS AND TARGET POPULATION(S): Briefly describe the research design and methods within the abstract and include data collection methods and participant information (i.e., age range and

demographic background of target population) for the project that you propose.

- PRODUCTS: Provide a brief description of the anticipated products of this project, including how project activities and findings will be distributed.
- EVALUATION: Briefly describe the evaluation methods used to assess program outcomes as well as the effectiveness and efficiency of the project in attaining goals and objectives.
- KEY TERMS: At the end of your abstract, include the following **key terms** found in Appendix E to describe: (a) your project (maximum of 10 content terms), (b) targeted populations (select all that apply), and (c) age ranges (select all that apply).

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**
I. Specific Aims: 1) Needs Assessment	(1) Need
I. Specific Aims: 2) Significance	(2) Response
I. Specific Aims: 3) Goals and Hypotheses	
II. Methodology/Research Strategy: 1) Study Design/Approach	(3) Study Design/Approach
II. Methodology/Research Strategy: 2) Scientific Innovation and Importance	(4) Impact
III. Impact and Dissemination	
IV. Organizational Information/Environment	(5) Resources/Capabilities
Budget and Budget Justification	(6) Support Requested
V. Feasibility	(7) Program Assurances
VI. Evaluation and Technical Support Capacity	
VII. Protection of Human Subjects	
VIII. Targeted/Planned Enrollment	

ii. *Project Narrative*

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

Successful applications will contain the information below. Please use the following section headers for the narrative:

Section 1: SPECIFIC AIMS -- Corresponds to Section V's Review Criteria #1 Need and #2 Response

Provide a brief introduction and overview of the proposed research project. The purpose of this section is to provide a compelling explanation of your project for the reviewers to clearly understand the scientific value of the proposed study.

1) *Needs Assessment -- Corresponds to Section V's Review Criterion #1* Need

- Briefly describe your study population(s)' unmet health needs and identify health disparities facing the study population(s);
- If relevant, include the social determinants of health (SDOH) and health inequalities of the population that your project will address;
- Explain the problems and research gaps that your study addresses; and
- Briefly outline how your project aligns with one of the following: Healthy People 2030 objectives, MCHB Strategic Research Issues, MCHB Strategic Plan Goals, or MCH Block Grant National Performance Measures.

2) *Significance -- Corresponds to Section V's Review Criterion #2,* Response

- Provide an overview of the existing literature that demonstrates the importance of your study's research objectives;
- Identify how your results may improve care and/or the ways that services are organized and delivered; and/or
- Describe how your study will advance health equity in MCH populations.

3) *Goals and Hypotheses -- Corresponds to Section V's Review Criterion #2,* Response

a) Goals and Objectives

- Briefly state the specific goals and objectives of your research study that you will accomplish during the grant cycle that address the problems, barriers, and gaps identified. The study objectives should be specific, measurable, achievable, relevant, time bound, inclusive, and equitable (SMARTIE).

b) Hypotheses and Specification of Variables

- Briefly state the specific questions that your study will answer. These should include predictions of findings (hypotheses), as well as the reasoning behind your predictions; and
- Include a summary table of the relevant variables. You should define your variables, including the type of variables (e.g., independent, dependent, mediating, and moderating).
  - You can create a graphic describing the theoretical model, conceptual framework, or the variables' relationships;
  - Make sure that any relationships shown in graphics are consistent with your variable table, the statement of hypotheses, and the plan for data analysis.

Section II: METHODOLOGY -- Corresponds to Section V's Review Criteria #3 Study Design/Approach and #4 Impact

Organize the Methodology section in the specified order using the instructions provided below. Start each section with the appropriate section heading – Study Design/Approach, and Scientific Innovation and Importance. Cite relevant publications in the Methodology section and provide the full reference in the Bibliography and References Cited section.

The Methodology section is recommended to be no more than 12 pages in length.

1) Study Design/Approach – Corresponds to Section V's Review Criterion #3 Study Design/Approach

- Describe the proposed interventions, overall study design, methodology, and analyses you will use to accomplish the specific aims of the project;
- Describe the procedures for data collection and instrumentation, as appropriate;
- Include how you will collect, analyze, and interpret the data, as well as any plans to coordinate data collection and analysis for multi-sites, as appropriate;
- Describe your enrollment and recruitment plan of your target population, including:
  - Demographic information on the target population (i.e., age, gender/sex, race/ethnicity, household income, education level, rural/urban status, etc.);
  - Eligibility inclusion/exclusion criteria. Include a description of strategies for diverse participant recruitment. Address issues regarding sampling design and randomization, as appropriate. Include expected enrollment number and power analyses, as appropriate;
  - Letters of Agreement from study sites supporting recruitment must be included in Attachment 1, if applicable; and

- Describe your plan to partner with at least one program or institution that works with underserved populations to ensure cultural competency, recruit study participants, and disseminate research findings.

- Preliminary Studies: Include information on preliminary studies as part of the Section (1) Study Design section. Provide a description of the PD/PI's preliminary studies pertinent to this application. This information will also help to establish the experience and competence of the investigator to pursue the proposed project. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

2) Scientific Innovation and Importance – Corresponds to Section V's Review Criterion #4, *Impact*

- Explain how your project will add scientific knowledge, expand the evidence base, improve technical capability and/or clinical practice; and
- Describe any novel, including refined or improved, theoretical concepts, approaches or methodologies, policies, instrumentation, or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, policies, or interventions.

SECTION III. IMPACT AND DISSEMINATION – Corresponds to Section V's Review Criterion #4, Impact

1) Public Health Impact

- Describe the public health impact that study results may have, e.g., how the study can affect care delivery and/or the health and well-being of MCH populations;
- Describe how the study results will be of regional and national significance, including their generalizability; and
- Discuss the potential scalability/sustainability of this project.

2) Publication and Dissemination Plan

It is expected your project will produce **at least three peer-reviewed publications**.

- Provide an action plan that describes:
  - The number and focus of your proposed peer-reviewed publications, as well as the names and impact factor of the journals where you plan to submit your papers;
  - How you will help put your findings into practice by distributing findings, reports, and/or project results broadly; and
  - How you will inform study participants of the results of your research.

SECTION IV. ORGANIZATIONAL INFORMATION/ ENVIRONMENT – Corresponds to Section V's Review Criterion #5, Resources/Capabilities

This information is used to judge the ability of your organization, your organization's resources, and staff to complete your study. NOTE: The SF-424 R&R Table of Contents Page refers to Environment as "Facilities & Other Resources." This section on "Environment" can be included as an attachment in the Other Project Information Form, box 10, or included as part of the research narrative.

1) Organizational Facilities and Other Resources

- Identify the facilities you will use (laboratory, clinical setting, computer lab, office, and/or other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work;
- Discuss ways in which the study will benefit from your organization's scientific environment;
- For Early Stage Investigators,[11] describe institutional investment in the success of the investigator. Examples may include computer and software support, collegial support, such as the availability of organized peer groups, logistical support, such as administrative management and oversight, and financial support, such as protected time for research with salary support; and
- If there are multiple sites, describe each site's resources.

2) Qualifications of Research Team's Key Personnel

- Keep in mind the objective review committee will use the following to evaluate the research team's qualifications and research strategy: (a) Preliminary Studies in Section II; Methodology/Research Strategy 2) Study Design; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches of key personnel.
- Please use the MCHB biographical sketch form found here: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-forResearch-Grant-Applicants-Jan2020-2023.docx. NOTE: The biographical sketch form counts against your total page limitation and may not exceed **five** pages per person. This information, allows MCHB to determine to what extent individuals of different backgrounds are participating. This information, in addition to other information including career stage, geographic location of the institution, educational level, assists MCHB in ensuring that federal grant

[11] An Early Stage Investigator is a program director / principal investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a federal independent research award. (https://grants.nih.gov/policy/early-investigators/index.htm)

and cooperative agreement awards are reaching a broad diversity of populations. A detailed description of information that should be included in the biographical sketches is available in Appendix F.

SECTION V. Feasibility– Corresponds to Section V's Review Criterion #7, Program Assurances

This section addresses questions around project feasibility. If funded, it is important that the recipient implements and completes the study as proposed and approved.

1) Proposed Sequence or Timetable

- Provide a sequence or timetable for the project that includes the steps that you will take to achieve each of the activities proposed during the entire period of performance. Use a timeline that includes each activity and identifies responsible staff.

2) Resolution of Challenges

- Discuss any challenges that you might encounter in designing and implementing the research activities described in the Study Design/Approach, and approaches that will be used to resolve such challenges. Examples include recruitment of study sites and study participants, staff training and standardization of research protocols across multiple sites, putting culturally/linguistically competent project staff in place quickly, recruiting participants from specific populations, etc.;
- Discuss alternative strategies should any of these potential challenges arise;
- Discuss your strategy to reach targeted/planned enrollment levels and how you will address the management of any high-risk aspects or anticipated challenges of the proposed goals; and
- If appropriate, point to any procedures, situations, or materials that may be harmful to the study participants, and precautions you would exercise.

SECTION VI. Evaluation and Technical Support Capacity – Corresponds to Section V's Review Criterion #7, Program Assurances

- Describe the systems and processes that will support your organization's performance management tracking and how the organization will collect and manage data;
- As appropriate, describe the 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 the research team's current experience, skills, and knowledge that will contribute to the success of your project; and
- Describe any potential obstacles that may affect implementing the program performance evaluation, and your plan to address those obstacles.

SECTION VII. Protection of Human Subjects – Corresponds to Section V's Review Criterion #7, Program Assurances

- Discuss plans to seek Institutional Review Board (IRB) approval or exemption. IRB approval is not required at the time of submission but must be received prior to the study;
- If awarded, nonexempt human subjects research must comply with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR part 46) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). 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; and
- All institutions that are engaged in nonexempt human subjects research as part of the project, including foreign applicants, must be covered by a Federalwide Assurance (FWA) approved by the Office for Human Research Protections (OHRP). Instructions on how to submit an FWA application, if awarded, can be found on OHRP's website at https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html.

SECTION VIII. TARGETED/PLANNED ENROLLMENT – Corresponds to Section V's Review Criterion #7, Program Assurances

Provide details about the diversity of the targeted/planned study enrollees. Information should include study sample totals by:

1) Ethnic Category (Hispanic Heritage): "Hispanic or Latino" or "Not Hispanic or Latino"

- Gender/sex distribution within each Ethnic Category (Hispanic Heritage);
- Total distribution by Ethnic Category (Hispanic Heritage);
- The "Ethnic Category (Hispanic Heritage): Total Sample" must be equal to the "Racial Categories: Total Sample." List any proposed racial/ethnic subpopulations; and
- The "Total Sample" means the number of subjects in the dataset that will be used in your analysis. They will be reported in two ways in the table: by self-reported "Ethnic Category (Hispanic Heritage)" and by self-reported "Racial Categories."

2) Racial Categories

- American Indian/Alaska Native
- Asian

- Native Hawaiian or Other Pacific Islander
- Black or African American
- White
- More than One Race
- Gender/sex distribution within each racial category
- Total sample by racial category

3) Socioeconomic status, as applicable [12]

- Level of Education
- Income-to-Poverty Ratio or Federal Poverty Level
- Occupational Status

4) Disability Status

5) Geographic Location

- Urban
- Rural

iii. *Budget*

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

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

As required by the Consolidated Appropriations Act, 2022 (P.L. 117-103), "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 R&R Application Guide* for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

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[12] Socioeconomic status can be determined by a family's income level, education level, and occupational status. Despite the differences in definition between poverty and socioeconomic status, researchers agree that there is a clear and established relationship between poverty, socioeconomic status, and health outcomes—including increased risk for disease and premature death. Healthy People 2020, accessed 10/28/20, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/poverty.

iv. *Budget Justification Narrative*

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

In addition, the MCH FIRST program requires the following:

Within Personnel Costs, include the staffing plan by providing position descriptions (roles, responsibilities, and qualifications of proposed project staff) in the "Budget Justification" section that you will add to SF-424 R&R Budget Period – Section F – K Form, Box K. This staffing plan should describe the complementary and integrated expertise of the investigators and show that the leadership approach, governance and organizational structure are appropriate for the project. The staffing plan should reflect the commitment of the research team in conducting and completing the study. (NOTE: A current PI of an MCH Research grant can serve for no more than 10 percent time on a new proposal in a capacity other than as PD/PI). Copies of biographical sketches for all senior/key personnel and other significant contributors must also be submitted as an attached file to each SF-424 R&R Senior/Key Person Profile.

The budget justification should be uploaded into the Budget Narrative Attachment Form. Biographical sketches for any key personnel must be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on Grants.gov. Due to the HRSA 80-page limit, the biographical sketches should be no more than two pages in length and follow the HRSA font/margin requirements. This OMB form does count against your page limit.

v. *Attachments*

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. **Clearly label each attachment**. You must upload attachments into the application. HRSA and the objective review committee will not open/review any *hyperlinked* attachments.

- *Attachment 1: Letters of Agreement/Letters of Support*
  Provide any documents that describe working relationships between your agency and other agencies and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the subcontractors and any deliverables. Include only letters of support that specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). Letters of agreement and letters of support must be recently signed and dated.

- *Attachment 2: List of Citations for Key Publications.*
  A list of citations for key publications by the key personnel that are relevant to the proposal can be included. **Do not include unpublished theses, or abstracts/ manuscripts submitted (but not yet accepted) for publication.**

In consideration of the **80-page limitation**, a list of citations only may be included.

- *Attachment 3: Surveys, Questionnaires, Data Collection Instruments, Clinical Protocols.*
  Surveys, questionnaires, other data collection instruments, clinical protocols, and informed consent documents may be submitted as an attachment as necessary, keeping in mind that these count in the 80-page limitation.

- *Attachment 4: Explanation on Delinquent Federal Debt, if applicable.*

- *Attachment 5: Proof of Non-profit Status. (Note: the non-profit status determination letter is not included in the page limit).*

- *Attachments 6–15: Other Relevant Documents*

3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

Effective April 4, 2022:

- The UEI assigned by SAM has replaced the Data Universal Numbering System (DUNS) number.
- Register at SAM.gov and you will be assigned a UEI.

You must register with SAM and continue to maintain active SAM registration with current information at all times when you have: an active federal award, an active application, or an active 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 registration, you must submit a notarized letter appointing the authorized Entity Administrator.

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

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

The Grants.gov registration process requires information in two separate systems:

- System for Award Management (SAM) (https://sam.gov/content/home | SAM Knowledge Base)
- Grants.gov (https://www.grants.gov/)

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

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 application due date under this NOFO is ***February 7, 2023 at 11:59 p.m. ET*.** HRSA suggests you submit your application 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 in HRSA's *SF-424 R&R Application Guide* for additional information.

5. Intergovernmental Review

MCH FIRST 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 R&R Application Guide* for additional information.

6. Funding Restrictions

You may request funding for a period of performance of up to 3 years, at no more than $300,000 per year (inclusive of direct **and** indirect costs). This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately.

Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division H of the Consolidated Appropriations Act, 2022 (P.L. 117-103) apply to this program. See Section 4.1 of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these and other restrictions will apply in the following fiscal years, as required by law.

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 specific uses of funding. It is imperative that you review and adhere to the list of statutory restrictions on the use of funds detailed in Section 4.1 of HRSA's *SF-424 R&R Application Guide*. 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**.

All program income generated as a result of awarded funds must be used for approved project-related activities. Any program income earned by the recipient must be used under the addition/additive alternative. You can find post-award requirements for program income at 45 CFR § 75.307.

V. Application Review Information

1. Review Criteria

HRSA has processes 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 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.

Reviewers will evaluate and score the merit of your application based upon these criteria.

Seven review criteria are used to review and rank the MCH-FIRST Program applications. Below are descriptions of the review criteria and their scoring points.

Criterion 1.	Need	10 points
Criterion 2.	Response	20 points
Criterion 3.	Study Design/Approach	30 points
Criterion 4.	Impact	10 points
Criterion 5.	Resources/Capabilities	15 points
Criterion 6.	Support Requested	5 points
Criterion 7.	Program Assurances	10 points
TOTAL		100 points

Criterion 1: NEED (10 points) -- Corresponds to Program Narrative Section I. Specific Aims: 1) Needs Assessment

1) Needs Assessment (6 points)

The extent to which the application:

- Describes the gap in research that the proposed study will address;
- States clearly the scientific rationale for this project; and
- Describes the health disparities and unmet health needs of their study's population.

2) Alignment with HRSA/MCHB Strategic Plan and Healthy People 2030 (4 points)

The extent to which the project explains its alignment with:

- MCHB Strategic Research Issues (Appendix A) and/or HRSA MCHB Strategic Plan and/or the MCH Block Grant National Performance Domains (Appendix A) and/or Healthy People 2030 and/or priorities listed in the Purpose section (See HRSA's SF-424 R&R Application Guide, Section 2.2: Administrative and National Policy Requirements).

Criterion 2: RESPONSE (20 points) -- Corresponds to Program Narrative Sections I. Specific Aims: 2) Significance and 3) Goals and Hypotheses

1) **Significance (5 points)**

The extent to which:

- The applicant shows knowledge of previous and current scientific research in the area of the project;
- The cited literature is relevant to the research problem and supports a rationale for the research; and
- The project addresses a critical problem or barrier to the field.

2) **Addressing Health Equity (5 points)**

- The application adequately addresses health inequities faced by underserved populations, and the study has the potential to advance health equity for MCH populations; and
- The applicant describes a concrete plan to partner with at least one program or institution serving underserved populations to ensure cultural competency, recruit study participants, and disseminate research findings.

3) **Goals and Hypotheses (10 points)**

The extent to which:

- The goals are clear, and the study objectives are SMARTIE (Specific, Measurable, Attainable, Realistic, Time-bound, Inclusive, and Equitable);
- The variables and the expected outcomes are clearly and briefly defined and summarized, especially how these outcomes will address the unmet needs of the target population;
- The hypotheses are rooted in the research literature, clearly stated, and are related to the research questions; and
- The associations depicted by the theoretical framework or model, the variables, the hypotheses, and the plan for data analysis are consistent.

Criterion 3: Study Design/Approach (30 points) -- Corresponds to Program Narrative Section ***II. Methodology/Research Strategy***: ***1) Study Design/Approach***

1) **Study Design/Approach (10 points)**

The extent to which:

- The overall research strategy, study design, statistical methodology, and analyses are clearly described, well-reasoned, and suitable to complete the project's specific aims;
- The method of randomization, if used, is clearly described, and proper controls are included;
- Major threats to the design's internal and external validity have been adequately acknowledged and addressed; and
- The project assures cultural competence in the planning and implementation of the research project.

2) **Population Description, Sampling, and Recruitment (10 points)**

The extent to which:

- The study population is clearly described (i.e., targeted age(s) or age ranges, expected racial/ethnic background and socioeconomic status, urban/rural, etc.);
- The eligibility criteria for entering the study are well defined;
- The sampling design is appropriate and includes an adequate and justified sample size. The expected differences between groups are defined by statistical and clinical significance;
- The recruitment plan is clearly described and feasible to complete within the period of performance, given recruitment methods; and
- The letters of agreement adequately demonstrate the support of recruitment at the study sites.

3) **Data Collection (5 points)**

The extent to which:

- The instruments that have been selected or developed are appropriate, reliable, and valid (i.e., psychometric properties); and
- Any self-reported data can provide convincing validity for intended measurements (e.g., self-reported blood pressure, parent-reported anthropometric data).

4) **Plan for Data Analysis (5 points)**

The extent to which:

- Plans for data analysis are adequately described including the rationale for the sequence of steps to be taken;
- The plans are appropriate given the nature of the data, design, and sampling; and
- Sufficient time is allocated for data analysis.

CRITERION 4: IMPACT (10 points) -- Corresponds to Program Narrative Sections Section II. Methodology: 2) Scientific Innovation and Importance; and III. Impact and Dissemination

1) **Scientific Innovation and Importance *(5 points)***

The extent to which:

- The application challenges and seeks to shift current research or clinical practice paradigms by enhancing existing or applying new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions; and
- The findings will be generalizable and are of regional or national significance and/or scope, and likely to exert a sustained influence on the MCH field.

2) **Public Health Impact and Dissemination (5 points)**

The extent to which:

- The expected outcomes are likely to have an impact on health care delivery, policy, and practice;
- There is a feasible and appropriate publication and dissemination plan described including a plan for publishing at least **three** peer-reviewed publications;
- The application clearly describes a plan to advance the transfer of findings into practice by disseminating findings and reports to key target audiences,

including study participants, researchers, providers, State Title V, and children with special health care needs programs and other program(s) serving MCH populations, policymakers, families, and the general public; and
- The project is scalable and sustainable.

CRITERION 5: RESOURCES/CAPABILITIES (15 points) -- Corresponds to Project Narrative Section IV: Organizational Information/Environment

1) **Organizational Capacities (5 points)**

The extent to which:

- The organization can provide quality facilities and staff to fulfill the needs and requirements of the proposed research project; and
- The project will benefit from the organization's scientific environment, the collaborative arrangements, and the communities and stakeholders engaged.

2) **Qualifications of Key Personnel (10 points)**

The extent to which:

- The Key/Senior Support Personnel Profiles and biographical sketches indicate that the Principal Investigator (PI), collaborators, staff, and other researchers are well qualified by training and/or expertise to conduct the research;
- The application describes relevant preliminary studies performed by key personnel, indicating the capacity to conduct the work as described; and
- The PI and other key personnel demonstrate current and/or past success in publishing the findings of their research.

CRITERION 6: SUPPORT REQUESTED (5 points) -- Corresponds to Budget and Budget Justification

The extent to which:

- The proposed budget is reasonable in relation to the scope of work, study objectives, and the complexity of the research activities;
- Budget line items are well described and supported in the budget justification;
- The time given to key personnel is realistic and appropriate to achieve project objectives; and
- Other current and pending support is clearly described, as applicable. (Note: A current PI of an MCH Research award (including a No Cost Extension (NCE) year) can serve for no more than 10 percent time on a new MCH Research proposal as Co-PI).

CRITERION 7: PROGRAM ASSURANCES (10 points) -- Corresponds to V. Feasibility; VI. Evaluation and Technical Support Capacity, VII. Protection of Human Subjects, and VIII. Targeted/Planned Enrollment

Once a project is funded, it is expected that it will show ongoing progress and completion as proposed and approved.

1) **Proposed timeline and evaluation (6 points)**

The extent to which:

- The proposed project provides a clear, detailed, and feasible timeline for the proposed activities and is able to be conducted within the proposed timeframe;
- Plans are in place to determine if the project objectives are being met according to the timeline; and
- The application anticipates and addresses potential barriers (e.g., meeting enrollment targets).

2) **Human Subjects Protections (4 points)**

The extent to which:

- The proposal complies with the HHS regulations for protection of human subjects (45 CFR part 46). See the instructions 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;
- The project includes clear and adequate plans for: 1) protection of human subjects from research risks and the applicant discusses plans to seek IRB approval. (IRB approval is not required at the time of application submission but must be received prior to starting any activities involving human subjects); and
- Adequate measures are in place to protect the security of the research data (data security).

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 R&R Application Guide* for more details. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (e.g., geographical distribution) described below in selecting applications for award.

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 July 1, 2023. See Section 5.4 of HRSA's *SF-424 R&R Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's *SF-424 R&R 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 will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- 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 https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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 (E.O. 14025), 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

Certificate of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, HRSA-supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document but are issued by application of this term and condition to the award. For additional information which may be helpful in ensuring compliance with this term and condition, see Centers for Disease Control and Prevention (CDC) Additional Requirement 36 (https://www.cdc.gov/grants/additional-requirements/ar-36.html).

3. Reporting

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

1) **DGIS Performance Reports.** Available through the 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. Please be advised the administrative forms and performance measures for MCHB discretionary grants will be updated on May 4, 2023. DGIS reports created on or after May 4, 2023 will contain the updated forms. To prepare successful applicants for their reporting requirements, the administrative forms and performance measures for this program are Form 1, Form 2, Form 3, Form 6, Form 7, Form 8, Products, Publications and Submissions Data Collection Form, Core 3, Capacity Building (CB 4), Capacity Building (CB 5), Capacity Building (CB 6) and Capacity Building (CB 8). The type of report required is determined by the project year of the award's period of performance. 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: 08/31/2025).

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	7/1/2023-6/30/2026 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	7/1/2023-6/30/2024 7/1/2024-6/30/2025	Beginning of each budget period	120 days from the available date
c) Project Period End Performance Report	7/1/2025-6/30/2026	Period of performance end date	90 days from the available date

2) **Progress Report**(s).
The recipient must submit a progress report narrative to HRSA **annually** via the Non-Competing Continuation Renewal in the EHBs, which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year), and include annual data on performance measures identified in the Project Narrative, if not captured by DGIS. Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA. The recipient must submit a progress report to HRSA annually and at the end of the project. More 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:

David Colwander
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
Phone: (301) 443-7858
Email: DColwander@hrsa.gov

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

Jessica DiBari, PhD, MHS
Senior Health Scientist, Office of Epidemiology and Research
Attn: MCH FIRST HRSA-23-067
Maternal and Child Health Bureau
Health Resources and Services Administration
Phone: (301) 443-4690
Email: MCHFIRST@hrsa.gov

Bridget Kerner, MS
Public Health Analyst, Office of Epidemiology and Research
Attn: MCH FIRST HRSA-23-067
Maternal and Child Health Bureau
Health Resources and Services Administration
Phone: (301) 287-0115
Email: MCHFIRST@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
Phone: 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 HRSA's Electronic Handbooks (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
Phone: (877) 464-4772 / (877) Go4-HRSA
TTY: (877) 897-9910
Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Technical Assistance

See TA details in Executive Summary.

Tips for Writing a Strong Application

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

Appendix A: Strategic Research Issues and Title V MCH Services Block Grant–National Performance Measures

Strategic Research Issues (SRI)

Full SRI Guidance

Guiding Principles

These are themes that inform MCHB's research goals. When conducting research, all funded research projects should keep the following in mind:

> Principle 1: Incorporate social determinants of health and health equity frameworks into MCH research.
>
> Principle 2: Improve the quality and accessibility of health and community resources and services for mothers, children, and families, especially those of underserved MCH populations.
>
> Principle 3: Strengthen the evidence base for the field of MCH.
>
> Principle 4: Accelerate the coordination, translation, and implementation of evidence-based/evidence-informed research.

Goals

The ways that our funded research aim to create change:

1. Improve the Health System for Mothers and Children
    a. Find gaps in the health care system and improve them by changing the system. Changes include using technology, public health data, and the medical home model of care delivery.

2. Promote the Health and Well-Being of Mothers
    a. Prevent death and serious injury, and support the well-being of women, before, during and after pregnancy and childbirth.

3. Promote the Health and Well-Being of Children
    a. Improve the health of children and youth across the life course, including those with special health care needs, and children with autism spectrum disorder and developmental disabilities

4. Promote the Health and Well-Being of Families
    a. Learn about what factors impact family health and how to engage the community.

5. Increase Evidence for Maternal and Child Health Practice
    a. Find the strategies, programs, and interventions that work best and how to best measure their impact.

6. Support Innovation and Collaboration in Research
    a. Study new technology, methods, and ideas in research, including supporting new researchers with different backgrounds.

Title V MCH Services Block Grant–National Performance Measures

No.	Performance Measures	MCH Population Domain
1	Well-Woman Visits and Preconception/ Inter-conception Health	Maternal Health
2	Low-Risk Cesareans	Maternal Health
3	Breastfeeding	Perinatal and Infant Health
4	Perinatal Regionalization	Perinatal and Infant Health
5	Safe Sleep	Perinatal and Infant Health
6	Developmental Screening	Child Health
7	Injury Prevention	Child Health
8	Physical Activity	Child Health
9	Adolescent Well-Visits and Preventive Services	Adolescent Health
10	Bullying	Adolescent Health
11	Medical Home	Children with Special Health Care Needs
12	Transition to Adulthood	Children with Special Health Care Needs
13	Oral Health	Cross-Cutting/Life Course
14	Smoking	Cross-Cutting/Life Course
15	Adequate Insurance Coverage	Cross-Cutting/Life Course

For more information on the Title V MCH Services Block Grant–National Performance Measure please visit: https://mchb.hrsa.gov/maternal-child-health-initiatives/title-v-maternal-and-child-health-services-block-grant-program. Please consult the following articles:

- Lu, MC, Lauver, CB, Dykton, C, Kogan, MD et al. Transformation of the Title V Maternal and Child Health Services Block Grant. *Maternal and Child Health* Journal 2015; 19(5): 927-931.
- Kogan, MD, Dykton, C, Hirai, AH, Strickland, BB et al. A New Performance Measurement System for Maternal and Child Health in the United States. Maternal and Child Health Journal 2015; 19(5): 945–957.

Appendix B: Logic Model

The following logic model illustrates HRSA's expectations and goals for the MCH Field-Initiated Innovative Research Studies Program:

PROGRAM PROCESS **What is the planned work for the program?**		**PROGRAM OUTCOMES** **What are the program's intended results?**	
ACTIVITIES **(What will program inputs do?)**	**OUTPUTS / PRODUCTS** **(What will be created as a result of the activity?)**	**SHORT-TERM / INTERMEDIATE** **(What will change as a result of the product/system implemented?)**	**LONG-TERM / IMPACT** **(What will change if short-term / intermediate outcomes are achieved?)**
Public Health Services and Systems, if applicable			
Partnerships, Collaboration, & Family Engagement Establish and foster partnerships with programs and institutions serving underserved populations to ensure cultural competency, recruit study participants, and disseminate research findings	Partnerships with institutions collaborating with underserved populations established (at least one)	Increase the # of MCH stakeholders who actively contribute and are committed to developing and translating research into practice (# of stakeholders, # of meetings, # of research questions developed with partners, # of study participants from underserved communities recruited due to the partnership, knowledge improvement among the partners on the issues studied)	Increased amount of research findings that are translated and integrated into MCH programs and practices
Education & Outreach Develop and implement a dissemination plan for communicating research findings to diverse stakeholders	Develop dissemination plan with a timeline and list of proposed products including non-peer-reviewed products aimed at stakeholders beyond the scientific research community (E.g., reports,	Increase the awareness and accessibility of the research findings from HRSA-funded research to the scientific and lay community	Expanded evidence base to inform the work of health care providers, other practitioners, public health systems, and Title V Block Grant programs

Develop and evaluate resources such as guidelines, tools, study protocols, or toolkits for use in clinical practice or intervention-based research in community settings, as applicable to their project.	blogs, web postings, videos, infographics, and lay summaries of research publications) Dissemination plan shared with diverse stakeholders to communicate research findings		
Research Design and conduct innovative applied or translational intervention research using rigorous scientific methodology	Complete applied intervention studies within 3 years of award At least three manuscripts published in peer-reviewed journals	Expand knowledge on emerging issues relevant to MCH populations	Advance the evidence base for MCH research Research findings are translated and adopted by clinical practice and MCH programs
Data & Information Systems Recruit, track, and report data on MCH FIRST study participants from diverse backgrounds including ethnicity, race, gender/sex, geographic location, and socioeconomic status Collect primary research data	Enrollment information and demographic data of MCH populations participated in intervention studies are recorded. (E.g., demographics by race, ethnicity, primary language, etc.) Primary data collected for the proposed research	Improved access and availability of project data (E.g., from collection race/ethnicity of participants) Increase the diversity awareness of MCH populations represented in HRSA-supported research	Improve the availability of quality data accessible to researchers Understand the gaps in recruitment of a diverse study population Advance the evidence on the effect of the interventions among diverse population to address health equity
Assessment, Evaluation, & QI Develop a plan for continuous quality improvement and	Continuous monitoring of ongoing processes and progress towards the goals and objectives of the project	Increased understanding of program needs, areas for improvement, and impact	Improve the efficacy of activities, programs, and systems

program evaluation			
Other Systems Capacity Building Prepare and submit grant applications for external funding opportunities outside of HRSA/MCHB's research grant program	Submit at least one grant application for external funding opportunities Increase the number of grant applications submitted for external funding opportunities outside of HRSA/MCHB's research grant program	Increased opportunity to expand on the researcher's MCHB funded grant Increased sustainability of evidence-based research informing MCH practice	Improved and advanced intervention research in MCH, especially among underserved populations

Appendix C: Research Program Application Completeness Checklist

Funding Opportunity Number: HRSA-23-067 **Application Due Date in Grants.gov:** February 7, 2023	
Requirement	**Yes**
Do you meet the eligibility criteria?	
Did you read the *R&R Application Guide* (https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-rr-app-guide.pdf)?	
Do you have a Unique Entity Identifier (UEI) that's been assigned by System for Award Management (SAM)?	
Did your Authorized Organization Representative (AOR) register in SAM (https://www.sam.gov/)?	
Is your Abstract in plain language, no more than 4,000 characters and single spaced?	
Does the Narrative of your application fully address: • Background and Significance? • Specific Goals and Objectives? • Project Design, Methods, and Evaluation? • Plan/Schedule of Implementation and Capability of Applicant? • Feasibility? • Evaluation and Technical Support Capacity? • Protection of Human Subjects? • Targeted/Planned Enrollment?	
Did you confirm that your application addressed all of the NOFO Review Criteria?	
Are your budget and budget justification narrative completed accurately and in the yearly funding limit? **NOTE:** The directions offered in the HRSA *SF-424 R&R Application Guide* differ from those offered by *Grants.gov*. Please follow the instructions included in the *R&R Application Guide* and, *if applicable*, the additional budget instructions in the NOFO	
Did you clearly label all of your Attachments?	
Did you include the Biographical Sketches in the Application?	
Do you know your institution's indirect cost rate?	
Did you use no less than 12-point font and are your page margins at least 1 inch wide in the Narrative and Attachment Sections of the Application? **NOTE:** The Biographical Sketches of Key Personnel can have .5" margins.	

Are your pages, including attachments, within the 80-page limit? **NOTE:** Pages which do not count toward the 80-page limit include: Cover Page, Indirect Cost Rate Agreement, Proof of Non-Profit Status, and Standard OMB approved forms.	

Appendix D: Frequently Asked Questions (FAQs)

1) **Where do I find application materials for the MCH Field-Initiated Innovative Research Studies (FIRST) Program?**
All application materials are available through Grants.gov.

2) **How can I download the complete application package for the NOFO?**
You can download the application by searching for the application number HRSA-23-067 on Grants.gov:
   - *Click on the hyperlink for HRSA-23-067*
   - *Click on the last blue tab entitled "PACKAGE."*
   - *Scroll down and click on the "Preview" hyperlink under the "Actions" column.*
   - *Select the "Download Instructions" button in the right-hand corner. This will download the application.*

3) **What is Grants.gov?**
Grants.gov is the website that the U.S. Government uses to inform citizens of grant opportunities and provide a portal for submitting applications to government agencies. More information can be found on the Grants.gov website.

4) **Is there anything that we need to do immediately to better prepare for our new grant application?**
Yes, make sure that the Authorized Organization Representative at your university or institution has registered the university/organization and himself/herself in Grants.gov. In order to submit your application (new or continuation), your university and your Authorized Organization Representative MUST be registered in Grants.gov. When your Authorized Organization Representative registers in Grants.gov, he/she will receive a Credential User Name and Password which will allow that individual to submit application forms in Grants.gov.

5) **What are the key take-home messages about Grants.gov?**

   1) *Make sure that the Authorized Organization Representative from your university/organization is registered in Grants.gov NOW. This process can take up to 1 month and it is better to complete it and have it out of the way before starting any grant application.*
   2) *Read the instructions on Grants.gov carefully and allow time for corrections. Enter information in fields even if it is "0" or the form will remain incomplete. Required fields are highlighted in yellow.*
   3) *There are resources available on the Grants.gov website to help you navigate this new system. Please visit Grants.gov to access these resources.*
   4) *Key information for budget preparation:*
      - *With the HRSA SF-424 R&R, report faculty and staff time in calendar month equivalents.*

- *Budget details about subcontracts are described in a section of the SF-424 R&R called sub-awards.*
- *Detailed budgets are required for each of the 3 years in the period of performance.*

6) **Can I get a copy of the NOFO from last year's competition?**
*Past funding announcements are not shared in order to avoid confusion among potential applicants. You can find past NOFOs on Grants.gov **but** the criteria for the FIRST Program has changed. Follow instructions provided in this NOFO (HRSA-23-067). All applications for this competition will be reviewed and scored based on the instructions and evaluation criteria outlined in this NOFO (HRSA-23-067).*

7) **What types of institutions can apply?**
Eligibility is limited to public or non-profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs (See 42 CFR § 51a.3(b)). Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

8) **The NOFO notes that the grant supports "applied research." What do you mean by "applied research"?**
In general, we define applied research as bringing basic research models and theories to application in practice—e.g., efficacy trials of new interventions, implementation studies, etc.

9) **We are interested in applying for the MCH FIRST Program. We are wondering if our ideas would be a good fit for the program.**
MCH FIRST is to advance the health and well-being of MCH populations by supporting innovative, applied, and translational intervention research studies on critical issues affecting MCH populations. *Applications are expected to demonstrate alignment with: MCHB strategic research issues; HRSA MCHB Strategic Plan; Healthy People 2030 objectives; or the Title V performance priority areas. You should highlight how your proposal aligns with the aforementioned priorities listed in this paragraph. All funding decisions are based on scientific merit as determined by an external review committee, and on availability of funds.*

10) **How do we align our project research questions with the national performance priority areas and outcome measures? Do we need to, first, establish our state's performance measures and community needs?**
The MCHB Strategic Research Issues, MCHB Strategic Plan, Healthy People 2030, and MCH Title V Program Performance Priority Areas are used as frameworks for

demonstrating the extent to which the proposed project clearly describes the unmet health needs of a maternal and child population.

11) **We are trying to apply for the announced grants, but our organization does not have an Indirect Cost Rate Agreement. What should we do?**
According to the HRSA SF-424 R&R Application Guide, "any non-federal entity that has never received a negotiated indirect cost rate, (except a governmental department or agency unit that receives more than $35 million in direct federal funding) may elect to charge a de minimis rate of 10 percent of modified total direct costs (MTDC) which may be used indefinitely." The HRSA SF-424 R&R Application Guide also contains information on how to negotiate the indirect cost rate.

12) **How do I know what my institution's indirect cost rate is?**
Your institution's indirect cost rate is negotiated by the institution with the U.S. Department of Health and Human Services (HHS). Your sponsored program office will be able to provide further information about the indirect cost rate.

13) **We are a university that would like to partner with the recipient of the Title V Block Grant which is our state's department of health. Is the intended recipient of these awards the block grant administrator?**
The recipient of the award is typically the PI's institution, which should meet eligibility criteria as given in the NOFO.

14) **Is there a requirement regarding minimum or maximum effort for the PI?**
The NOFO does not specify any minimum or maximum time requirement for the PD/PI, but applicant PDs/PIs should allocate and devote sufficient time to justify their commitments to the project. You must demonstrate in the proposal how the time devoted by the PD/PI meets the review criteria and how the proposed PD/PI's allocated time would potentially be sufficient for the success of the project. Additionally, this NOFO states:

- *The current PD/PI of an active HRSA/MCHB/Office of Epidemiology and Research (OER)/Division of Research (DOR) award can serve for **no more than 10 percent time** on a new proposal.*

15) **Is it possible for postdoctoral fellows to apply as PI for the MCH Research Program if they are affiliated with a university?**
The NOFO does not contain language that excludes postdoctoral fellows from serving as PI on the MCH Research grants. Ultimately, the determination of who may or may not serve as PI depends on the rules of the institution.

16) **Can someone who is currently a PI on another agency grant be a PI on an MCH Research grant?**
Yes, a PI on another (non-HRSA/MCHB) agency's grant can be a PI on a FIRST grant; however, if selected for funding, the new recipient will need to verify that percent time across all federally funded grants does not exceed 100 percent.

17) **We have more than one investigator in our institution planning to apply to this NOFO. Is more than one application per institution allowable?**
Yes, multiple applications from an organization with the same Unique Entity Identifier (UEI) are allowable if the applications propose separate and distinct projects. For example, different investigators (or research teams) from the same institution can apply for the same funding opportunity.

18) **Which format should we follow for the biographical sketch?**
Please use the MCHB biographical sketch form found here: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx. Please note that even though the document has an OMB clearance number, it is not a standard form and your response counts against the page limit.

19) **Are there page limits for the submitted application?**
Yes, the total size of all uploaded files included in the page limit may not exceed 80 pages when printed by HRSA. Any pages that go over the limit will be deleted and the modified application will be sent to the review committee.

20) **What counts towards the page limits?**
The page limit applies to the:

- *Project and budget narratives*
- *Attachments*
- *Letters of commitment and support required in application guide and the*
- *NOFO*
- *Biographical sketches*

The page limit does not apply to the following:

- *Standard OMB-approved forms (including the new Project Abstract Summary) that are included in the application package*
- *Indirect Cost Rate Agreement*
- *Proof of Non-Profit Status*

Preliminary studies can be included in the Approach section of the Research Strategy, if applicable, and would be included in the recommended 12-page limit for the Methodology Section as described in the narrative. If an application exceeds required page limitations, the pages over the limit will be deleted.

21) **Are there any page limitations to the narrative?**
There is no page limitation to the narrative. However, MCHB/OER highly recommends the methodology section be no more than 12 pages. Methodology includes: Significance, Innovation, and Approach.

22) **Does the Specific Aims section have a page limitation?**
The Specific Aims section does not have a page limitation. However, this section typically runs three to five pages.

23) **Where do I include the staffing plan?**
The staffing plan information is included in the budget narrative attachment that should be uploaded into the budget form Box K.

24) **Can I submit a proposal on autism spectrum disorder (ASD) for the MCH FIRST Program competition?**
The NOFO states: "Projects addressing autism spectrum disorder (ASD) will not be considered for the MCH FIRST competition." A separate competition for autism research may be held, subject to the availability of funds. Please sign up for our listserv in order to receive an announcement when NOFOs are released.

25) **Where can I find information on previous awards for the MCH Research Program?**
Information on current and past funded MCH Field-Initiated Research projects can be found on our website. Feel free to search our funded projects at https://mchb.hrsa.gov/research/projects.asp

26) **Who should I talk to if I have further questions?**
Please contact:
- *For programmatic questions, the Project Officer listed in the NOFO via email.*
- *For budget questions, the Grants Management Specialist listed in the NOFO via email.*

27) ***Can I ask the program officer listed in the NOFO to read my proposal for their comments and suggestions?***
No. Though questions are welcome throughout the open competition phase, please be aware that the point of contact/project officer has no authority to determine the validity or success of your proposal. The project officer cannot provide feedback or guidance on your draft proposal. Your proposal will be reviewed by an independent review panel comprised of experts in the field.

Appendix E: Key Terms for Project Abstracts

a) **Content Terms (maximum of 10)**

Health Care Systems & Delivery
- Access to Health Care
- Capacity & Personnel
- Clinical Practice
- Health Care Quality
- Health Care Utilization
- Health Disparities
- Health Information Technology
- Home Visiting
- Innovative Programs and Promising New Practices
- Perinatal Regionalization
- Telehealth

Primary Care & Medical Home
- Coordination of Services
- Community-Based Approaches
- Integration of Care
- Medical Home
- Oral Health
- Preconception/Inter-conception Health & Well-Woman Care
- Primary Care
- Well-Child Pediatric Care

Insurance & Health Care Costs
- Cost Effectiveness
- Health Care Costs
- Insurance Coverage

Prenatal/Perinatal Health & Pregnancy Outcomes
- Cesarean
- Labor & Delivery
- Low Birthweight
- Perinatal
- Postpartum
- Pregnancy
- Prenatal Care
- Preterm

Nutrition & Obesity
- Breastfeeding
- Nutrition & Diet
- Obesity & Weight
- Physical Activity

Parenting & Child Development
- Cognitive & Linguistic Development
- Fathers
- Parent-Child Relationship
- Parenting
- Physical Growth
- Social & Emotional Development

School Settings, Outcomes & Services
- Child Care
- Early Childhood Education
- School Health Programs
- School Outcomes & Services

Screening & Health Promotion
- Early Intervention
- Illness Prevention & Health Promotion
- Immunization
- Health Education & Family Support
- Screening
- Sleep

Illness, Injury & Death
- Emergency Care
- Infant Illness & Hospitalization
- Maternal Illness & Complications
- Mortality
- Safety & Injury Prevention
- Sudden Infant Death Syndrome/Sudden Unexpected Infant Death
- Trauma & Injury

Mental/Behavioral Health & Well-being
- Bullying & Peer Relationships
- Depression
- Mental Health & Well-being
- Risk Behaviors

- Smoking
- Stress
- Substance Use
- Violence & Abuse

Special Health Care Needs & Disabilities
- Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder
- Asthma
- Chronic Illness
- Developmental Disabilities
- Special Health Care Needs
- Youth with Special Health Care Needs Transition to Adulthood

Lifespan & Social Determinants
- Neighborhood
- Lifespan
- Social Determinants of Health

b) Underserved Communities (as many as apply):
- African American/Black
- Asian/Pacific Islander
- Hispanic/Latino
- Immigrant
- Indigenous/Native American/Alaskan Native
- Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ+) Persons
- Members of Religious Minorities
- Other Persons of Color
- Persons Otherwise Adversely Affected by Persistent Poverty or Inequality
- Persons who Live in Rural Areas
- Persons with Disabilities or Special Health Care Needs

c) Targeted Age Range(s) (as many as apply):
- Women's Health & Well-being (Preconception/Interconception/Prenatal)
- Prenatal (until 28th week of gestation)
- Perinatal (28th week of gestation to 4 weeks after birth)
- Infancy (1–12 months)
- Toddlerhood (13–35 months)
- Early Childhood (3–5 years)
- Middle Childhood (6–11 years)
- Adolescence (12–18 years)
- Young Adulthood (19–25 years)

Appendix F: Guidance on Biographical Sketches

As described under Budget Justification Narrative, biographical sketches should use the appropriate MCHB form, may not exceed five pages per person, and count against the total page limitation for the application.

The following information should be included on all biographical sketches:

- **Race/Ethnicity Data:** Provide race and ethnicity data for the PI (required) and all key personnel (optional) according to the chart on the MCHB Biographical sketch form. The race/ethnicity chart can be modified to include only the relevant rows and columns. This information helps MCHB ensure that federal grant and cooperative agreement awards are reaching diverse populations.
- **Personal Statement**: Briefly describe why you are well suited for your role(s) in this network. The relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise. You may also list up to four peer-reviewed publications that highlight your experience and qualifications for this project.
- **Positions and Honors:** List in chronological order previous positions, ending with your current position. List relevant honors. Include current membership on any federal government public advisory committee.
- **Contribution to Science:** Briefly describe one to three of your most important contributions to science. For each contribution, detail the background that frames the scientific problem, the central finding(s), and the impact of the findings to the field or the how the findings apply to health or technology, and your specific role in the work. For each of contribution, list up to **four** peer-reviewed publications or other relevant products. The description of each contribution should be no longer than half a page, including figures and citations.
- **Research Support:** List both selected ongoing and completed research projects for the past 3 years (federal or non-federal). Begin with the projects that are most relevant to the research proposed in the application. Briefly name the overall goals of the projects and your responsibilities.
- **Do not confuse "Research Support" with "Other Support."**
    - *"Research Support"* highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers to judge your qualifications for your role in the proposed project.
    - *"Other Support"* information is required for all applications that are selected to receive an award to show other sources of federal grant support for the applicant. HRSA staff will request complete and up-to-date "other support" information from you

after peer review. This information will be used to check that your research has not already been federally funded.

Appendix G: Relevant Websites

While HRSA does not endorse any organization/website, the following list, although not exhaustive, may be helpful references:

Bright Futures
http://brightfutures.aap.org/

Developing Healthy People 2030
https://www.healthypeople.gov/2020/About-Healthy-People/Development-HealthyPeople-2030

HRSA/MCHB Division of Workforce Development
http://www.mchb.hrsa.gov/training

Human Research Protections / Human Subjects Assurances
http://www.hhs.gov/ohrp
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Inclusion Across the Lifespan - Policy Implementation
http://grants.nih.gov/grants/funding/children/children.htm

Logic Models
https://www.cdc.gov/eval/tools/logic_models/index.html

Making Websites Accessible: Section 508 of the Rehabilitation Act
http://www.section508.gov/

National Academy of Medicine
https://nam.edu/

National Center for Cultural Competence
http://nccc.georgetown.edu/

National Resource Center for Patient/Family-Centered Medical Home (formerly the National Center for Medical Home Implementation)
https://medicalhomeinfo.aap.org/Pages/default.aspx