U.S. Department of Health and Human Services

Health Resources & Services Administration

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2023

Maternal and Child Health Bureau

Division of Child Adolescent and Family Health

Pediatric Emergency Care Applied Research Network (PECARN)

Funding Opportunity Number: HRSA-23-073

Funding Opportunity Type(s): Competing Continuation, New

Assistance Listings Number: 93.127

Application Due Date: April 11, 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: January 11, 2023

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See Section VII for a complete list of agency contacts.

Authority: 42 U.S.C. § 300w-9 (Title XIX, § 1910 of the Public Health Service 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 Pediatric Emergency Care Applied Research Network (PECARN) program. The purpose of this demonstration program is to improve pediatric emergency care by supporting the development and dissemination of evidence-based guidelines for hospital EDs and prehospital emergency medical services (EMS). This program will achieve this goal by supporting a multi-center research network that will demonstrate how conducting and disseminating rigorous clinical research advances equitable pediatric emergency care.

Funding Opportunity Title:	Pediatric Emergency Care Applied Research Network (PECARN)
Funding Opportunity Number:	HRSA-23-073
Due Date for Applications:	April 11, 2023
Anticipated FY 2023 Total Available Funding:	$4,950,000
Estimated Number and Type of Award(s):	Up to 7 cooperative agreements
Estimated Annual Award Amount:	Up to $700,000 per award subject to the availability of appropriated funds: • Category 1: 6 at $700,000 per year • Category 2: 1 at $700,000 per year Additionally, one site selected by the network as the PECARN Chair will receive an additional $50,000.
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2023 through August 31, 2027

	(4 years)
Eligible Applicants:	States and accredited schools of medicine in States.[1] See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information. Tribes and tribal organizations are not eligible.

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 Application Guide*. Visit HRSA's How to Prepare Your Application page for more information.

Technical Assistance

HRSA has scheduled the following webinar:

Day and Date: January 26, 2023
3 p.m. – 4 p.m. ET
Weblink: https://hrsa-gov.zoomgov.com/j/1615967775?pwd=WTlkSnRHWXArNGRjNEljbGVhY2l0UT09

Meeting ID: 161 596 7775
Passcode: HRSA2023

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

Call-In Number: 1-833 568 8864 US Toll-free
Meeting ID: 161 596 7775
Passcode: 49809497

HRSA will record the webinar and make it available at: https://mchb.hrsa.gov/fundingopportunities/default.asp.

[1] For purposes of this NOFO, under 42 U.S.C. 201(f), the term "States" includes, in addition to the several States, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. The term "Trust Territory of the Pacific Islands" encompasses the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and the Commonwealth of the Northern Mariana Islands.

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Pediatric Emergency Care Applied Research Network (PECARN) program, hereafter referred to as PECARN or "the network." The purpose of this demonstration program is to improve pediatric emergency care by supporting the development and dissemination of evidence-based guidelines for hospital emergency department (ED) and prehospital emergency medical services (EMS). This program will achieve this goal by supporting a multi-center research network that will demonstrate how conducting and disseminating rigorous clinical research advances equitable pediatric emergency care.

This Notice of Funding Opportunity (NOFO) solicits applications for funding for the seven research nodes described below that will comprise the network. The network will work in conjunction with the EMSC Data Center (EDC), which is funded through a separate HRSA cooperative agreement (HRSA-022-087).

The PECARN program has two categories of research nodes or "nodes", each led by a Research Node Center (RNC) which will also be the recipient of funds. You may apply for one award in one of these categories:

Category 1 ("Research Nodes"): Each recipient/RNC will lead a Research Node comprised of three (3) Hospital Emergency Department Affiliates (HEDAs) and one co-located EMS affiliate.[2] The RNC is co-located at one of the three HEDAs. Research Nodes will coordinate multi-center prehospital EMS and hospital ED clinical care research. Six (6) Research Nodes will be funded at $700,000 each.

Category 2 ("EMS Research Node"): This recipient/RNC will lead an EMS Research Node comprised of three (3) EMS affiliates. In addition, this RNC will help to coordinate multi-center, prehospital EMS clinical care research that may take place with the nine EMS affiliates[3] in PECARN. One (1) EMS Research Node will be funded at $700,000.

In addition, this notice includes the opportunity to receive additional funding to support activities of the PECARN chairperson. The PECARN chairperson is selected by the network for the purposes of leading the network and liaising with HRSA. The Research Node recipient that supports the selected Chairperson will be awarded an additional $50,000 annually to support the specific activities listed in the Appendix: Additional PECARN Background.

For more details, see Program Requirements and Expectations.

[2] The EMS affiliate is located within the catchment area of one of the participating Emergency Departments.
[3] The nine PECARN EMS affiliates are the six EMS affiliates who are part of the Category 1 Research Nodes and the three EMS affiliates in the one EMSC Research Node.

2. Background

Authority

The PECARN Program is authorized by the 42 U.S.C. § 300w-9 (Title XIX, § 1910 of the Public Health Service Act). This legislation was first passed by Congress in 1984 to fund demonstration projects to expand and improve emergency medical services for children. The PECARN program works to ensure that all children and adolescents receive appropriate emergency medical care, no matter where they live, attend school, or travel throughout the nation. PECARN is administered by the EMSC Program within the Maternal and Child Health Bureau (MCHB) Division of Child, Adolescent, and Family Health. MCHB is part of the Health Resources and Services Administration, an operating division of the U.S. Department of Health and Human Services.

When children and adolescents experience an injury or critical illness and require emergency care, the delivery of age appropriate, effective emergency care is essential for their survival and subsequent health outcomes.[4] Most pediatric ED visits occur in community hospitals where fewer than 15 pediatric patients are seen a day, and only a small proportion of prehospital EMS patient encounters are for pediatric patients.[5] Learning how these settings can provide optimal pediatric emergency care is central to HRSA's EMSC program. To achieve this goal, HRSA supports a coordinated research network of pediatric hospital EDs and pre-hospital EMS agencies that are able to carry out rigorous research that leads to the development of pediatric emergency guidelines that can be effectively disseminated to and implemented in community EDs and EMS settings.

PECARN was launched in 2001 with four initial nodes and has evolved each grant cycle to address pediatric emergency care issues where there is clinical uncertainty about the best way to provide care for children and adolescents. In 2019, HRSA expanded PECARN to include pre-hospital EMS, where pediatric evidence-based training and guidelines were lacking.[6] This cycle, PECARN will focus on research and dissemination of pediatric emergency practices that advance health equity,[7] as that term is further

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[4] Remick K, Gausche-Hill M, Joseph MM, Brown K, Snow SK, Wright JL; AMERICAN ACADEMY OF PEDIATRICS, Committee on Pediatric Emergency Medicine, Section on Surgery; AMERICAN COLLEGE OF EMERGENCY PHYSICIANS, Pediatric Emergency Medicine Committee; EMERGENCY NURSES ASSOCIATION, Pediatric Committee; Pediatric Readiness in the Emergency Department; POLICY STATEMENT; Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children. Pediatric Readiness in the Emergency Department. J Emerg Nurs. 2019 Jan;45(1):e3-e18. doi: 10.1016/j.jen.2018.10.003. Epub 2018 Nov 1. Erratum in: J Emerg Nurs. 2019 Jan;45(1):3. PMID: 30392719.

[5] Data from the National Emergency Medical Services Information System (NEMSIS).

[6] Institute of Medicine. 2007. *Emergency Medical Services: At the Crossroads*. Washington, DC: The National Academies Press. https://doi.org/10.17226/11629.

[7] 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 .

defined below.

Since being established, PECARN has enrolled more than 150,000 children in clinical studies and developed significant improvements in emergency care for febrile infants, and children with head, neck, and abdominal trauma, sickle cell disease, fracture-related pain, and suicidal ideation. These studies have been conducted in collaboration with more than 500 faculty researchers who have mentored over 150 new researchers. PECARN has exceeded a 70% research funding success rate and has published more than 220 peer-reviewed articles. Compared to other global pediatric emergency research networks, PECARN has the highest number of publications, citations, and *h-index*, a metric that measures both the productivity and impact.[8]

PECARN Structure and Function

PECARN is comprised of seven nodes (six Research Nodes and one EMS Research Node) and the EDC. As an established research network, PECARN has developed organizational structures, procedures and policies that address network and research processes. New award recipients will be expected to become aware of, support, and, as needed, work with peers in the network to evolve these preexisting network rules.[9]

Research Node Types and the Research Node Center

The network is comprised of six (6) Research Nodes and one (1) EMS Research Node. Both types of nodes are led by the Principal Investigator (PI) of the Research Node Center (RNC), who has primary responsibility for leading and coordinating their node. For the Category 1 Research Nodes, the RNC needs to be co-located with one of the HEDAs, and the EMS affiliate must be within the catchment or service area of one of the HEDAs. For the Category 2 EMS Research Node, the RNC leads and coordinates three EMS affiliates each located in a different state.

The EDC

Research coordination for PECARN is supported by the EDC, which is funded under a separate award. The EDC provides comprehensive, independent data and research coordination to support the development, successful funding, implementation, and publication of multi-center randomized clinical trials and other types of clinical research.[10]

Network Leadership

PECARN has two main committees that facilitate administrative leadership and research coordination: the Executive Committee and the Steering Committee.

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[8] Barrett MJ, Dalziel S, Lyttle M, O'Sullivan R. A Bibliometric Analysis of Global Pediatric Emergency Medicine Research Networks. Pediatric Emergency Care. 2022 Apr 1;38(4):e1179-84.

[9] Network rules can be found at the following website: https://pecarn.org/

[10] More information about the EDC can be found here: https://www.hrsa.gov/grants/find-funding/HRSA-22-087.

The Executive Committee collaborates on the review of all network and research related administrative decisions to ensure decisions fall within the scope of this cooperative agreement and the PECARN by-laws. Members include the nodal PIs and the PI of the EDC. The HRSA Project Officer serves as a liaison to this committee, and the Executive Committee Chairperson serves as a liaison to HRSA.

The Steering Committee is responsible for assessing, coordinating, and guiding PECARN research. Membership includes the nodal PIs, the PI of the EDC, and representatives from the RNC, HEDAs and EMS affiliates. The Steering Committee evaluates research concepts and proposals. For a study to be considered a PECARN study, a majority of Steering Committee members must vote in agreement. The voting membership of the Steering Committee consists of the Research Node PIs, the PI of the EDC, and representatives from HEDAs and EMS affiliates. The HRSA Project Officer reviews steering committee's decisions and may seek revisions to proposed research.

Members of the RNCs, HEDAs, and EMS affiliates are expected to participate in network activities, leadership committees, workgroups and abide by PECARN policies, procedures, and study protocols.

PECARN Chairperson
PECARN PIs identify a new Executive Committee Chairperson every 3 years to lead the Network and serve as a liaison to HRSA. For more information, please refer to the Purpose and Appendix: Additional PECARN Background.

Additional Information
More information about PECARN structure, leadership, policies, and procedures is available at http://www.pecarn.org. The Appendix: Additional PECARN Background includes additional information about PECARN functions and reporting requirements.

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

Goal 1: *Assure access to high quality and equitable health services to optimize health and well-being for all MCH populations*
Goal 2: *Achieve health equity for MCH populations*
Goal 3: *Strengthen public health capacity and workforce for MCH*
Goal 4: *Maximize impact through leadership, partnership, and stewardship*

This program addresses three of MCHB's goals. PECARN aims to assure access to high quality emergency services for all children (Goal 1); achieve health equity by addressing the emergency health care needs of children living in under-represented, vulnerable, and/or historically marginalized communities (Goal 2); and support diversity in the pediatric emergency research workforce (Goal 3).

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

HRSA MCHB is committed to advancing 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.[11]

II. Award Information

1. Type of Application and Award

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

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

In addition to the usual monitoring and technical assistance (TA) provided directly to award recipients, HRSA program involvement will include:

- Assuring experienced HRSA personnel participate in the planning and development of all phases of this cooperative agreement;
- Participating in the design, direction, evaluation activities, and meetings including, but not limited to, Chair, Executive Committee, and Steering Committee meetings;
- Providing guidance to the recipient to establish, review, and update priorities for activities conducted under the auspices of the cooperative agreement, especially as related to emerging issues such as public health emergencies;
- Reviewing meeting agendas, network policies and procedures, research concepts, and protocols before sharing with the Steering Committee;

[11] 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.

- Facilitating and monitoring recipients' compliance with NOFO requirements and participating in periodic meetings and/or communications with recipients to assess progress;
- Supporting the dissemination of publications completed under the cooperative agreement, and cooperation on the referral of inquiries and requests for publications and other information; and
- Facilitating effective collaborative relationships with federal and state agencies, HRSA-funded grants, and other entities relevant to the project's mission.

In addition to adhering to all applicable federal regulations and public policy requirements, the cooperative agreement recipient's responsibilities will include:

- Completing all activities proposed in the application Program Requirements and Expectations, including assuring that all administrative forms and performance measures will be reported in accordance with the requirements of the cooperative agreement;
- Collaborating on rapid response requests related to emerging issues to be determined by the federal project officer on a case-by-case basis;
- Responding in a timely manner to the federal project officer's review, comments, questions, and requests;
- Assuring the federal project officer has the opportunity and enough time to review and comment on all developing research concepts and protocols;
- Assuring the federal project officer has the opportunity and enough time to review and comment on all products prior to dissemination;
- Providing to HRSA an electronic copy of, or electronic access to, each product including presentations and other dissemination materials developed under the auspices of this cooperative agreement;
- Assuring that HRSA is identified as a funding sponsor on all written products and at meetings and conferences relevant to cooperative agreement activities;
- Assuring the federal project officer is involved in the translation and dissemination of research findings for general EMS audiences;
- Partnering with funded EMSC programs, for dissemination purposes, to leverage resources and avoid duplicative efforts;
- Ensuring that all products developed or produced, either partially or in full, under the auspices of this cooperative agreement are fully accessible and available for free to members of the public;

- Consulting with the federal project officer: on new activities; before scheduling any meetings, including project national coalition meetings under the auspices of this cooperative agreement and at which HRSA staff attendance would be appropriate; on participation in meetings and/or conferences related to this cooperative agreement during the period of the award;

- Participating in meetings and/or conference during the period of the award, including the national EMSC all grantee meeting (Years 1 and 3);

- Working with the EDC to create a de-identified public use dataset from study data that will be made publicly available at least 3 years after completion of all follow-up procedures for the final subject that was enrolled in the study; and

- Collaborate with the HRSA Project Officer and the EDC in the collection and reporting of ongoing Research Network impact data such as number of research studies, study enrollees, publications, investigators, and mentees.

2. Summary of Funding

HRSA estimates approximately $4,950,000 to be available annually to fund a total of seven recipients. Each recipient will lead a node within the network. The network will include six Category 1 Research Nodes and one Category 2 Research Node. You may apply for a ceiling amount of up to $700,000 annually (reflecting direct and indirect, costs) per year or $750,000 if you are selected as the PECARN Chairperson.

The period of performance is September 1, 2023 through August 31, 2027 (4 years). Funding beyond the first year is subject to the availability of appropriated funds for the EMSC Program in subsequent fiscal years, satisfactory progress, and a decision that continued funding is in the best interest of the Federal Government.

Note: The Recipient may request supplemental funding at any point in their period of performance to address unique TA needs that are connected to, but not duplicative of, the funded scope of work. HRSA may provide support for such supplemental projects if funding is available and allocable, the request is reasonable and allowable, sufficient time remains in the budget period to approve the request, and the activities are aligned with HRSA priorities and nonduplicative of work performed by HRSA or other funding recipients.

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

Limitations on Indirect Cost Rates

Indirect costs under training awards to organizations other than state or local governments or federally recognized Indian tribes, will be budgeted and reimbursed at 8 percent of modified total direct costs rather than on the basis of a negotiated rate agreement, and are not subject to upward or downward adjustment. Direct cost

amounts for equipment, tuition and fees, as otherwise allowable, and subawards and subcontracts in excess of $25,000 are excluded from the direct cost base for purposes of this calculation.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include States and accredited schools of medicine in States. The terms “accredited” and “school of medicine” for the purpose of this funding opportunity (and under 42 U.S.C. 300w-9(c)) have the same meaning as set forth in section 799B(1)(A) and (E) of the Public Health Service Act (42 U.S.C. 295p(1)(A) and (E)).

Tribes and tribal organizations are not eligible.

Pursuant to section 1910(a) of the PHS Act, no more than three awards under this authority may be made in a state (i.e., to a state or a school of medicine in such state). HRSA will not provide funds to more than three award recipients within each state in a given fiscal year. HRSA will make competitive awards under this announcement in accordance with the rank order established by the objective review committee, but if awarding funds to the next ranking applicant would result in a fourth award to any state, HRSA will skip that applicant and make the award to the next eligible applicant, ensuring compliance with this statutory restriction.

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 clearly state which Category of funding you are applying for in the application. You may not apply for funding as a recipient under both Category 1 and Category 2. If you apply for funding under both projects, your applications will be considered non-responsive and will not be considered for funding under this NOFO.
- Fails to satisfy the deadline requirements referenced in Section IV.4

Multiple Applications

NOTE: Multiple applications from an organization are not allowed. HRSA will only accept and review your **last** validated electronic submission before the Grants.gov application due date.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA ***requires*** you to apply electronically. HRSA encourages you to apply through Grants.gov using the SF-424 workspace application package associated with this 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.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for HRSA-23-073 in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. *You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.*

2. Content and Form of Application Submission

Application Format Requirements

Section 4 of HRSA's *SF-424 Application Guide* provides general instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, and certifications. You must submit the information outlined in HRSA *SF-424 Application Guide* in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in this NOFO and HRSA's *SF-424 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 Application Guide* for the Application Completeness Checklist to assist you in 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 **70 pages** when printed by HRSA.

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.vi Attachments.

If you use an OMB-approved form that is not included in the workspace application package for HRSA-23-073 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 redact any pages considered over the page limit. The redacted 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, within the maximum specified page limit, and validated by Grants.gov under HRSA-23-073 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 attach an explanation in the *Other Relevant Documents*.

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

Temporary Reassignment of State and Local Personnel during a Public Health Emergency

Section 319(e) of the Public Health Service (PHS) Act provides the Secretary of the Department of Health and Human Services (HHS) with discretion upon request by a state or tribal organization to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with § 319(e), which sunsets / terminates on September 30, 2023. Please reference detailed information available on

the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) website.

Program Requirements and Expectations

PECARN is a multi-center research network that will conduct rigorous clinical research and disseminate these findings to advance equitable pediatric emergency care.

You must address the following program requirements and expectations:

Lead a Research Node or EMS Research Node

- Establish written agreements with their HEDAs and EMS affiliates that describe in detail the structure, procedures, processes, and policies of how the affiliates will function as a Research Node. Include plans to ensure clear roles, effective communication, and quality assurance across the node;
- Develop a comprehensive statement of work defining the goals and objectives of the Research Node, including the proposed projects to be undertaken through this cooperative agreement;
- Detail the role, experience, and capacity of the Nodal PI, the PI at each HEDA, and the scientific advisor at each EMS affiliate;
- Explain the process for generating and reviewing research ideas generated by members of the Research Node;
- Each HEDA PI and each EMS affiliate scientific advisor, with support from the RNC, will be responsible for the following:
  - Adhering to all policies established by the RNC and the Steering Committee, attending relevant PECARN meetings, and participating in subcommittees and working groups;
  - Initiating and participating in the development of research concepts and protocols of clinical trials and observational studies to be conducted by the network;
  - Participating in research studies approved by the Steering Committee, and working with HRSA, EDC, and other recipients to fully comply with all training and protocol requirements of each study;
  - Providing routine clinical care to patients participating in protocols, and experimental/standard care in accordance with approved research protocols;
  - Having the resources to successfully manage research staffing needs, provide training to implement a study protocol, and monitor protocol-specific requirements;
  - Enrolling adequate numbers of representatively diverse research participants required for studies, maintaining patient records and essential documents

required for each protocol, and permitting site monitors to examine those records;

- Collecting clinical and laboratory data for research purposes, including biological specimens when indicated, and possessing adequate information technology and data systems to support scientific studies;

- Submitting study data in a timely manner to the EDC in accordance with Steering Committee, HRSA, and EDC policies, and agreeing to not report data prior to collaborative reporting by PECARN;

- Agreeing to multi-faceted site monitoring by representatives of its RNC, EDC, and HRSA for quality control, compliance with protocol specifications, accuracy of data recording, and completeness of reporting of adverse reactions to treatments;

- Adhering to good clinical practice and other regulatory requirements concerning human subjects protections (including all federal, institutional, and PECARN defined policies and procedures);

- Establishing data linkages between prehospital and HEDA hospital systems;

- Budgeting for support of the projects that identifies the personnel, equipment, materials, and other costs required to successfully conduct high-quality work according to the requirements of specific PECARN protocols; and

- Reporting financial and program requirements, including access to data and materials, to facilitate PECARN operations and project oversight and monitoring.

Support and Strengthen the Network:

- The Nodal PI will serve on the Executive Committee.
- The Nodal PI will participate in monthly Executive Committee meetings, or more frequently, as needed.
- Nodal PIs may transition leadership by temporarily assigning the future Nodal PI the role of Nodal Co-PI. Nodal Co-PIs will only be included in the Executive Committee for a brief transitional period or under special circumstances.
- The Nodal PI, HEDA PI, EMS affiliate scientific advisors, and nodal representatives will fully participate on the Steering Committee and understand the responsibilities of the Steering Committee including assessing, voting, training, and carrying out PECARN research. The Steering Committee will meet quarterly, or more frequently, as needed.

- The Nodal PI will ensure that their node will demonstrate interest and commitment to participate in research protocol and special topic workgroups including, for example, those related to EMS; Diversity, Equity and Inclusion; Child Abuse; Injury Prevention; and Dissemination.

- As part of the Executive Committee, the Nodal PI will facilitate collaboration with the Steering Committee to:

  - Update existing PECARN by-laws and policies to incorporate priorities; and

  - Develop and implement a consensus driven guide for aligning proposed research with PECARN priorities; describing the public health impact of proposed PECARN research; and disseminating research findings to advance health equity and maximally improve pediatric emergency care.

Carry Out Clinical Research

- The Research Node will have the capacity, experience, and expertise to partner within the network, and use the network infrastructure to collaboratively carry out EMSC research including:

  - Developing high-priority, high-impact research studies, and explaining the process for generating and reviewing research ideas generated by members of the Research Node;

  - Developing diverse early-stage researchers in the area of pediatric emergency medicine by supporting these investigators to submit successful research concepts that are supported by PECARN;

  - Obtaining extramural funding for research studies;

  - Conducting multi-center clinical studies, using rigorous study designs and methodologies, ensuring fidelity of study implementation; and efficiently publishing and broadly translating and disseminating findings and guidelines;

  - Fostering collaboration among local, state and regional ED and EMS providers to ensure implementation of research findings;

  - Establishing and maintaining a data infrastructure to ensure data are available for research and knowledge translation activities,[12] planning how prehospital to hospital data linkages will be established, ensuring

[12] Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. Implement Sci. 2012 May 31;7:50. doi: 10.1186/1748-5908-7-50. PMID: 22651257; PMCID: PMC3462671.

availability of adequate IT support, data use agreements, data storage, and allocated expertise and agreements;

- Participating in the PECARN ED data registry, to the extent possible;

- Choosing data linkage options A and/or B. Research Nodes can choose either, and EMSC Research Nodes must choose option B.
  - Option A: Identify at least one Hospital Emergency Department Affiliate to participate in the PECARN ED Data Registry managed by the EDC.
  - Option B: Link patient encounter data between at least one participating prehospital EMS agency and their associated hospital systems which will allow studies of both prehospital and hospital clinical care and associated health outcomes;

Focus on Health Equity

- Address gaps in knowledge and potential solutions to advance health equity and eliminate disparities in pediatric emergency care;

- Include children from under-represented, vulnerable, and/or historically marginalized groups in research studies; and

- Collaborate with EMSC training programs to support diverse pediatric emergency research investigators and developing partnerships with national programs focused on increasing diversity in the academic medical research workforce.

Effectively Disseminate Research Findings to Emergency Medical Care Providers

- Develop a dissemination plan concurrently with study proposals;

- Assign dedicated personnel that will participate in the Dissemination Committee and support the creation of resources that can be shared with and used by other EMS educators to increase the uptake of PECARN research and guidelines;

- Develop and support relationships with EMSC State Partnership Managers in each state with a PECARN HEDA or EMS affiliate to support dissemination;

- Support relationships with EMSC Targeted Issues grantees, the Pediatric Pandemic Network, MCHB Title V programs, and Poison Control Centers to share PECARN results and guidelines; and

- Collaborate with the EMSC Innovation and Improvement Center (EIIC) to disseminate resources and expand uptake of PECARN findings and guidelines.

Demonstrate Progress Towards Improving Pediatric Emergency Care

You will propose quantifiable targets that can be met by the end of the period of performance (August 31, 2027) for each of the indicators listed below. You may also propose additional outcomes and/or indicators.

Program Outcomes Table:

Program Outcomes	Quantifiable Indicators of Success
Improved infrastructure for conducting high quality research on pediatric emergency care	# of proposed concepts, approved protocols, and studies implemented within each Hospital Emergency Department Affiliate (HEDA) and/or the prehospital EMS agency sites of the node
Increased number of studies designed to address health equity	# of PECARN studies that address pediatric emergency issues that differentially impact children in historically marginalized communities (e.g., Sickle Cell Disease, asthma, appropriate pain management)
Strengthened extramural funding for pediatric emergency care research	# and percent of PECARN-approved study concepts receiving external grant funding
Improved power and scope of research findings through data linkages	# of studies initiated using linked data between prehospital EMS and hospital settings # and % of affiliates within each Research Node submitting data to the PECARN data registry # of studies initiated using data from the PECARN data registry
Strengthened pipeline of new researchers in pediatric emergency care	# of submitted research concepts submitted by new researchers
Expanded evidence on effective pediatric emergency care	# of publications cited as evidence in published pediatric clinical care guidelines[13,14,15]
Increased dissemination and translation of PECARN research findings	# and type of dissemination activities (e.g., scientific presentations, educational webinars, trainings, CME opportunities, resources, tools, guidelines, newsletters) that translate research findings into practice for EMS and ED providers

[13] Examples of such guidelines include “UpToDate” https://www.uptodate.com/contents/table-of-contents/emergency-medicine-adult-and-pediatric

[14] Examples of such organizations include the American Academy of Pediatrics (AAP), Emergency Nurses Association (ENA), American College of Emergency Physicians (ACEP), National Association of EMS Physicians (NAEMSP), and National Association of State EMS Officials (NASEMSO).

[15] Examples of such guidelines include “UpToDate” https://www.uptodate.com/contents/table-of-contents/emergency-medicine-adult-and-pediatric

Program Outcomes	Quantifiable Indicators of Success
	# and professional disciplines of participants reached by dissemination activities

Program-Specific Instructions

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

i. *Project Abstract*

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

NARRATIVE GUIDANCE

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

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need and (2) Response
Methodology	(2) Response and (3) Evaluative Measures
Work Plan	(2) Response (3) Evaluative Measures and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures (4) Impact and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities and (6) Support Requested
Budget Narrative	(6) Support Requested

ii. *Project Narrative*

This section provides a comprehensive description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments,

and organized in alignment with the sections and format below so that reviewers can understand the proposed project.

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

- *INTRODUCTION -- Corresponds to Section V's Review Criterion # 1 Need*
    - Briefly describe the purpose of the proposed project that is consistent with Section I: Purpose.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criteria 1 Need and Criteria 2 Response*
    - Identify needs, challenges, and gaps in pediatric emergency care and pediatric emergency care research in both prehospital EMS and ED settings that can be addressed through research.
    - Describe the need for and benefits of using a pediatric research network to conduct multi-site randomized controlled trials with the aim of improving emergency care for children.

- *METHODOLOGY -- Corresponds to Section V's Review Criteria 2 Response and 3 Evaluative Measures*
    - Propose detailed descriptions of the methods for accomplishing each of the activities stated in the Program Requirements and Expectations section of this NOFO.
    - Provide targets for each of the indicators listed in the Program Outcomes Table in the Program Requirements and Expectations section of this announcement.
    - Include a plan to disseminate reports, products, and/or project outputs so key target audiences receive project information. Include a list of responsible staff, specific milestones, and expected outcomes.
    - Describe how the researchers will function in partnership with the network in terms of study origination, design, execution, and administration.
    - Demonstrate a thorough knowledge and understanding of multi-site pediatric emergency care research across the EMS continuum and in ED and/or prehospital EMS agency settings.
    - Include two Research Concepts as Attachment #2 which will demonstrate your ability to generate meaningful research ideas for the network. For Category 1 applicants, at least one of the concepts should describe the relevance of the research findings for pediatric emergency

care in community emergency departments. For both Category 1 and 2, at least one of the concepts should focus on addressing gaps in prehospital pediatric emergency care. Each research concept should be no more than two pages in length and should include:

- The clinical and public health significance;
- How the concept aligns with the newly developed PECARN priorities;
- Specific research objectives;
- Research methods, including study design, statistical sampling frame, and evaluation plan;
- Funding strategy, including approach to successfully competing for extramural funding;
- How the research findings may lead to improvements in pediatric emergency care; and
- Dissemination plan to improve ED or EMS care broadly.

- *WORK PLAN -- Corresponds to Section V's Review Criteria 2 Response and Criteria, Criteria 3 Evaluative Measures, and Criteria 4 Impact*
  - Include the following work plan (Attachment #1): Description of activities or steps that you will use to achieve each of the objectives and project goals proposed during the entire period of performance in the Methodology section.
  - Include a timeline that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities, including developing the application.
- *RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion 2 Response*
  - Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges. You are expected to demonstrate sufficient administrative and programmatic capacity within your research node to anticipate and overcome challenges for successfully implementing project activities.
  - Propose mechanisms for collaborative resolution among the Research Node participants.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria 3 Evaluative Measures, 4 Impact, and 5 Resource/Capabilities*
    - Describe a plan for monitoring and evaluating nodal processes and the progress towards achieving the project's goals and objectives. This plan should include how the RNC, HEDAs, and EMS affiliate will contribute new research ideas to PECARN and have timely publication of research findings.
    - Discuss how the RNC will monitor HEDA and EMS affiliate site performance and include plans for assisting sites experiencing challenges or that do not meet performance targets.
    - Include biosketches as Attachment #4 for all key personnel; key personnel include the Nodal PI, HEDA PIs, EMS Affiliate Scientific Advisor, and the Nodal Administrator, who will coordinate the RNC.
    - For the EMS affiliate, describe support of the EMS affiliate's leadership and involvement of the EMS affiliate's scientific advisor in this collaboration. A Letter of Support should be included.
    - Describe the systems and processes that will support your organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. Include potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.
    - Highlight experience establishing electronic data collection system and data linkages for prehospital and hospital systems and with providing data to an ED Data Registry.
    - Include notation of access to an Institutional Review Board (IRB) or a Central IRB and experience with exemptions from informed consent. Describe procedures for obtaining IRB approval for research protocols.
    - Include specific information on the frequency of IRB meetings; typical review times for study protocols at each HEDA site; and information for the amount of time needed to obtain IRB approval for studies completed by the Research Node.
- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criteria 5 Resources/Capabilities and 6 Support Requested*
    - Describe the ability of the RNC to effectively coordinate the Research Node and the Nodal PI's ability to provide leadership to the Research

Node and to PECARN; in this section, information provided about the RNC as a HEDA site in Section III does not need to be repeated.

- Provide a description of the organizational plan for management of the project, including an explanation of the roles and responsibilities of project personnel, project collaborators, and consultants.
- Include letters of commitment from participating HEDAs and EMS Affiliates that clearly describe the nature of the collaborative relationship. (Attachment #3).
- For each HEDA site and each EMS affiliate site describe how the site supports research capacity of the node:
    - Each HEDA and EMS affiliate site demographics (e.g., total number of annual pediatric visits to ED by age, racial and ethnic subgroups, types of condition and trauma care; square miles of EMS affiliate in catchment area, total number of annual EMS calls by age, race, and ethnic subgroups, total population served by EMS affiliate and the number and percent of annual EMS pediatric calls, types of conditions, highest level of care, and number of paramedics).
    - Structure of each HEDA and EMS affiliate site that illustrates how the site facilitates research (e.g., resources available at the site such as electronic health records, presence of trained research personnel, trauma center designation, etc. that create a conducive environment to conduct research);
    - List of HEDA-based and EMS affiliate-based pediatric emergency studies that have been undertaken and completed during the past 5 years. For each study, provide the following information:
        - Brief description of the study including study type (interventional versus observational);
        - Number of patients enrolled at the site; and for multi-center studies, the percent of patients enrolled at the site that contributed to the overall study;
        - Involvement in data collection;
        - Whether the study was part of a research network or PECARN; and
        - List of publications and how they impacted EMSC care delivery.

- Include an organizational chart (Attachment #5) that describes the functional structure of the Research Node Center, HEDAs, and EMS affiliate personnel.
- Describe the capability of the Nodal PI to lead the Research Node and the responsibilities, experience, and skills of all key personnel, including the Nodal PI, all HEDA PIs, and EMS scientific advisors. For the RNC PI, describe current availability along with current study/research duties and time allocated to each duty.
- Describe the Research Node operation and the relationship between the research, clinical practices, and administrative functional units within the Research Node.
- For competing continuation applications only, include a progress report (Attachment #6).

iii. *Budget*

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

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

As required by the Consolidated Appropriations Act, 2023 (P.L. 117-328), "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 Rate Limitation of HRSA's *SF-424 Application Guide* for additional information. Note that these or other salary rate limitations may apply in the following fiscal years, as required by law.

iv. *Budget Narrative*

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

Personnel: *The following guidelines are recommended for personnel levels based on past experience with PECARN:*

- The Nodal PI (the applicant) at a minimum of 20 percent Full Time Equivalent (FTE). The Nodal PI may also serve as the HEDA PI for their site. The Nodal PI serving as Chair should anticipate an additional 5 percent FTE.

- A nodal administrator (NA) at each RNC with a minimum of 75 percent FTE to support the activities of the Research Node and PECARN administration.

- Funding at 10 percent FTE for a HEDA PI at each of the two or three HEDA sites and for the scientific advisor for the EMS affiliate.

- A full-time (100 percent FTE) Research Coordinator (RC) for each HEDA and 50 percent RC for the EMS affiliate.

- For each node, at minimum, 10 percent FTE to address, advise, and support dissemination needs.

- Each recipient will be expected to contribute to the leadership of the network by chairing subcommittees or serving as the Chair or Vice Chair of the PECARN Steering Committee. Each recipient should plan to budget an additional 5 percent of time for the Nodal PI or a HEDA PI to serve in this role. There are four major PECARN subcommittees and three Steering Committee leadership positions so each recipient should budget for 1-2 leadership positions.

Travel: The budget should include travel expenses as described below:

- Travel expenses for the Nodal PI, the HEDA PI, the EMS affiliate scientific advisor, the NA, and the RC (and other persons as needed) to attend up to two in-person Steering Committee meetings a year. At least one meeting will be held in the Washington, D.C. area and the other in a major U.S. city.

- Travel funds required for two individuals (the Nodal PI and another individual with a designated role in the project, usually the NA) per site to attend the EMSC program's award recipient meeting (held on Years 1 and 3).

- Travel expenses for the Nodal PI and NA to attend one executive committee meeting a year in the Washington, DC area. For budgeting purposes, this meeting can be combined with the EMSC Award Recipient meeting listed above by adding a day to the EMSC Award Recipient meeting.

- Training for at least one research coordinator from each site should be budgeted for travel twice a year.

- Travel for delivering presentations at scientific meetings should be budgeted as appropriate.

Registration/Meeting Expenses: Each Research Node should budget an estimated $10,000 per meeting (total of $20,000 per year) to cover PECARN meeting expenses such as room rental, audiovisual costs etc. The EMSC Innovation and Improvement

Center (funded by a separate cooperative agreement from HRSA EMSC)[16] coordinates the meeting logistics in partnership with PECARN and hotel meeting costs are invoiced to recipients.

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.** Your indirect cost rate agreement 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: Work Plan

Attach a work plan for the project that includes all information detailed in the Project Narrative. If you will make subawards or expend funds on contracts, describe how your organization will ensure proper documentation of funds.

Attachment 2: Two PECARN Research Concepts

To demonstrate the ability to generate such ideas, two concept proposals must be submitted. At least one of these proposals must describe knowledge translation project that tests effective mechanisms to spread uptake of new clinical evidence into widespread practice in prehospital EMS agencies and/or community EDs. One concept proposal should be for the prehospital setting.

Attachment 3: Letters of commitment from participating HEDAs and EMS Affiliates

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

Attachment 4: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in Evaluation and Technical Support Capacity , not to exceed two pages in length per person. If a biographical sketch is included for an identified individual not yet hired, include a letter of commitment from that person with the biographical sketch.

Attachment 5: Project Organizational Chart

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

Attachment 6: Progress Report

(FOR COMPETING CONTINUATIONS ONLY; does not count in page limit)
A well-documented progress report is a required and important source of material for HRSA in preparing annual reports, planning programs, and communicating

[16] Information is available at: https://emscimprovement.center/

program-specific accomplishments. The accomplishments of competing continuation applicants are carefully considered; therefore, you should include previously stated goals and objectives in your application and emphasize the progress made in attaining these goals and objectives. HRSA program staff reviews the progress report after the Objective Review Committee evaluates the competing continuation applications. See Section V.2 Review and Selection Process for a full explanation of funding priorities.

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

(1) The period covered (dates).

(2) Specific objectives - Briefly summarize the specific objectives of the project.

(3) Results - Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.

Attachment 7-15: Other Relevant Documents 15 is the maximum number of attachments allowed.

Include here any other documents that are relevant to the application, including letters of support. Letters of support must be dated and specifically indicate a commitment to the project/program,

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 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 ***April 11, 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 Application Guide* for additional information.

5. Intergovernmental Review

PECARN is not subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

6. Funding Restrictions

You may request funding for a period of performance of up to 4 years, at no more than $700,000 per year (inclusive of direct and indirect costs). If appropriate, a potential Chair site can request up to $750,000. 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, 2023 (P.L. 117-328) apply to this program. See Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these and other restrictions will apply in 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 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 procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has 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. However, if a progress report is submitted with a competing continuation application, HRSA program staff will review the report after the objective review process.

Six review criteria are used to review and rank PECARN applications. Below are descriptions of the review criteria and their scoring points.

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

The extent to which the application:

- Identifies appropriate needs, challenges, and gaps in conducting pediatric emergency care research in ED and prehospital EMS settings that can be addressed through research;
- Identifies high priority areas for pediatric emergency care research based on and supported by relevant literature to support choosing these priority areas, and
- Demonstrates a thorough knowledge and understanding of multi-site clinical research across the EMS continuum.

Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's Methodology, Work Plan, and Resolution of Challenges

The extent to which the application effectively describes and is responsive to the Program Requirements and Expectations including:

- Proposes goals, objectives activities (scientific or other) that can address the project objectives;
- Develops a feasible work plan and timeline, which should effectively describe the activities or steps to be used in achieving each of the objectives proposed in the methodology section and includes milestones to assess progress of stated objectives;
- Proposes project activities, personnel, and resources, as well as a plan to maintain communication among the HEDAs and EMS affiliates and ensure consistent and timely, high-quality work; and
- Demonstrates sufficient identification of challenges likely to be encountered and the reasonableness of approaches to resolving identified challenges.

Criterion 3: EVALUATIVE MEASURES (10 points) – Corresponds to Section IV's Methodology and Evaluation and Technical Support Capacity

The extent to which the applicant:

- Monitors evaluation procedures;
- Ensures that evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities; and
- Demonstrates that the program objectives can be evaluated by performance measures, and attributes to project activities.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Methodology and Work Plan and Evaluation and Technical Support Capacity

The extent to which the proposed project will support broad dissemination of PECARN research results including:

- Describing a dissemination plan that will translate research findings to pediatric emergency care evidence-based guidelines for prehospital emergency medical services (EMS) and hospital emergency department (ED) providers;
- Ensuring the dissemination plan is detailed, feasible, and supported by dedicated personnel;
- Focusing on dissemination in partnership with the EIIC and EMSC State Partnership Managers

Criterion 5: RESOURCES/CAPABILITIES (30 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information

The extent to which the application demonstrates that:

- Project personnel are highly experienced with demonstrated success in pediatric emergency care research;
- Resources and organizational support are sufficiently available (e.g., staffing, space, fiscal support, information technologies, and equipment) to carry out the project activities, including properly account for federal funds, and document costs to avoid audit findings;
- Administrative and organizational structures and key partnership roles are well defined and aligned to carry out the project activities, including having a detailed organizational chart.
- The capacity of the proposed RNC to successfully lead Research Nodes or the EMS Research Node; and
- The commitment and capacity of the Nodal PI, HEDA PIs, EMS Affiliates Scientific Advisor to support and strengthen network collaborations and research and meet the Program Requirements and Expectations.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's Budget and Budget Narrative

The extent to which the application:

- Provides a detailed budget request and justification for each year of the 4-year period of performance, which includes required travel.
- Shows reasonableness of the proposed budget for each year of the period of performance in relation to the objectives, the complexity of the research activities, and the anticipated results.
- Describes that the key personnel have adequate time devoted to the project to achieve project objectives.

2. Review and Selection Process

The objective review process provides an objective evaluation of applications to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. See Section 5.3 of HRSA's *SF-424 Application Guide* for more details.

Funding Priorities

This program includes a funding priority, as authorized by the Public Health Service Act, Title XIX, Section 1910 (42 U.S.C. 300w-9). A funding priority is the favorable

adjustment of combined review scores of individually approved applications when applications meet specified criteria. HRSA staff adjusts the score by a set, pre-determined number of points. The PECARN has one funding priority:

Priority 1: Progress Report (5 Points)
HRSA program staff will grant up to 5 funding priority points to competing continuation applications based on the degree of successful progress described within the Progress Report (Attachment 6).

3. Assessment of Risk

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

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

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

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

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

VI. Award Administration Information

1. Award Notices

HRSA will release the Notice of Award (NOA) on or around the start date of September 1, 2023. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

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

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

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

Accessibility Provisions and Non-Discrimination Requirements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS 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 Application Guide* **and** the following reporting and review activities:

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 Financial Form 1, 2,4,6, and 7; Core Form 2 and 3; Capacity Building 5 and 6; Publications, Conference and Web-Based Products; and Products and Submissions Data. 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	September 1, 2023 to August 31, 2027 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	September 1, 2024 to August 31, 2026	Beginning of each budget period (Years 2–5, as applicable)	120 days from the available date
c) Project Period End Performance Report	September 1, 2026 to August 31, 2027	Period of performance end date	90 days from the available date

1) **Progress Report**(s). The recipient must submit a progress report to HRSA on an annual basis. More information will be available in the NOA.

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

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:

Marc Horner
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
Phone: (301) 443-4888
Email: mhorner@hrsa.gov

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

Patricia Fanflik, PhD
Health Scientist, Division of Child, Adolescent and Family Health Maternal Child
Maternal and Child Health Bureau
Health Resources and Services Administration
Phone: (301) 443-2564
Email: pfanflik@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 Application Guide*.

Appendix: Additional PECARN Background

Activities of the PECARN Chair

- Serve as liaison to facilitate a working relationship between HRSA and the network;
- Coordinate and manage the PECARN Steering Committee meetings;
- Organize network communications across the network sites and the EDC;
- Represent PECARN at national committees and meetings, including the annual HRSA Maternal and Child Health Bureau's Research Network meeting;
- Provide briefings and presentations to national organizations;
- Oversee and update PECARN policies and procedures;
- Update all PECARN members on new/ongoing activities; and
- Oversee the activities of the Nodal Administrator who will become the PECARN Secretary during the time that the Nodal PI serves as the PECARN Chair.

Research Site Monitoring Reporting Requirements to the EDC
As part of the externally funded research grant monitoring activities of the EDC, the HRSA award recipients agree to furnish the following information to the EDC to ensure the efficiency and productivity of the network and implemented studies:

1. Grant Protocol-Specific Reports: Recipients are required and agree to provide periodic reports of protocol-specific projects, as requested by HRSA directly or through the EDC. At a minimum, the nodes must provide timely enrollment information in a format and according to a schedule defined by the EDC and/or the HRSA PO for all HEDAs and participating EMS affiliate sites. Other protocol-specific reports, such as adverse event reports and other reports needed to monitor the safety and clinical effectiveness of drugs, treatments, or other interventions under investigation, will be required in order to allow HRSA and the PECARN Steering Committee to monitor the research projects undertaken in the PECARN.

2. Investigational New Drug (IND) Reports: For projects involving IND, recipients are required and agree to provide reports according to regulations and guidelines established by the Food and Drug Administration (FDA).

3. Manuscript Analysis Request Form (MARF): A publication plan and manuscript analysis request form will be submitted to the PECARN Steering Committee for each planned primary or secondary manuscript as early as possible in the study planning process and before enrollment ends.

4. Final Publications: Prompt and timely presentation and publication in the scientific literature of findings resulting from research undertaken in the PECARN is required. A primary publication from the research should be published no later than 2 years after the last patient has been enrolled or data collection completed. Investigators must agree to abide by HRSA and PECARN policies concerning all publication of PECARN studies. Prior to the submission of manuscripts for

publication, recipients agree to submit publications to the PECARN Steering Committee for internal peer review and approval. HRSA's Office of Communications will be consulted in advance of publication in order to coordinate announcements of new HRSA-supported research results with other HRSA dissemination activities.

Quality Control and Monitoring

For protocols requiring an IND, the Nodal PI or study specific sponsor is primarily responsible for study control and monitoring as defined by FDA rules and regulations. All participants under this award will cooperate with Nodal PI or specific study sponsor, HRSA, and EDC to support RNC operations and advise all investigators of specific requirements concerning investigational drug management.

With regards to laboratory quality control and data management issues, the RNC and HEDA and participating EMS affiliate sites agree to participate in protocol-defined measures to follow methodological and analytic guidelines established by the Network which includes representation from PECARN award recipients, EDC and HRSA. This approach supports the fidelity of study implementation and allows the award recipients to address challenges in a timely manner. All study sites must participate in multiple methods risk-based site monitoring that can include on site or remote monitoring methods.

Subject Safety/Oversight

The RNC, HEDA and participating EMS affiliate sites will adhere to protocol-specific measures established by the Network, which includes representation from PECARN award recipients, EDC and HRSA to assure the safety and protection of the rights of volunteers who may participate in clinical trials and observational studies to be conducted as a result of this cooperative agreement. Any project that may utilize human subjects or data from human subjects should consult their Institutional Review Board (IRB), a central IRB for a study, or the federal Office for Human Research Protections for the requirements of IRB review.
(http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)

The Nodal PI and all HEDAs and participating EMS affiliate investigators assume and accept the primary responsibility for ensuring PECARN studies are conducted in compliance with all federal regulations and PECARN policies and procedures. All investigators agree and assure that adequate records will be maintained throughout the project, and that access to these records will be available to enable outside monitors (including EDC staff) to assess compliance with applicable federal laws and regulations.

Adverse Experience Reporting

The Nodal PI agrees to implement and adhere to an adverse event tracking system operated by the EDC.

Data Confidentiality

Pursuant to 42 USC 299c-3(c), information obtained in the course of any HRSA supported study that identifies an individual or entity must be treated as confidential in accordance with any explicit or implicit promises made regarding the possible uses and disclosures of such data. PECARN and the EDC provide procedures for ensuring the confidentiality of the identifying information to be collected, including who will be permitted access to this information, both raw data and machine-readable files, and how personal identifiers and other identifying or identifiable data will be restricted and safeguarded.

Identifiable patient health information collected by recipients under this NOFO will be managed in accordance with 45 CFR Parts 160 and 164, the Federal Privacy Rule developed by the Department of Health and Human Services (HHS) pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These regulations serve to limit the disclosure of personally identifiable patient information by covered entities and define when and how such information can be disclosed. Thus, health care plans ordinarily will require either patient authorization for disclosures of identifiable information to be made to researchers or waivers of such authorizations obtained from an Institutional Review Board (IRB) or Privacy Board (defined in the regulations), which will involve review to ensure that identifiable health information will be appropriately safeguarded by the investigators. The HHS Office of Civil Rights is the enforcement body for this regulation. Additional information about the regulations, their implementation, and alternative methods of permissible disclosures to researchers (limited data sets with data use agreements, de-identified data sets, data about deceased persons, and data use to develop protocols) can be obtained from: http://www.hhs.gov/ocr/hipaa. The award recipient will work with the DCC to ensure appropriate data sharing agreements of the Business Associate Agreement (BAA) are in place in a timely manner for operation of the network.

The recipient should ensure that computer systems containing confidential data have a level and scope of security that equals or exceeds that established by the HIPAA Security Rules, if applicable, and of that established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III - Security of Federal Automated Information Systems. The National Institute of Standards and Technology (NIST) published An Introduction to Computer Security: the NIST Handbook available at http://csrc.nist.gov/publications/nistpubs/800-12/. These applicability confidentiality and security standards apply to any to subcontractors and vendors.