

U.S. Department of Health and Human Services

HRSA

Health Resources & Services Administration

Maternal and Child Health Bureau

Division of Child, Adolescent, and Family Health

Emergency Medical Services for Children Data Center

Funding Opportunity Number: HRSA-22-087

Funding Opportunity Type(s): Competing Continuation, New

Assistance Listings (AL/CFDA) Number: 93.127

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2022

Application Due Date: January 18, 2022

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

HRSA will not approve deadline extensions for lack of registration.

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

Issuance Date: October 19, 2021

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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)

EXECUTIVE SUMMARY

508 Compliance Disclaimer

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

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2022 Emergency Medical Services for Children (EMSC) Data Center. The purpose of this program is to support activities that demonstrate expansion and improvement in the delivery of high-quality emergency services for all children throughout our nation. The recipient will achieve this purpose by serving as a central data coordinating center that (1) provides support for large multi-center randomized clinical research trials focused on emergency medical services for children; (2) collects and provides annual surveillance on national performance measures that meaningfully describe the EMSC Program's impact in 59 states and jurisdictions; and (3) collaborates with national partners to coordinate and support national data collection efforts to assess the readiness of prehospital and hospital emergency systems to care for children.

Also in this notice is the opportunity to apply for additional funding to build capacity to advance EMSC data integration and dissemination. Applying for the EDC Supplemental funding is optional.

Funding Opportunity Title:	Emergency Medical Services for Children Data Center (EDC)
Funding Opportunity Number:	HRSA-22-087
Due Date for Applications:	January 17, 2022
Anticipated Total Annual Available FY 2022 Funding:	EDC: \$3,200,000 EDC Supplement (optional): Up to \$500,000 may be available each year
Estimated Number and Type of Award(s):	EDC: Up to one (1) cooperative agreement EDC Supplement (optional): Up to one (1) supplement per year, pending availability of funds.

Estimated Annual Award Amount:	<p>EDC: Up to \$3,200,000 per year based on listed criteria subject to the availability of appropriated funds.</p> <p>EDC Supplement (optional): Annual supplement, up to \$500,000, dependent on the availability of funds each year. May be awarded in any of the 4 budget years for a funding period of one (1) year.</p>
Cost Sharing/Match Required:	No
Period of Performance:	<p>EDC: July 1, 22 through June 30, 2026 (4 years)</p> <p>EDC Supplement (optional): 1-year one-time supplement with the July 1, 2022 through June 30, 2026 period of performance</p>
Eligible Applicants:	State governments and accredited schools of medicine. See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

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

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Thursday, November 4, 2021
Time: 3 – 4 p.m. ET
Call-In Number: 1-833-568-8864
Participant Code: 36697355
Weblink: <https://hrsa.gov.zoomgov.com/j/1613682452?pwd=TWxRQWV2VDFPRLpxdFdNUkNEMWhxdz09>

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

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Emergency Medical Services for Children (EMSC) Data Center. The purpose of this program is to support activities that demonstrate expansion and improvement in the delivery of high-quality emergency services for all children throughout our nation by:

- 1) Providing independent, comprehensive research support for large multi-center randomized clinical trials and other types of clinical research conducted by and associated with the Pediatric Emergency Care Applied Research Network (PECARN);
- 2) Enhancing and collecting performance measure data that align with the combined efforts of the EMSC State Partnership (SP) and the EMSC Innovation and Improvement Center (EIIC) to expand and improve EMSC in states/jurisdictions; and
- 3) Collaborating with national partners to coordinate and support nationally representative data collection efforts to assess the expansion of prehospital and hospital pediatric readiness initiatives.

This work will support the EMSC Program's efforts to reduce disparities in access to high quality pediatric emergency services and improve health equity in care across the continuum of emergency medical services for children. Also provided for in this notice is the opportunity to apply for the EDC Supplement funding to support building capacity to advance EMSC data integration and dissemination activities. Applying for the EDC Supplement is optional. For additional information on the EDC Supplement, please refer to [Appendix 1: Description of the EDC Supplemental Funding](#).

Program Objectives

- 1) Provide independent, comprehensive research support for large multi-center randomized clinical trials and other types of clinical research related to improving and expanding emergency medical services for children conducted by and associated with PECARN. Specific activities will include:
 - Coordinating research activities to include developing multi-center research protocols; managing single institutional review board policies; delivering implementation training for clinical studies; providing statistical support and analysis; creating data transfer and management tools; preparing and participating in manuscript development and tracking; supporting ancillary study activities; and participating in executive, steering, and subcommittees;
 - Expanding the impact of PECARN's research data and data registries by de-identifying PECARN data and creating a series of public use datasets that are maintained and made available for three years after the date that the last patient completes the study and follow-up; supporting the expansion of the PECARN data registry; optimizing

- access to PECARN research data and data registries for clinical and health services research; developing PECARN's capacity to link or collaborate with other research networks; increasing alignment with national-level pediatric readiness efforts by assessing and promoting the uptake of PECARN-developed decision rules and evidence-based practices in community Emergency Departments (ED); and strengthening research that focuses on understanding and addressing health inequities in EMSC; and
- Providing rapid analyses of federally supported datasets and registries (e.g., PECARN's multicenter electronic health record registry of pediatric emergency care) on issues related to public health emergencies and emerging needs to inform MCHB's public health responses.
- 2) Enhance and collect performance measure data that align with the EMSC SP and the EIIC's¹ combined efforts to expand and improve EMSC care in states and jurisdictions.
- Provide technical assistance (TA) for data collection and program evaluation that will enable EMSC SP recipients to collect data which measures EMS agencies' ability to care for children and provide regular assessments of progress in key aspects of prehospital pediatric readiness statewide;
 - Develop and implement the annual and/or biannual collection of state and nationally representative data on prehospital and hospital EMSC performance measures;
 - Provide access to data that supports effective quality improvement (QI) strategies to increase prehospital EMS and EDs' capacity in their state.
- 3) Collaborate with national partners to coordinate and support nationally representative data collection efforts to assess the expansion of prehospital and hospital pediatric readiness initiatives.
- Coordinate with national partners to develop, expand, and maintain data collection methods and portals which enhance the National Pediatric Readiness Project² and the National Prehospital Pediatric Readiness Project;³
 - Develop and maintain web-based data collection portals to provide timely program feedback on prehospital EMS and EDs' degree of pediatric readiness; and

¹ Visit the EIIC website to learn about their work at <https://emscimprovement.center/>.

² To learn more at the National Pediatric Readiness Project, please visit: <https://emscimprovement.center/domains/pediatric-readiness-project/>

³ To learn more about the National Prehospital Pediatric Readiness Project, please visit: <https://emscimprovement.center/domains/prehospital-care/prehospital-pediatric-readiness/>

- Provide access to data that supports effective QI strategies to increase prehospital EMS and EDs' capacity to provide up-to-date, evidence-based pediatric emergency services.

Also in this notice is the opportunity to apply for additional funding to support building capacity to advance EMSC data integration and dissemination. Specifically, the additional funds should help with improving and expanding database development, maintenance, and integration using cost effective, reliable, cutting-edge technologies to facilitate annual or biannual data collection, data analyses and information sharing for dissemination. Applying for the EDC Supplement is optional.

2. Background

About MCHB and Strategic Plan

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

Goal 1: Assure access to high quality and equitable health services to optimize health and well-being for all 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 MCHB Goals 1 and 2 by working to:

- Monitor and improve equitable access to a continuum of high-quality emergency medical services for children that address medical and social determinants of health across the life course;
- Strengthen state- and community-based comprehensive systems of emergency medical care for children that equitably improve well-being;
- Collect and use data on race, ethnicity, culture, language, income, disability status, health status, gender, sexual orientation, geographic location, or other factors to measure and address disparities and advance equity for children in their access and outcomes; and
- Leverage MCHB resources to improve access to emergency care services for health of all children that are marginalized, including those affected by racism and ableism.

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

Health Equity

Definition of Equity: The consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have

been denied such treatment, such as Black, Latino, Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.⁴ MCHB is committed to promoting equity in health programs for mothers, children, and families. As such, the definition of equity provides a foundation for the development of programs that intend to reach underserved communities and improve equity among all communities.

Comprehensive Research Support for EMSC PECARN

Emergency Medical Services for Children Data Center (EDC) is authorized by the Public Health Service Act, Title XIX, 1910 (42 U.S.C. 300w-9). The EDC is administered by the Emergency Medical Services for Children (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.

The EMSC Program was established in 1984 to expand and improve emergency medical services for children, in response to a growing recognition that children have unique needs in emergencies -- needs that vary from those of adults due to physiological, developmental, and psychological differences. The EMSC Program aims to ensure that all of the nation's children have access to high quality, evidence-based pediatric emergency care through a portfolio that consists of five individual inter-related programs (PECARN, SP, Targeted Issues, EICC, and the EDC). These programs work to ensure that both prehospital EMS systems and EDs incorporate the most effective and appropriate pediatric clinical care, processes, equipment, and knowledge to treat and manage pediatric patients who experience trauma or medical emergencies.

The HRSA EMSC PECARN supports the research network infrastructure that enables pediatric emergency care researchers to address gaps in clinical evidence by collaboratively designing, conducting, and disseminating research that improves the treatment and management of children and youth in prehospital EMS and hospital EDs settings. PECARN research aims to address pediatric emergency care challenges by conducting studies that require multi-site randomized control trials. Results of these studies inform clinical care guidelines and practice. To ensure data collected by PECARN studies are made available to the public, the EDC is required to de-identify PECARN data and create a series of public use datasets that are maintained and available for 3 years after the date when the last patient completes the study and follow-up. Current PECARN cooperative agreement recipients provide the EDC with final study data according to schedules developed and approved by the PECARN Steering Committee. The current grant cycle of PECARN research node recipients includes 7

⁴ 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>.

research nodes that together include 18 EDs and 9 prehospital EMS agencies.⁵ To date, PECARN and the EDC have implemented 74 multi-institutional clinical studies, enrolling more than 143,000 children, resulting in more than 190 peer-reviewed journal articles and 21 public use datasets to enable future pediatric emergency care research and innovation. In the new funding period, the EDC will provide comprehensive research support for PECARN; expand the impact of PECARN's research; strengthen health equity research; and modernize federally supported datasets to inform emerging public health needs. For additional background information on the relationship between the EDC and PECARN, please refer to [Appendix 2: Additional Background on the Relationship between the EDC and PECARN](#).

Developing Performance Measures for EMSC SP and EIIC

The EDC supports the development and collection of EMSC performance measurement data to better assess the EMSC Program's progress toward expanding and improving EMSC across the states and jurisdictions. In 2017, the EDC published the EMS for Children Performance Measures Implementation Manual for State Partnership Grantees. The purpose of the implementation manual was to provide EMSC SP recipients a "roadmap to improve the ease, accuracy, and consistency of data collection and reporting for their performance measures."⁶ The EDC supported the national data collection of nine (9) EMSC National Performance Measures, which captured improvements in pediatric care across prehospital EMS and hospital EDs, and EMSC Program sustainability. In the new funding period, the EDC will continue to improve the quality and timeliness of meaningful performance measures, provide technical assistance for performance measures data collection, implement annual or biannual data collection, and support assessments of QI strategies.

Advancing Pediatric Emergency Readiness

The HRSA EMSC Program collaborates with multidisciplinary partners to support the National Pediatric Readiness Project (NPRP), a national QI initiative to ensure that all U.S. EDs have the essential guidelines and resources in place to provide effective emergency care to children. In 2013, the EDC provided support to the NPRP to launch a web-based assessment of all EDs in the U.S. to assess their progress in implementing the national pediatric readiness guidelines, outlined in the 2009 Joint Policy Statement, "Guidelines for Care of Children in the Emergency Department." Over 4,000 (83%) hospital EDs responded. Of those responding, 69% of EDs reported treating less than 14 children per day and had an average pediatric readiness score of 69 out of a possible 100 points.⁷ A second national NPRP assessment of U.S. EDs, based on the updated 2018 Joint Policy Statement titled, "Pediatric Preparedness in the

⁵ Visit the PECARN website to understand the structure of the PECARN network and to learn about past and present studies at <http://www.pecarn.org>.

⁶ More information can be found at:

https://www.nedarc.org/performanceMeasures/documents/EMS%20Perf%20Measures%20Manual%20Web_0217.pdf

⁷ Gausche-Hill M, Ely M, Schmuhl P, et al. A National Assessment of Pediatric Readiness of Emergency Departments. *JAMA Pediatr.* 2015;169(6):527–534. doi:10.1001/jamapediatrics.2015.138

Emergency Department,”⁸ was conducted in 2021. The results of this assessment will provide data to further advance QI efforts to improve pediatric emergency care.

In 2019, the HRSA EMSC Program convened national and federal partners to develop and implement pediatric readiness in the prehospital setting, which launched the National Prehospital Pediatric Readiness Project (NPPRP).⁹ The NPPRP is a national initiative established to address gaps in prehospital EMS based on the 2020 joint-policy statement technical report entitled, “Pediatric Readiness in Emergency Medical Services Systems.”¹⁰ The joint policy statement highlights key approaches to improving prehospital EMS for children, including increasing the number of agencies that have a pediatric champion; ensuring ambulances have appropriate pediatric equipment and medications; providing routine pediatric emergency care education and training; developing quality improvement initiatives and strategies based on pediatric-specific guidelines; and integrating EMS physician medical oversight in prehospital EMS systems.¹¹ In addition to supporting educational tools, the NPPRP partners are developing and planning the implementation of a national assessment of pediatric readiness in prehospital EMS agencies.¹²

In the new period of performance, the EDC will identify and implement innovative approaches to assess the improvements in pediatric readiness in prehospital EMS systems and hospital EDs across the nation.

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.

HRSA program involvement will include:

⁸ Remick K, Gausche-Hill M, Joseph MM, Brown K, Snow SK, Wright JL; American Academy of Pediatrics Committee on Pediatric Emergency medicine and Section on Surgery; American College of Emergency Physicians Pediatric Emergency Medicine Committee; Emergency Nurses Association Pediatric Committee. Pediatric Preparedness in the Emergency Department. *Pediatrics*. 2018;142(5):e20182459

⁹ More Information can be found at: <https://emscimprovement.center/domains/prehospital-care/prehospital-pediatric-readiness/>

¹⁰ Owusu-Ansah S, Moore B, Shah MI, et al. AAP Committee on Pediatric Emergency Medicine. Section on Emergency Medicine, AAP EMS Subcommittee, Section on Surgery. Pediatric Readiness in Emergency Medical Services Systems. *Pediatrics*. 2020;145(1): e20193308

¹¹ American Academy of Pediatrics, Committee on Pediatric Emergency Medicine American College of Emergency Physicians, Emergency Medical Services Committee Emergency Nurses Association, Pediatric Committee National Association of Emergency Medical Services Physicians, Standards and Clinical Practice Committee National Association of Emergency Medical Technicians, Emergency Pediatric Care Committee. Policy statement: pediatric readiness in emergency medical services systems. *Pediatrics*. 2019;145(1):e20193307

¹² For more information, Please visit: <https://emscimprovement.center/domains/prehospital-care/prehospital-pediatric-readiness/>

- Participating in the planning and scheduling of meetings conducted during the period of the cooperative agreement;
- Participating in regular meetings and communications with the recipients to assess progress;
- Providing clearance of the planning, development, implementation, and evaluation of products and tools funded under this cooperative agreement;
- Participating in the design, direction, and evaluation of innovative activities;
- Facilitating efforts in the provision of technical support and training/education to specified individuals;
- Reviewing procedures to be established for ongoing monitoring and successful accomplishment of the scope of work proposed;
- Supporting the identification and engagement of federal and state contacts and professional and national organizations with whom the recipient will be asked to develop cooperative and collaborative relationships;
- Co-leading evaluative meetings dedicated to the ongoing development, evolution, refinement, and/or retirement of EMSC performance measures;
- Providing review and advisory input of any draft and final publications, audiovisuals, and other materials produced under the auspices of this cooperative agreement; and
- Reviewing and considering for approval all travel for meetings and conferences.

The cooperative agreement recipient's responsibilities will include:

- Establishing bi-monthly check-ins with EDC leadership, with ad-hoc meetings as needed with federal EMSC Program staff. At least two meetings must be in-person each year, if permissible and safe;
- Responding in a timely and flexible manner to collaborating on short-term, long-term, and ongoing projects as well to rapid-response requests, to be determined by HRSA staff on a case-by-case basis;
- Providing summary de-identified aggregate data to the federal Project Officer (PO), including data on emergent issues if requested;
- Consulting with federal Project Officer regarding the selection and hiring of new key project staff;
- Consulting with the PO when planning and implementing new activities;
- Consulting with the PO when scheduling any meetings, including project advisory/Steering Committee meetings, that pertain to the scope of work and at which the PO's attendance would be appropriate (as determined by the PO);
- Providing the PO with adequate time and opportunity to review, provide advisory input, and approve at the program level, any publications, audiovisuals, and other materials produced, as well as meetings planned, under the auspices of this cooperative agreement (such review should start as part of concept development and include a review of drafts and final products);
- Providing the PO with an electronic copy of, or electronic access to, each product developed under the auspices of this project;
- 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 and coordinating attendance at national meetings or conferences with the PO to keep informed of and involved in initiatives of national significance to the EDC and its recipients;
- Co-leading, with the federal program staff, evaluative meetings dedicated to the ongoing development, evolution, refinement, and/or retirement of EMSC performance measures;
- Providing technical expert guidance, such as survey methodology, data analytics, framing, and visualization, for annual and/or biannual performance measure data;
- Participating in the planning of and providing technical support during EMSC grant recipient site visits or other meetings as requested;
- Seeking prior approval for all travel to ensure coordination with other EMSC award recipient activities;
- Submitting a quarterly travel schedule with all planned travel (due 30 days before the start of each quarter), format to be determined in partnership with the PO;
- Acknowledging that HRSA/MCHB has full access rights to all data generated under this cooperative agreement and that the government has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use any products derived from activities conducted under this cooperative agreement; and
- Assuring seamless transfer of all web-based and non-web-based materials developed and stored throughout this cooperative agreement within 90 days of the project period expiration.

HRSA/MCHB and the recipient have a joint responsibility to develop a plan of action for issues to be addressed during the period of performance. The plan will include the sequence in which the issues will be addressed, what approaches and strategies will be used to address them, and how relevant information will be transmitted to specified target audiences and used to enhance project activities and advance the EDC.

2. Summary of Funding

HRSA estimates approximately \$3,200,000 to be available annually to fund one recipient. The actual amount available will not be determined until enactment of the final FY 2022 federal appropriation.

You may apply for a ceiling amount of up to \$3,200,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately.

The period of performance is July 1, 2022 through June 30, 2026 (4 years). Funding beyond the first year is subject to the availability of appropriated funds for the EDC in subsequent fiscal years, satisfactory progress, and a decision that continued funding is in the best interest of the Federal Government.

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

In addition, up to \$500,000 per year may be available annually to fund one (1) EDC optional supplement to support building capacity to advance EMSC data integration and dissemination described in Attachment 7. In this application, you may apply for a ceiling amount of up to \$500,000 total costs (includes both direct and indirect, facilities and administrative costs) to be awarded through this supplement opportunity. The recipient may be awarded a one-time, 1-year supplement during 1 of the 4 budget years. The actual amount available will not be determined until the enactment of the final FY 2022 federal appropriation and appropriation going forward until 2026.

<u>Base funding opportunity under this NOFO</u>			
Type of Award	Estimated Number of Awards	Estimated Funding of Award Per Year	Total Program Funds/Year
Emergency Medical Services for Children Data Center	1	\$3,200,000	\$3,200,000

<u>Optional supplemental funding opportunity under this NOFO</u>			
Type of Award	Estimated Number of Awards	Estimated \$ of Award	Total Program Funds/Year
Optional EDC Supplement	1 recipient per year	Recipient may receive a one-time award of up to \$500,000 once in any of the 4 budget periods.	Up to \$500,000 per year pending availability of funds.

See HRSA [Grants Policy Bulletin 2017-03 Indirect Cost Rate Agreements in the NOFO](#).

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include state governments and accredited schools of medicine in states and jurisdictions. The term “school of medicine” for the purpose of this funding opportunity (and under 42 U.S.C. 300w-9(c) has the same meaning as set forth in § 799B(1)(A) of the Public Health Service Act (42 U.S.C. 295p(1)(A)).¹³ The term “state” for the purpose of this funding opportunity 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

¹³ See definition at: <https://www.law.cornell.edu/uscode/text/42/295p>

Pacific Islands.

Per legislation, only three EMSC grant awards per state may be awarded to each state during any fiscal year.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

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

- Exceeds the ceiling amount
- Fails to satisfy the deadline requirements referenced in [Section IV.4](#)

NOTE: Multiple applications from an organization are not allowable.

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

IV. Application and Submission Information

1. Address to Request Application Package

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

The NOFO is also known as “Instructions” on Grants.gov. You must select “Subscribe” and provide your email address for HRSA-22-087 in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. *You are ultimately responsible for reviewing the [For Applicants](#) page for all information relevant to this NOFO.*

2. Content and Form of Application Submission

Application Format Requirements

Section 4 of HRSA’s [SF-424 Application Guide](#) provides general instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, etc. You must submit the information outlined in the HRSA *SF-424 Application Guide* in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA’s [SF-424 Application Guide](#) except where instructed in the NOFO to do otherwise. You must

submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

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

Application Page Limitation

The total size of all uploaded files included in the page limit may not exceed the number of pages listed in the table below when printed by HRSA.

EDC Base Award	80 pages
EDC Supplement (<i>Optional as Attachment 7</i>)	10 additional pages

The page limit for the EDC includes the project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Please note: Effective April 22, 2021, the abstract is no longer an attachment that counts in the page limit. The abstract is the standard form "Project Abstract Summary." Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-22-087, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit.**

Any application exceeding the page limit of 80 pages total for the EDC base award application, and 90 pages if applying for the supplemental funding will not be read, evaluated, or considered for funding.

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

The page limit for the supplement includes the project narrative, budget narrative, and any other descriptive information. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in [45 CFR § 75.371](#), including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3321).

- 3) If you are unable to attest to the statements in this certification, you must include an explanation in *Attachment 8-15: Other Relevant Documents*.

See Section 4.1 viii of HRSA's [SF-424 Application Guide](#) for additional information on all certifications.

Program-Specific Instructions

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

i. Project Abstract

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

Place the following at the top of the abstract:

Address

Project Director Name

Contact Phone Numbers (Voice, Fax)

Email Address

Website Address, if applicable

For abstract information content, include the following:

- **PROBLEM:** Briefly state the principal needs and problems addressed by the project.
- **GOAL(S) AND OBJECTIVES:** Identify the major goal(s) and objectives for the 4-year period of performance. **METHODOLOGY:** Describe the activities used to attain the objectives.
- **COORDINATION:** Describe the coordination planned with appropriate national, regional, state, and/or local partners to implement the proposed project. **POPULATION:** Briefly describe the population group(s) to be served.
- **EVALUATION:** Briefly describe the evaluation methods that will assess program outcomes and the effectiveness and efficiency of the project in attaining goals and objectives.
- **ANNOTATION:** Provide a three- to five-sentence description that identifies the project's purpose, the needs and problems that are addressed, the goals and objectives of the project, the activities that will be used to attain the goals, and the materials that will be developed.

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

ii. Project Narrative

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

Use the following section headers for the narrative:

- INTRODUCTION -- Corresponds to Section V’s Review Criterion [1 Need](#)

Briefly describe the purpose of the proposed project that is consistent with Section I: Purpose of this NOFO.

Provide an overview of how the project will accomplish the following:

- Provide independent, comprehensive research support for large multi-center randomized clinical trials and other types of clinical research associated with the PECARN;
- Enhance and collect performance measure data that measure the EMSC SP and the EIIC’s combined efforts to expand and improve EMSC care in states/jurisdictions; and
- Collaborate with national partners to coordinate and support nationally representative data collection efforts to assess the expansion of prehospital and hospital pediatric readiness initiatives.

- NEEDS ASSESSMENT -- Corresponds to Section V’s Review Criterion [1 Need](#)

The needs assessment should help reviewers understand the need for the EDC and should exhibit an expert understanding of the EDC processes, needs, and the activities/tasks included in this cooperative agreement as well as the expected outcomes.

- Briefly describe the need to provide support to and coordination of the PECARN, EMSC SP, and EICC programs, and national partners working to advance pediatric readiness and the delivery of equitable and quality pediatric emergency care that is consistent with specific activities described in Section I. Describe the significance of the project in terms of its potential impact for improving EMSC nationally, with a focus on data collection, analysis and utilization.
- Briefly discuss any relevant barriers in the field of pediatric emergency care that the project intends to overcome. This section should help reviewers understand the:
 - role of the EDC in a research network;
 - role of the EDC in supporting ongoing program evaluation, specifically the EMSC Program performance measures and data system support;
 - role of the EDC in prehospital and hospital pediatric readiness initiatives;
 - issues, including inequities, related to pediatric emergency care services and research (including issues related to human subjects protections and single institutional review board policies and procedures);
 - data collection and analysis including natural language processing and machine learning approaches and the technical support personnel to implement these approaches;
 - general infrastructure and technological support needs of the EDC (e.g., software/hardware to ensure secure transmission and storage of protected health information), and cutting edge data collection and analysis (e.g., natural language processing and machine learning approaches).
- **METHODOLOGY -- Corresponds to Section V's Review Criterion [2 Response](#)**

Propose clear and feasible methods including goals and objectives to meet the expectations described in this NOFO. Objectives should be specific, measurable, achievable, relevant, and time-bound (SMART) and align with the objectives in this NOFO. Describe how the proposed project will address the public health need and incorporate a health equity lens in the activities of this program.

Ensure the following core objectives and activities are integrated into the proposal.

Objective 1: Provide independent, comprehensive research support for large multi-center randomized clinical trials and other types of clinical research associated with PECARN. Specific activities are detailed below.

Coordinate PECARN Research Activities:

- Support the development of multi-center research protocols that have been approved by the PECARN Steering or Executive Committees;

- Support the development of operational and procedural manuals, protocols, and forms; quality control systems, data collection modules, and an electronic communications system for research nodes and their respective Hospital Emergency Department Affiliates or Emergency Medical Services Affiliates;
- Provide training for research nodes and their respective Hospital Emergency Department Affiliates for standardization of PECARN study protocols across sites;
- Manage single institutional review board policies, activities, and implementation;
- Coordinate and support Data Safety Monitoring Boards;
- Ensure network-wide compliance with human subject protections;
- Provide support and guidance for the regulatory functions and requirements associated with the study protocols, procedures, and Institutional Review Board (IRB) approval process including the Single IRB;
- Revise and maintain network policies and procedures that support the network's mission and comply with federal rules and regulations in conjunction with the PECARN Nodal Principal Investigators and MCHB Project Officer or designee;
- Organize and conduct multi-site monitoring activities in conjunction with MCHB Project Officer or designee;
- Serve as a central resource for PECARN generated network data including creating data collection, transfer and management tools, data integration, and quality assurance;
- Provide statistical support and analysis of data for planned primary study analyses, and secondary analyses, that are approved by the PECARN Steering or Executive Committees;
- Assist in support of ancillary studies that have been approved by the PECARN Steering or Executive Committees;
- Assist in preparing abstracts for presentation at scientific meetings;
- Participate in the preparation of manuscripts and tracking for publication;
- Facilitate communication between EDC staff and other components of PECARN, including MCHB, Data Safety Monitoring Boards, and PECARN Research Node Centers and their respective Hospital Emergency Department Affiliates and Emergency Medical Services Affiliates;
- Provide an operational structure capable of coordinating EDC functions for several protocols simultaneously;

- Provide MCHB and PECARN information on the efficiency and productivity of the network that includes metrics regarding concept development, grant submission, study implementation, and related manuscript publications; and
- Participate in executive, steering, and subcommittees, and as a voting member of the PECARN Executive Committee and PECARN Steering Committee.

Lead Dissemination of PECARN Studies:

- Expand the impact of PECARN's research data and data registries;
- De-identify PECARN data and create a series of public use datasets that are available 3 years after the last patient completes the study and follow-up;
- Support the expansion of the PECARN data registry;
- Modernize data evaluation including developing partnerships or building capacity within the EDC to use natural language processing and/or machine learning;
- Provide rapid analyses of federally supported datasets on issues related to public health emergencies and emerging needs to inform MCHB's public health responses;
- Develop PECARN's capacity to link or collaborate with other research networks;
- Participate on the PECARN Dissemination working group;
- Increase alignment with national-level pediatric readiness efforts by assessing and promoting the uptake of PECARN-developed decision rules and evidence-based practices in community EDs; and
- Increase and strengthen research that focuses on understanding and addressing health inequities in EMSC.

Objective 2: Enhance and collect performance measure data that align with the EMSC SP program and the EIIC's combined efforts to expand and improve EMSC care in states and jurisdictions. The recipient will provide analytical support to EMSC grant recipients and national stakeholders to enhance and improve state data systems needed to advance the delivery of quality pediatric emergency care. This includes providing statistical and data management technical assistance to EMSC grant recipients and researchers. Specific activities are detailed below.

Data-related TA to EMSC SP Recipients:

- Provide technical support to ensure that sufficient tools and TA are available for states to collect EMSC Program Performance Measures that are used to assess the ongoing quality of pediatric emergency care provided in prehospital and hospital settings; and
- Support learning communities among states to assist them in sharing lessons learned to improve data collection of EMSC performance measures through facilitated workshops, expert panels, and networking opportunities.

Annual and/or Biannual Data Collection

- Assist HRSA/MCHB with ongoing development, refinement, and/or retirement of EMSC performance measures. The EDC plays a vital role in modifying and developing new measures that address care delivery gaps. This may include modifications to the accompanying guidance manual for EMSC program managers and a data dictionary for HRSA; and
- Facilitate and implement annual or biannual collection of state and nationally representative data on prehospital and hospital EMSC performance measures.

Effective QI Support

- Support states to collect, analyze, and utilize data to enhance and improve pediatric emergency care;
- Assist states in linking state performance data with other national data sets focused on emergency medical services in the prehospital and hospital setting; and
- Disseminate results from EMSC SP performance measure assessment in the form of peer-reviewed articles for the field and general publications for the public.

Objective 3: Collaborate with national partners to coordinate and support nationally representative data collection efforts to assess the expansion of prehospital and hospital pediatric readiness initiatives. Specific activities are detailed below.

- Coordinate with national partners to develop, expand, and maintain data collection methods and portals which enhance the NPRP and the NPPR Projects;
- Develop and maintain web-based data collection portals to provide timely program feedback on prehospital EMS and EDs' degree of pediatric readiness;
- Collaborate with EIIC and national partners to develop and implement strategies dedicated to shared established requirements in the training of emergency care professionals and/or increasing reciprocity in education courses. This will improve the compatibility and reach of national pediatric readiness training efforts such as continuing education credits, data factsheets, and linkages to resources;
- Provide access to data that supports effective QI strategies to increase prehospital EMS and EDs' capacity to provide up-to-date, evidence-based pediatric emergency services; and
- Provide data and support to researchers interested in advancing the evidence base for pediatric readiness, with an emphasis on building linkages to health outcomes and further examining inequities in care.

Integrate EDC Activities with the Overall Goals of the EMSC Program:

- Collaborate with the EMSC EIIC and SP programs to establish and sustain EMSC programs in states and jurisdictions;

- Collaborate across the EMSC portfolio, including the EIIC, on strategic planning for the EMSC Program and support the development of tools that may rely on data as activities and projects evolve;
 - Schedule monthly updates with the EIIC to review ongoing projects;
 - Participate in the strategic engagement of the EMSC stakeholder group; and
 - Participate in the planning and content for EMSC grant recipient meetings.
- **WORK PLAN** -- Corresponds to Section V's Review Criterion [2 Response](#)
 - Provide a work plan as **Attachment 1** that describes the activities or steps that you will use to achieve each of the proposed objectives and covers the entire period of performance.
 - Describe an effective plan for managing the project, including its personnel, resources, and activities. Describe how you will maintain communication among any subcontractors and how they will ensure consistent and timely, high quality work regardless of which organization is leading the specific task.
 - Submit a logic model for designing and managing the project as **Attachment 6**. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for this notice, the logic model should summarize the connection between the:
 - Goals of the project (e.g., reasons for proposing the intervention, if applicable);
 - Assumptions (e.g., beliefs about how the program will work and support resources, based research, best practices, and experience);
 - Inputs (e.g., organizational profile, collaborative partners, key personnel, budget, and other resources);
 - Target population (e.g., the individuals to be served);
 - Activities (e.g., approach, listing key intervention, if applicable);
 - Outputs (i.e., direct products of program activities); and
 - Outcomes (i.e., the results of a program, typically describing a change in people or systems).

Although there are similarities, a logic model is not a work plan. A work plan is an “action” guide with a timeline used during program implementation; the work plan provides the “how-to” steps. You can find additional information on developing logic models at the following website:

<http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf>.

- RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion [2 Response](#)

Discuss challenges you are likely to encounter in designing and implementing the activities described in the Work Plan, and approaches you will use to resolve such challenges. You must also describe any potential obstacles for implementing the program performance evaluation and how those obstacles will be addressed. Discuss possible challenges with EMSC recipients and how the challenges will be resolved.

- EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria [3 Evaluative Measures](#) and [4 Impact](#)
 - Evaluation:
 - Include an evaluation plan (Attachment 5) for the program performance evaluation that will contribute to continuous QI. This plan should monitor ongoing processes and the progress towards the goals, objectives, and requirements of the project. Each goal described in the methodology should include an evaluative measure to assess achievement. The plan should be capable of demonstrating and documenting measurable progress toward achieving the stated goals/objectives and link to improving the success of EMSC recipients and EMSC stakeholders in furthering the EMSC Programs' mission. Outline the extent to which relevant baseline measurements will demonstrate improvements in the selected measures when compared with subsequent measurements. Describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.
 - Personnel and Technical Support Capacity
 - Describe appropriate support staff to conduct the work of the project.
 - Application budgets must reflect the actual needs of the proposed project. Include staff experience and full-time equivalents (FTEs) allotted to carry out all aspects of this proposed project.
 - Describe the experience, skills, knowledge, and published materials for current and proposed staff. Describe the availability of staff and how their specific expertise will support each objective as described earlier in this NOFO. Staffing must include, at a minimum one (1) FTE to address database management and integration; one (1) FTE devoted to statistical methods and analysis; and one (1) FTE devoted to maintaining and expanding platforms to support EMSC performance measurements and pediatric readiness assessments.
 - The EMSC Program requires that funds for personnel and resources are allocated to demonstrate your commitment and capacity to execute and achieve each of the NOFO objectives within the timelines expected. Include a staffing plan and job descriptions for key personnel

in **Attachment 2** and biographical sketches for key personnel in **Attachment 3**.

- Describe the systems and processes that will support the organization's performance management requirements through effective tracking of performance outcomes. Include 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.
 - Discuss your organization's resources to accomplish the proposed goals, methods, and scope of activities described in the application.
 - Demonstrate your organization's knowledge of how to use other state and national data systems such as the National Emergency Medical Systems Information System (NEMSIS) to promote improved delivery of pediatric care at the national or state level.
 - Describe the organizational plan for the management of the project, including an explanation of the organizational roles and responsibilities of project personnel, project collaborators, and consultants.
- **ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion [5 Resources and Capabilities](#)**
- Provide information on the structure, resources, and infrastructure available at your institution to conduct the scope of current activities, and describe how these all contribute to the ability of your organization to serve as an EMSC Data Center.
 - Succinctly describe your organization's current mission, structure, and scope of current activities, and how these elements all contribute to the organization's ability to implement the program requirements and meet program expectations.
 - Include an organizational chart as **Attachment 4**.
 - Describe previous work of a similar nature in the past 5-10 years that demonstrates the ability to serve as an EMSC Data Center.
 - Highlight past experience related to managing a data center that demonstrates qualifications for the work described in this NOFO, specifically, successful collaboration with EMSC recipients, government entities, and national organizations working to integrate EMSC into the nation's health care systems.
 - Describe the resources available for carrying out the project and conducting its activities, including the capability for collecting and storing data in a secure way, the ability to conduct virtual meetings or trainings, as well as facilities and physical space, equipment, and information technology resources. You should include resources contributed by other agencies or organizations and describe their purpose.

- Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings.

iii. **Budget**

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

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

As required by the Consolidated Appropriations Act, 2021 (P.L. 116-260), Division H, § 202 and Division A of the FY 2022 Extending Funding and Emergency Assistance Act (P.L. 117-43), "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." See Section 4.1.iv Budget – Salary Limitation of HRSA's [SF-424 Application Guide](#) for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

iv. **Budget Narrative**

See Section 4.1.v. of HRSA's [SF-424 Application Guide](#).

In addition, the EDC Program requires the following:

Provide a narrative that explains the amounts requested for each line item in the budget. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. The budget period is for one year. However, you must submit one-year budgets for each of the subsequent budget periods within the requested period of performance (4 years) at the time of application. Line item information must be provided to explain the costs entered in the SF-424A. You must clearly explain how each item in the "other" category is justified. For subsequent budget years, the budget narrative should highlight the changes from year to year, or clearly state that no substantive budget changes are expected during the project period. The budget narrative **MUST** be concise. Do **NOT** use the budget narrative to expand the project narrative.

v. **Program-Specific Forms**

- 1) Performance Standards for Special Projects of Regional or National Significance (SPRANS) and Other MCHB Discretionary Projects

HRSA has modified its reporting requirements for SPRANS projects, Community Integrated Service Systems (CISS) projects, and other grant/cooperative agreement programs administered by MCHB to include national performance

measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, MCHB's authorizing legislation. Performance measures for other MCHB-funded grant/cooperative agreement programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect. An electronic system for reporting these data elements has been developed and is now available.

2) **Performance Measures for the Emergency Medical Services for Children Data Center**

Core	
C 1	Grant Impact
C 2	Quality Improvement
C 3	Health Equity
Capacity Building	
CB 2	Technical Assistance
CB 3	Impact Measurement
CB 5	Scientific Publications
CB 6	Products

To inform successful applicants of your reporting requirements, the listing of MCHB administrative forms and performance measures for this program can be found in Section "VI. Award Administration Information" of this NOFO.

NOTE: The performance measures and data collection information is for your PLANNING USE ONLY. These forms are not to be included as part of this application.

vi. **Attachments**

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limitation.** Your indirect cost rate agreement and proof of non-profit status (if applicable) will not count toward the page limitation. **Clearly label each attachment.** You must upload attachments into the application. Any *hyperlinked* attachments will *not* be reviewed/opened by HRSA.

Attachment 1: Work Plan

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

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

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

Attachment 3: Biographical Sketches of Key Personnel

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

Attachment 4: Project Organizational Chart

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

Attachment 5: Evaluation Plan

Provide an evaluation plan for the program performance that will contribute to continuous QI.

Attachment 6: Logic Model

Provide a logic model, a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements.

Attachment 7: Optional EDC Supplemental Funding

Provide a detailed description of the scope of the project to support building capacity to advance EMSC data integration and dissemination activities. The optional EDC Supplement may be up to 10 pages in length and does not count against the 80 page limit of the EDC application.

Attachments 8–15: 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 Agreement, Memoranda of Understanding, Descriptions of Proposed/Existing Contracts (project-specific), and/or Letters of Support*. Letters of support must be dated and specifically indicate a commitment to the project/program (e.g., in-kind services, dollars, staff, space, equipment).

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

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

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

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

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

For more details, see Section 3.1 of HRSA's [SF-424 Application Guide](#).

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

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

4. Submission Dates and Times

Application Due Date

The due date for applications under this NOFO is *January 18, 2022 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before**

the deadline to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA’s [SF-424 Application Guide](#) for additional information.

5. Intergovernmental Review

The Emergency Medical Services for Children Data Center 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 \$3,200,000 per year (inclusive of direct **and** indirect costs). This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project’s objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division H of the Consolidated Appropriations Act, 2021 (P.L. 116-260) and Division A of the FY 2022 Extending Funding and Emergency Assistance Act (P.L. 117-43) apply to this program. See Section 4.1 of HRSA’s [SF-424 Application Guide](#) for additional information. Note that these or other restrictions will apply in following fiscal years, as required by law.

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

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

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 critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

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

Six review criteria are used to review and rank Emergency Medical Services for Children Data Center applications. Below are descriptions of the review criteria and their scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's [INTRODUCTION](#) and [NEEDS ASSESSMENT](#)

The extent to which the application demonstrates:

- The purpose of the proposed project focusing on each major objective of the EDC.
- The significance of the project in terms of its potential impact for improving EMSC nationally.
- An understanding of the EMSC Program, and the role of a data-coordinating center to support state EMSC data collection systems.
- An understanding of the issues involved in implementing and collecting data on pediatric emergency care research.
- Relevant barriers in the field of pediatric emergency care that the project hopes to overcome.

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's [METHODOLOGY](#), [WORK PLAN](#) and [RESOLUTION OF CHALLENGES](#)

This section addresses the methodology, work plan, and resolution of challenges. The extent to which the proposed project responds to the program requirements specified in the "Purpose" section, included in the program description. The extent to which the activities described in the application are capable of addressing the problem and attaining the project objectives.

Sub-criterion Specific to Objective 1: Provide independent, comprehensive research support for large multi-center randomized clinical trials and other types of clinical research associated with PECARN (10 points)

The strength which the application describes and demonstrates:

- The ability to provide coordination for study design, implementation, and data analysis for the PECARN network.

- An adequate plan for providing support activities including training and data management that includes quality assurance procedures.
- An adequate plan for coordinating regulatory and clinical coordination functions for multiple sites and multiple studies (e.g., tracking IRB approvals, providing assistance to site investigators, monitoring site performance).
- An appropriate plan for creating public-use data sets that includes appropriate procedures for de-identifying datasets and secure procedures for providing data to external investigators.
- A clear understanding of the challenges inherent in collecting and processing multi-center data and meaningful solutions to address such barriers.
- The ability to assist with the dissemination of PECARN studies.

Sub-criterion Specific to Objective 2: Enhancing and collecting performance measure data that align with the combined efforts of the EMSC State Partnership (SP) and the EMSC Innovation and Improvement Center (EIIC) to expand and improve EMSC in states/jurisdictions (10 points)

The strength to which the application describes and demonstrates:

- An adequate plan to provide states with training and data-related TA, including assistance with data collection for the EMSC performance measures.
- An adequate plan to provide data-related assistance and training to EMSC SP and other EMSC award recipients, researchers, and national stakeholders.
- How the recipient will integrate activities with the overall goals and objectives of the EMSC Program.

Sub-criterion Specific to Objective 3: Collaborate with national partners to assess prehospital and hospital pediatric readiness initiatives to ensure equitable emergency services for all children in our nation (10 points)

The strength to which the application describes and demonstrates:

- An adequate plan for coordinating with national partners to develop, expand, and maintain data collection methods and portals, which enhance the National Pediatric Readiness Project and the National Prehospital Pediatric Readiness Project.
- An adequate plan for developing and maintaining web-based data collection portals to provide timely program feedback on prehospital EMS and EDs' degree of pediatric readiness.
- An adequate plan for providing access to data that supports effective QI strategies to increase prehospital EMS and EDs' capacity to provide up-to-date, evidence-based pediatric emergency services.

Sub-Criterion Corresponding to Section IV's WORK PLAN (5 points)

The extent to which the application demonstrates:

- The quality and feasibility of the work plan (Attachment 1) that effectively describes the activities or steps to be used in achieving each of the objectives proposed in the methodology section.
- The extent to which the application demonstrates an effective plan for managing the project, including its personnel and resources and activities to ensure consistent and timely, high-quality work.

Criterion 3: EVALUATIVE MEASURES (10 points) – Corresponds to Section IV’s [EVALUATION AND TECHNICAL SUPPORT](#)

The extent to which the methods proposed to monitor and evaluate the project results are effective, and the extent to which the evaluation plan describes and demonstrates:

- The ability to show that all project objectives have been met.
- Specific measures the applicant will use to monitor the services they provide to all EMSC award recipients.
- Sufficient identification of challenges likely to be encountered in the program implementation and the reasonableness of approaches to resolve identified challenges.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV’s [EVALUATION AND TECHNICAL SUPPORT](#)

- The extent to which the application demonstrates the ability to improve the success of EMSC award recipients and EMSC stakeholders (i.e., those involved in the delivery of emergency care to children or systems that support this effort) in furthering the EMSC mission.
- The extent to which the application describes the significance of the project in terms of its potential impact for improving EMSC nationally, specifically focusing on data collection, analysis, and utilization.

Criterion 5: RESOURCES/CAPABILITIES (25 points) – Corresponds to Section IV’s [EVALUATION AND TECHNICAL SUPPORT CAPACITY AND ORGANIZATIONAL INFORMATION](#)

Sub-Criterion Corresponding to Section IV’s Project Personnel (15 points)

The extent to which the available resources and personnel for administration of the EDC are fully described and can accomplish the proposed goals and scope of activities described in the application:

- The personnel or proposed personnel demonstrate necessary content area expertise to carry out all aspects of the proposed project, including describing how their roles and responsibilities align with proposed goals and activities.
- The applicant has the technical expertise to coordinate multi-center research trials including study design, statistical methods, data quality assurance, data management, human subject regulations, data safety monitoring boards, and coordinating functions including site monitoring and systems integration.

- The applicant demonstrates expertise in the ability to increase the working knowledge and capacity of EMSC award recipients to collect, analyze data, and use these findings to improve the delivery of pediatric care.
- The extent to which the applicant can plan, coordinate, and collaborate with national partners in data collection methods to enhance the National Pediatric Readiness Project and the National Prehospital Pediatric Readiness Project.
- The extent to which the applicant has the expertise and ability to support QI strategies that increase prehospital EMS and EDs' capacity to provide up-to-date, evidence-based pediatric emergency services.
- The applicant demonstrates knowledge of how to use other state and national data systems such as the National Emergency Medical Systems Information System (NEMSIS) to promote improved delivery of pediatric care at the national or state level.

Sub-Criterion - Organizational Capacity (10 points)

- The capabilities of the applicant and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project; the overall extent to which the applicant has the existing resources/facilities to support the project.
- The degree to which the applicant provides evidence of infrastructure capabilities in state data system development, research, administration, operational management, protocol development, clinical data information systems, and management of regulation documents.
- The extent to which the setting/parent institution of the applicant has the appropriate infrastructure to achieve project objectives and the extent to which the organizational and physical environment is supportive of the applicant and the project.
- The adequacy of the proposed plans for overall EDC management and operations, including those factors that will contribute to collaborative interactions.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's
BUDGET AND BUDGET NARRATIVE

- The reasonableness of the proposed budget in relation to the objectives, the complexity of the activities, the scope of the work, and the anticipated results.
- The extent to which the application budgets reflect the actual needs of the proposed project.
- The extent to which the application's staff experience and expertise allotted to this program will enable the applicant to carry out all aspects of this proposed project.

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](#).

3. Assessment of Risk

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

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

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

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

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

VI. Award Administration Information

1. Award Notices

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

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's [SF-424 Application Guide](#).

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

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

Accessibility Provisions and Non-Discrimination Requirements

Federal funding recipients must comply with applicable federal civil rights laws. HRSA supports its recipients in preventing discrimination, reducing barriers to care, and promoting health equity. Non-discrimination legal requirements for recipients of HRSA federal financial assistance are available at the following address:

<https://www.hrsa.gov/about/organization/bureaus/ocrdi#non-discrimination>. For more information on recipient civil rights obligations, visit the HRSA Office of Civil Rights, Diversity, and Inclusion [website](#).

[Executive Order on Worker Organizing and Empowerment](#)

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

Requirements of Subawards

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

Data Rights

All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced

under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by others. If applicable, the specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government’s copyright license and data rights.

3. Reporting

Award recipients must comply with Section 6 of HRSA’s [SF-424 Application Guide](#) and the following reporting and review activities:

- 1) **DGIS Performance Reports.** Available through the HRSA Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report **annually**, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at <https://grants4.hrsa.gov/DGISReview/ProgramManual?NOFO=HRSA-22-087&ActivityCode=UJ5>. The type of report required is determined by the project year of the award’s period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	July 1, 2022 - June 30, 2026 <i>(administrative data and performance measure projections, as applicable)</i>	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	July 1, 2022 - June 30, 2023 July 1, 2023 - June 30, 2024 July 1, 2024 - June 30, 2025	Beginning of each budget period (Years 2–5, as applicable)	120 days from the available date
c) Project Period End Performance Report	July 1, 2025 - June 30, 2026	Period of performance end date	90 days from the available date

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

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

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:

Devon Cumberbatch
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-7532
Email: dcumberbatch@hrsa.gov

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

Patricia L. Fanflik, PhD
Health Scientist, Emergency Medical Services for Children
Attn: Funding Program
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room #18N104B
Rockville, MD 20857
Telephone: (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
Telephone: 1-800-518-4726 (International callers dial 606-545-5035)
Email: support@grants.gov
[Self-Service Knowledge Base](#)

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

HRSA Contact Center
Telephone: (877) 464-4772 / (877) Go4-HRSA
TTY: (877) 897-9910
Web: <http://www.hrsa.gov/about/contact/ehbhelp.aspx>

VIII. Other Information

Technical Assistance

HRSA has scheduled following technical assistance:

Webinar

Day and Date: Thursday, November 4, 2021
Time: 3 – 4 p.m. ET
Call-In Number: 1-833-568-8864
Participant Code: 36697355
Weblink: [https://hrsa-
gov.zoomgov.com/j/1613682452?pwd=TWxRQWV2VDFPRlpxdFdNUkNEMWhx
dz09](https://hrsa.gov.zoomgov.com/j/1613682452?pwd=TWxRQWV2VDFPRlpxdFdNUkNEMWhxdz09)

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

Tips for Writing a Strong Application

See Section 4.7 of HRSA's [SF-424 Application Guide](#).

Appendix 1: Description of the EDC Supplemental Funding

EDC Supplemental Funding – (OPTIONAL: NOT SCORED DURING OBJECTIVE REVIEW. ATTACHMENT 7 DOES NOT COUNT AGAINST THE 80-PAGE LIMIT OF THE EDC. This attachment is only required if you are requesting additional funding. Applying for this additional funding does not impact the EDC application score. Additional funding will be finalized post-award.

You must apply for the EDC base funding to apply for this additional funding. The EDC supplemental funding narrative must be no longer than five (5) pages; this narrative (Attachment 7) does NOT count against the 80-page limit of the EMSC Data Center application.

Additional funds should be used to support the recipient in building their capacity to advance data integration and dissemination to improve and/or expand optimal pediatric emergency services and pediatric emergency readiness for the nation's children. The supplement is dependent on the availability of funds each year. Funds may be awarded in any of the 4 budget years for a funding period of one (1) year.

Your plan should include a detailed description of the scope of the project including purpose; gap in data integration that this project will address; data sources, data integration and harmonization strategies, and data analysis; dissemination plan for data set and/or findings; and assessment of the impact on EMSC. Possible foci for this project include, but are not limited to: expanding the PECARN data registry to more easily harmonize data integration, analysis, and dissemination of findings; strengthening the EMSC performance measure platform to more easily collect, integrate, and disseminate performance measurement data and pediatric readiness data to EMSC state partners; or expanding pediatric prehospital and hospital data collection platforms to incorporate non-represented agencies and hospitals including for example, tribal EMS agencies and EDs.

Your plan must document experience working with data integration and dissemination to produce improvements and expansions in EMSC.

A separate line item budget justification is required for the EDC supplement funding. You may request up to \$500,000 inclusive of indirect costs for the proposed additional funding.

Appendix 2: Additional Background on the Relationship between the EDC and PECARN

For more information on the topics below, see the HRSA-19-052 PECARN NOFO, available here: <https://www.hrsa.gov/grants/find-funding/hrsa-19-052>

Quality Control and Monitoring

PECARN sites comply with quality control and monitoring with federal studies as detailed by the external funding that the PECARN receives, including for protocols requiring an investigational new drug application. It will be the responsibility of the study principal investigator to oversee quality control and monitoring as defined by FDA rules and regulations, with support from EDC, as needed.

Concerning laboratory quality control and data management issues, the PECARN sites agree to participate in protocol-defined measures to follow methodological and analytic guidelines established by the EDC or PECARN and HRSA. All study sites must participate in multiple methods risk-based site monitoring by the EDC that may include onsite or remote monitoring methods.

Subject Safety/Oversight

The EDC establishes protocol-specific measures for PECARN sites to ensure 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. PECARN studies will comply with current IRB standards. PECARN research sites and the EDC are required to consult their applicable IRB or the Federal Office of Human Research Protection for any project that may utilize human subjects or data from human subjects. For the requirements of IRB review, visit <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

The principal investigator and all Hospital Emergency Department Affiliates investigators assume and accept the primary responsibility for ensuring PECARN studies are conducted in compliance with all federal regulations and PECARN policies and procedures. Since the EDC is responsible for storing, analyzing, and publishing data, as required by federal regulations, the EDC is also responsible for ensuring all PECARN protocols are submitted through an approved single or central IRB to obtain approval for the EDC's role in each study.

Documentation of IRB approval from all sites is needed before submission of data to the EDC. All PECARN and EDC investigators must agree and ensure that adequate records will be maintained, 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

All PECARN sites are required to adhere to an "adverse event tracking system" operated by the EDC. The EDC also provides guidance and training to sites on adverse events reporting.

Data Confidentiality

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.

The recipient must 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 and that established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III - Security of Federal Automated Information Systems available at: <https://www.cio.gov/policies-and-priorities/circular-a-130/> .

Publication of Data

PECARN has established publication policies and the EDC plays an integral role in assisting investigators with statistical analysis, manuscript preparation, and monitoring timelines for publications, as well as following those established policies. To ensure the availability of the best evidence for optimal pediatric emergency care, prompt and timely presentation and publication in the scientific literature of PECARN research findings is required.