

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Maternal and Child Health Bureau  
Division of Child, Adolescent, and Family Health

***Pediatric Emergency Care Applied Research Network (PECARN)***

**Funding Opportunity Number:** HRSA-19-052

**Funding Opportunity Type(s):** Competing Continuation, New

**Catalog of Federal Domestic Assistance (CFDA) Number:** 93.127

**NOTICE OF FUNDING OPPORTUNITY**

Fiscal Year 2019

**Application Due Date: March 8, 2019**

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

**Issuance Date: December 31, 2018**

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Authority: Public Health Service Act, Title XIX, Section 1910 (42 U.S.C. 300w-9).

## EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2019 Emergency Medical Services for Children Pediatric Emergency Care Applied Research Network (PECARN) program. The purpose of this program is to establish and maintain a multi-institutional research network that conducts high-quality, rigorous studies using pooled samples of pediatric patients to determine optimal pediatric emergency care. This Program will demonstrate an effective 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 acute illnesses and injuries in children and youth in hospital emergency departments and prehospital Emergency Medical Services settings.

Funding Opportunity Title:	Pediatric Emergency Care Applied Research Network (PECARN)
Funding Opportunity Number:	HRSA-19-052
Due Date for Applications:	March 8, 2019
Anticipated Total Annual Available FY 2019 Funding:	\$4,950,000
Estimated Number and Type of Award(s):	Up to seven cooperative agreements
Estimated Award Amount:	Up to \$700,000 per year, subject to the availability of appropriated funds:  Category I: Six at \$700,000 per year Category II: One at \$700,000 per year  <ul style="list-style-type: none"> <li>• A total of seven cooperative agreements at \$700,000 each.</li> <li>• Additionally, one site selected by the network as the PECARN Chair will receive an additional \$50,000.</li> </ul>
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2019 through August 31, 2023 (4 years)
Eligible Applicants:	Applications may be submitted by state governments and accredited schools of medicine. See <a href="#">Section III-1</a> of this notice of funding opportunity (NOFO) for complete eligibility information.

### **Application Guide**

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online at

<http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf>, except where instructed in this NOFO to do otherwise.

### **Technical Assistance**

HRSA has scheduled the following technical assistance:

#### *Webinar*

Day and Date: Tuesday January 8, 2019

Time: 2 p.m. ET

Call-In Number: 1-866-917-4660

Participant Code: 68594605

Weblink: [https://hrsa.connectsolutions.com/pecarn\\_nofa/](https://hrsa.connectsolutions.com/pecarn_nofa/)

An archive recording of the call will be available within a week of the call at:  
<https://mchb.hrsa.gov/fundingopportunities/>.

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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) Pediatric Emergency Care Applied Research Network (PECARN) Program, hereafter referred to as PECARN. The purpose of this program is to establish and maintain a multi-institutional research network that conducts high-quality, rigorous studies using pooled samples of pediatric patients to determine optimal pediatric emergency care.

## Goal

This Program will demonstrate an effective 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 acute illnesses and injuries in children and youth in hospital emergency departments (EDs) and prehospital Emergency Medical Services (EMS)<sup>1</sup> settings. PECARN studies that identify effective clinical practice directly inform efforts to spread and standardize the delivery of optimal pediatric emergency medicine across the nation, ultimately improving survival and health outcomes among children.

PECARN will consist of seven research nodes, as well as a [Data Coordinating Center](#) (DCC) (the DCC is funded by HRSA through a separate cooperative agreement). This NOFO solicits applications for the seven research node cooperative agreements. There are two categories of award. You may only apply for one category.<sup>2</sup>

- **Category 1 (Research Nodes):** Six awards at \$700,000 each. Each recipient of Category 1 funding will develop and maintain a group of three EDs and one co-located EMS agency,<sup>3</sup> resulting in a total of 18 EDs and 6 EMS agencies supported through this funding opportunity. Together these recipients will collectively conduct research and disseminate findings on the efficacy of treatment and management of acute illnesses and injuries in children.
- **Category 2 (EMS Research Node):** One award at \$700,000. This recipient will develop and maintain a network of three multi-state EMS agencies and provide leadership to and coordinate the six EMS agencies from Category 1 in an EMS Consortium to design and conduct multi-site prehospital EMS research across all nine EMS agencies.

Please see [Section II: Award Information](#) for the list of specific expectations of recipients.

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<sup>1</sup> NHTSA Office of EMS (n.d.). What is EMS? Retrieved October 18, 2018 at <https://www.ems.gov/whatisems.html>

<sup>2</sup> Multiple applications from an organization with the same Dun and Bradstreet Data Universal Numbering System (DUNS) number are not allowable. See Section IV: Application and Submission Information.

<sup>3</sup> Located within the catchment area of one of the participating Emergency Departments

## Activities

The PECARN network has four overarching activities that apply to both Categories unless otherwise indicated:

- 1) Conduct high priority, high-impact EMSC research using rigorous study designs and methodologies via a network of multi-site ED and prehospital EMS settings. Studies will be supported by a network organizational structure that ensures efficiency, productivity, fidelity of study implementation, and provides the ability to:
  - a) Develop research studies;
  - b) Obtain extramural funding for research studies;
  - c) Conduct multi-site clinical studies;
  - d) Publish and disseminate results of research studies; and
  - e) Develop early stage investigators<sup>4</sup> in the area of pediatric emergency medicine and ensure that these investigators are submitting research proposals to PECARN.
- 2) Establish and maintain a data infrastructure within the network and each site to ensure data are available for research and knowledge translation activities. Note: Category 1 applicants can choose either or both options below (Option A and/or B). Category 2 applicants must choose option A.
  - a) Option A: Link patient encounter data between at least one participating prehospital EMS agency and their associated hospital systems which will allow studies of both prehospital and hospital clinical care and associated health outcomes;
  - b) Option B: Identify at least one Hospital Emergency Department Affiliate to participate in the ED Data Registry managed by the DCC.
- 3) Develop and implement two network-wide plans that include both prehospital EMS and hospital research: (1) research priorities to help guide selection of study concepts, and (2) dissemination activities to facilitate translation of research results to clinical practice and to the stakeholder community.
- 4) Foster collaboration among ED and EMS personnel, nurses, practitioners, and researchers to expand research opportunities and ensure implementation of research findings.

## 2. Background

The EMSC Program is authorized by the Public Health Service Act, Title XIX, Section 1910 (42 U.S.C. 300w-9). The program works to ensure that all children and adolescents receive appropriate emergency medical care, no matter where they live, attend school, or travel. Legislation first passed by Congress in 1984 authorized the use of federal funds to expand and improve emergency medical services for children.

In 2015, an estimated 34 million children sought care in EDs in the United States, representing about a quarter of all ED visits.<sup>5</sup> The majority of pediatric ED visits occur

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<sup>4</sup> For example, see <https://grants.nih.gov/policy/early-investigators/index.htm>

<sup>5</sup> Whitfill T, Auerbach M, Scherzer DJ, Shi J, Xiang H, Stanley RM. Emergency Care for Children in the United States: Epidemiology and Trends Over Time. *The Journal of Emergency Medicine*. 2018 May 21, pp. 1-12.

in community hospitals where fewer than 15 pediatric patients are seen a day. In addition, less than 10 percent of prehospital EMS patient encounters are for pediatric patients.<sup>6</sup> When children experience an injury or critical illness requiring emergency care, the delivery of appropriate, effective clinical care is essential to improve survival and subsequent health outcomes. However, because most institutions treat children far less frequently than adults and because children have unique medical needs requiring specialized equipment and other resources,<sup>7</sup> research to define appropriate and effective care in the pediatric emergency medicine setting can be challenging. In particular, single institutions often do not treat a sufficient volume and variety of pediatric patients, especially those experiencing the same medical or trauma emergency, to derive conclusive results on the best course of treatment.

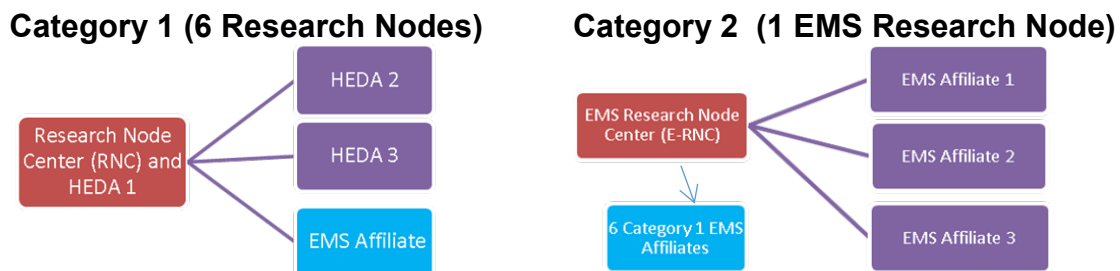
HRSA launched the PECARN program in 2001 to overcome these challenges, enabling recipients to collaborate across institutions and obtain the diverse, representative sample sizes needed to produce scientific evidence on effective, high quality care. Since 2001, HRSA has sustained funding for the PECARN program while modifying the design to encompass prehospital EMS research.

### PECARN Structure and Function

[PECARN](#) is an established research network with preexisting structures, policies, and procedures that will continue to apply to recipients of these new cooperative agreements. You need to understand the structures, functions, and activities of PECARN to verify that your proposed activities are in alignment with these policies and procedures. Network success is dependent on full participation of all recipients in functioning collaboratively and contributing to all aspects of network operations. The information below describes the PECARN Research nodes which will be funded through this NOFO, as well as the roles of the EMSC DCC and PECARN Committees.

#### Research Nodes

The Research Node is the operational unit of PECARN. There are two categories of Research Nodes, each of which consists of a Research Node Center (RNC) and affiliates. The RNC is the recipient for this NOFO and provides administration and operations support as well as scientific leadership and management of studies in their node.



**Category 1:** Each of the six Category 1 Research Node awards will consist of a Research Node Center (RNC), three Hospital Emergency Department Affiliates

<sup>6</sup> Data from the National Emergency Medical Services Information System (NEMSIS).

<sup>7</sup> Institute of Medicine Committee on the Future of Emergency Care in the US. Emergency care for children: growing pains. Washington, DC: National Academy Press; 2007.

(HEDAs) and an EMS affiliate. The RNC is co-located at one of the three HEDAs. The EMS affiliate must be within the catchment or service area of one of the HEDAs in order to promote linkage of prehospital and ED data systems to follow outcomes for patient encounters. The RNC has primary responsibility for:

- Establishing and maintaining a Research Node infrastructure;
- Building partnerships with the HEDAs and the EMS affiliate; and
- Providing the HEDAs and EMS affiliate with administration and operations support, communications, and quality assurance.

**Category 2:** The Category 2 EMS Research Node consists of a prehospital EMS Research Node Center (E-RNC) that includes three EMS affiliates in separate states. The E-RNC has primary responsibility for:

- Establishing and maintaining a Research Node infrastructure;
- Building partnerships with the three EMS affiliates;
- Providing the three EMS affiliates with administration and operations support, communications, and quality assurance; and
- Providing prehospital research leadership and coordination across the six EMS affiliates of the Category 1 recipients, forming one prehospital EMS Research Consortium within PECARN.

**Outcomes**

PECARN progress and impact will be assessed using the program outcomes and indicators below. Each applicant to this NOFO will propose quantifiable targets to achieve by the end of the period of performance (August 31, 2023) for each of the below listed indicators. Applicants may also propose additional outcomes and/or indicators.

<b>Program Outcomes</b>	<b>Quantifiable Indicators of Success</b>
Improved infrastructure for conducting high quality research on pediatric emergency care	# of studies implemented within each Hospital Emergency Department Affiliate and the prehospital EMS agency sites  Average # of days between IRB approval and first study participant enrollment at study sites  Average # of months from last patient enrollment to submitted manuscript(s) of study results
Increased number of studies designed and implemented, including studies that aim to identify and spread effective and appropriate clinical practices	# of research concepts proposed to the PECARN Steering Committee  # of protocols approved by the PECARN Steering Committee
Strengthened pipeline of extramural research funding for pediatric emergency medicine	# and percent of PECARN-approved study concepts receiving external grant funding
Improved volume and power of research findings due to data linkages	# of studies initiated using linked data between prehospital EMS and hospital settings



	# of Research Nodes submitting data to the PECARN data registry # of studies initiated using data from the PECARN data registry
Strengthened pipeline of researchers in pediatric emergency medicine	# of submitted research concepts submitted by future investigators and non-Principal Investigators
Expanded evidence base on effective and appropriate clinical care in pediatric emergency medicine	# of manuscripts submitted to peer reviewed journals # of publications cited as evidence within clinical practice guidelines published by pediatric emergency and medical care leadership organizations <sup>8</sup>
Increased dissemination and translation of PECARN research findings	# of scientific presentations at continuing education conferences for practicing prehospital EMS and hospital clinicians # of educational outreach activities to help the EMSC grantee network translate research findings into practice

**EMSC Data Coordinating Center (DCC)**

HRSA has established a central [DCC](#) under a separate cooperative agreement to provide PECARN Research Nodes funded under this NOFO with data collection and management, quality assurance, statistical analyses, and coordination of select PECARN activities. It also serves as a central repository for PECARN generated data, as well as a PECARN data registry housing ED data from participating Research Nodes. DCC activities are described in this NOFO at:

<https://mchb.hrsa.gov/fundingopportunities/?id=fca6e519-82ea-4bf8-b481-1267b651e776>

The purpose of the DCC is to assist the network in conducting multi-center clinical studies and provide information to assist HRSA in ensuring the efficiency and productivity of the network. All RNCs, HEDAs and EMS affiliates will cooperate with the DCC throughout the funding period to enable study monitoring and assure regulatory compliance and adherence to good clinical practices in all studies. In addition, they will cooperate with the DCC by implementing PECARN-wide data standards for collection and analysis of data generated under PECARN, and provide the DCC with timely data for purposes of monitoring the safety and progress of studies conducted under PECARN. Research Nodes will provide the DCC final study data according to schedules developed and approved by the Steering Committee. Study data collected by PECARN studies will be shared via a de-identified public use dataset will be made available by the DCC 3 years after the last patient completes the study and any follow-up. The purpose is to ensure further use and dissemination of research. See the [Appendix](#) for additional information on Site Monitoring Reporting to the DCC.

<sup>8</sup> Examples of such organizations include the American Academy of Pediatrics (AAP), Emergency Nurses Association (ENA), American College of Emergency Physicians (ACEP), National Association of EMS Physicians (NAEMSP), and National Association of State EMS Officials (NASEMSO).

## **PECARN Committees**

The RNCs, HEDAs, and EMS affiliates are expected to participate in PECARN Committees as described below.

*Executive Committee:* This committee consists of Principal Investigators (PIs) of the research nodes (known as the nodal PI), the PI of the DCC, and the HRSA Project Officer. The HRSA Project Officer is a liaison with the Executive Committee and reviews all decisions to ensure they fall within the scope of this cooperative agreement.

*Steering Committee:* This committee constitutes the primary governing body of PECARN. The voting membership of the committee consists of the PIs of each Research Node, the PI of the DCC, the HRSA Project Officer, and representatives from HEDAs and EMS affiliates. The Steering Committee is responsible for overseeing the scientific aspects of the network. The HRSA Project Officer reviews and concurs with committee decisions. The committee typically meets in person at least two times a year and may hold additional in-person meetings as needed. At least one meeting will be in the Washington, DC metro area and another meeting will be in a major U.S. city. The committee will also meet a minimum of three times virtually each year, and timing of the meetings will correspond to the needs of extramural grant development and submission.

## **PECARN Chairperson**

PECARN recipients identify a new Steering Committee Chairperson every 3 years to lead the Network and serve as a liaison to HRSA. The recipient that houses/supports the individual selected to be Chair will be awarded an additional \$50,000 annually to support the specific activities listed in the [Appendix](#).

Section II (Award Information 1) of this NOFO provides additional details on required roles and responsibilities of HRSA, the RNCs, HEDAs, and participating EMS affiliate sites for this application.

## **PECARN Results to Date**

PECARN has the capacity to answer long-standing, important clinical questions in pediatric emergency medicine, largely due to its ability to conduct randomized controlled trials and clinical studies on a large scale. PECARN has leveraged the analytical power of the HRSA-supported network infrastructure to seek research funding from entities like the National Institutes of Health, experiencing a 70 percent success rate for all external grant proposals. Since its inception, PECARN has implemented 34 multi-center research studies and published more than 140 peer-reviewed publications and 140 abstracts for conference presentations. In addition, more than 117,000 children have been enrolled in PECARN studies.

PECARN studies have increased provider knowledge and resulted in practice change. For example, the PECARN Head Injury study<sup>9</sup> resulted in a clinical decision rule designed to accurately identify children at very low risk of brain injury after head trauma.

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<sup>9</sup> Kuppermann N1, Holmes JF, Dayan PS, et.al. Pediatric Emergency Care Applied Research Network (PECARN). Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study. *Lancet*. 2009 Oct 3;374(9696):1160-70

This finding changed practice and reduced unnecessary radiation exposure for children.<sup>10,11,12</sup>

Other questions that PECARN studies have answered include:<sup>13</sup>

- Do steroids work for children with bronchiolitis?
- When can CT scans for children be avoided after head injury?
- When can CT scans be avoided after abdominal injuries?
- Can RNA technology be used to determine whether infants with fever have a bacterial or viral infection?
- What is the best treatment for children with Status Epilepticus?
- Is it safe to give children with Diabetic Ketoacidosis intravenous fluids?

### **Additional Background**

- More information about PECARN is available at <http://www.pecarn.org>.
- All participating Research Nodes, HEDAs, and EMS affiliates must agree to abide by PECARN study protocols and PECARN policies and procedures available at: <http://www.pecarn.org/helpfulResources/documents/Approved%20PECARN%20Policies%2008.07.18.pdf>.
- PECARN has developed a logic model illustrating the relationships between network activities and goals available at: [http://pecarn.org/helpfulResources/documents/PECARN\\_Logic%20Model%2008.08.18.pdf](http://pecarn.org/helpfulResources/documents/PECARN_Logic%20Model%2008.08.18.pdf)
- The [Appendix](#) includes additional information about PECARN functions and reporting requirements.

PECARN should prioritize studies in critical illness or trauma that are likely to have a high impact on the clinical care and health outcomes for children, and/or studies of rare events requiring pooling of samples from multi-center research sites. Examples of these study topics would include shock, sepsis, seizure, respiratory illness, cardiac arrest, and behavioral health. Applicants should also remember the emphasis that HRSA is placing on opioid and substance use disorder, and applications featuring studies in this space would also be welcomed. Building on the history of PECARN, HRSA is introducing changes in this Notice designed to more effectively demonstrate how the Network can fill gaps in the clinical evidence needed to define optimal pediatric emergency care and ultimately improve survival and health outcomes of children who require emergency care.

These changes include:

- Fully integrating a multi-state EMS Research Node to lead the EMS research within PECARN to strengthen the PECARN research in the prehospital EMS setting.
- Adding a focus on improving data systems and linkages to allow for ongoing assessment and research, information on health outcomes, and to promote translation of studies to clinical practice.

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<sup>10</sup> Dayan PS, Ballard DW, Tham E, et.al. Use of Traumatic Brain Injury Prediction Rules With Clinical Decision Support. *Pediatrics*. 2017 Apr;139(4). e2 0162709

<sup>11</sup> For more information, see: <https://www.mdcalc.com/pecarn-pediatric-head-injury-trauma-algorithm>

<sup>12</sup> Jennings RM, Burtner JJ, Pellicer JF, et.al. Reducing Head CT Use for Children With Head Injuries in a Community Emergency Department. *Pediatrics*. 2017 Apr;139(4);2016-1349.

<sup>13</sup> Information on PECARN and publications can be found at: <http://www.pecarn.org/>

## **II. Award Information**

### **1. Type of Application and Award**

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

Funding will be provided in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

#### **HRSA program involvement will include:**

- 1) Assuring the availability of HRSA personnel to participate in the planning and development of all phases of PECARN;
- 2) Participating in, including the planning of, meetings conducted during the period of the cooperative agreement including, but not limited to, Executive Committee and Steering Committee meetings;
- 3) Reviewing meeting agendas and network policies and procedures established for conducting project activities;
- 4) Reviewing research concepts, protocols, or award submissions prior to their consideration before the full Steering Committee;
- 5) Facilitating and monitoring recipients' compliance with NOFO requirements and participating in periodic meetings and/or communications with recipients to assess progress;
- 6) Participating, as appropriate, in the dissemination of research findings, best practices, and lessons learned from the project; and
- 7) Facilitating effective collaborative relationships with federal and state agencies, HRSA-funded grants, and other entities relevant to the project's mission.

#### **The cooperative agreement recipient's responsibilities will include:**

- 1) The Research Node Centers will establish written agreements with their HEDAs and EMS affiliates that include, at a minimum:
  - a. A statement of work defining the goals and objectives of the projects to be undertaken through this cooperative agreement;
  - b. A budget for support of the projects that clearly identifies the personnel, equipment, materials, and other costs required to successfully conduct high quality work according to the requirements of specific PECARN protocols and policies;
  - c. Financial and program reporting requirements, including access to data and materials, to facilitate PECARN operations and project oversight and monitoring;
  - d. A requirement that each HEDA have a designated lead investigator and each EMS affiliate have a lead scientific advisor (Category 1) or investigator (Category 2) who agrees to fully cooperate with the Steering Committee, DCC, and HRSA to assure proper implementation of PECARN studies;
  - e. A plan for nodal communication and quality assurance;

- f. For Category 1 recipients, a requirement that the catchment area of the EMS affiliate must be within the catchment area of at least one of the HEDAs and that the EMS affiliate leadership such as the Medical Director is involved; and
  - g. A description of resources provided pertaining to:
    - 1. Staffing and training needed to implement a study protocol;
    - 2. A training and monitoring system to ensure protocol-specific requirements;
    - 3. Additional assistance such as quality control to ensure the successful completion of the scientific goals of the research project.
- 2) Responsibilities of the HEDAs and EMS affiliates include:
- a. Initiating and participating in the development of concepts and protocols of observational studies and clinical trials to be conducted by the network;
  - b. Participating in research studies approved by the Steering Committee and education training programs required for each study protocol;
  - c. Enrolling adequate numbers of representatively diverse research participants required for studies;
  - d. Providing routine clinical care to patients participating in protocols and experimental/standard care in accordance with approved research protocols;
  - e. Maintaining patient records and essential documents required for each protocol and permit site monitors to examine those records;
  - f. Collecting clinical and laboratory data for research purposes, including biological specimens when indicated;
  - g. Adhering to all policies established by the RNC and the Steering Committee;
  - h. Collecting and submitting study data in a timely manner to the DCC in accordance with Steering Committee, HRSA, and DCC policies;
  - i. Agreeing to not report data prior to collaborative reporting by PECARN;
  - j. Possessing adequate information technology and systems supported by each site's designated institutional staff;
  - k. Agreeing to multi-faceted site monitoring by representatives of its RNC, DCC, HRSA (or designees) for use of treatments, compliance with protocol specifications, quality control, accuracy of data recording, and completeness of reporting of adverse reactions to treatments;
  - l. Adhering to good clinical practice and other regulatory requirements concerning human subjects protections (including all federal, institutional, and PECARN defined policies and procedures);
  - m. Attending relevant PECARN meetings and participating in subcommittees and working groups;
  - n. Working cooperatively with HRSA, other recipients, and the DCC, and complying fully with all protocol requirements of each study;
  - o. For EMS affiliates, establishing data linkages between prehospital and HEDA hospital systems.

- 3) Additional responsibilities of all recipients:
  - a. Participate in a national EMSC grantee meeting in (in Years 2 and 4) as described in the Section IV. *Application and Submission Information/ iv. Budget narrative*.
  - b. Work with the DCC to create a de-identified public use dataset from study data that will be available three (3) years after completion of all follow-up procedures for the final subject enrolled in the study.
  - c. Collaborate with the HRSA Project Officer and the DCC in the collection and reporting of ongoing Research Network impact data such as number of research studies, study enrollees, publications, investigators, and mentees.

## 2. Summary of Funding

HRSA expects approximately \$4,950,000 to be available annually to fund a total of seven recipients (six in Category 1 and one in Category 2). You may apply for a ceiling amount of up to \$700,000 total cost (includes both direct and indirect, facilities and administrative costs) per year or \$750,000 if you wish to be considered as the PECARN Chairperson. If you are interested in being considered for the PECARN Chairperson supplement, include a statement in the application indicating this, along with a proposed budget narrative for the supplemental amount (up to \$50,000 for direct and indirect costs). However, do not include this amount in your SF-424A nor the total requested amount.

The period of performance is September 1, 2019 through August 31, 2023 (4 years). Funding beyond the first year is subject to the availability of appropriated funds for the EMSC Program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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

## III. Eligibility Information

### 1. Eligible Applicants

Eligible applicants 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 section 799B(1)(A) of the Public Health Service Act (42 U.S.C. 295p(1)(A)).<sup>14</sup>

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

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<sup>14</sup> See definition at: <https://www.law.cornell.edu/uscode/text/42/295p>

that applicant and make the award to the next eligible applicant, ensuring compliance with this statutory restriction.

## 2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

## 3. Other

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

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

NOTE: Multiple applications from an organization with the same DUNS number are not allowable.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

## IV. Application and Submission Information

### 1. Address to Request Application Package

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

If you're reading this notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) and reviewing or preparing the workspace application package, you will automatically be notified in the event HRSA changes and/or republishes the NOFO on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the [For Applicants](#) page for all information relevant to desired opportunities.*

## 2. Content and Form of Application Submission

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

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

### **Application Page Limit**

The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

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

### **Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification**

- 1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
- 3) Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included as an Attachment: Other Relevant Documents.

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

### **Program-Specific Instructions**

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

#### ***i. Project Abstract***

See Section 4.1.ix of HRSA's [SF-424 Application Guide](#). Include the information requested at the top of the abstract. Clearly indicate Category 1 or Category 2.



Prepare the abstract so that it is clear, accurate, concise and without reference to other parts of the application because it is often distributed to provide information to the public and Congress. Briefly state the problem, goals and objectives, proposed activities, coordination, anticipated products and plans for evaluation.

**ii. Project Narrative**

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and well organized so that reviewers can understand the proposed project. **Unless otherwise stated, the narrative elements described below apply to both Category 1 and Category 2.**

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

- Section I. Background and Significance
- Section II. Goals and Objectives
- Section III. Project Design: Methods and Evaluation
- Section IV. Capability of RNC, HEDAs, and EMS Affiliate
- Section V. Organizational Information

**Section I – Background and Significance –Corresponds to Section V’s Review Criterion #1 Need**

- Identify needs, challenges, and gaps in conducting pediatric emergency care research in both ED and prehospital EMS sites, and of using evidence-based research to improve the care of children.
- Provide an assessment of high priority research needs in pediatric emergency care, the current literature available to inform those study designs, and the opportunities for multi-site research studies to address these needs and advance the field.
- Demonstrate a thorough knowledge and understanding of multi-site pediatric emergency care research across the EMS continuum and in ED and/or prehospital EMS agency settings.

**Section II – Goals and Objectives –Corresponds to Section V’s Review Criteria # 2 Response, #3 Evaluative Measures and #4 Impact**

This section of the narrative must include:

- A numbered list of the proposed goals and objectives to be accomplished by your research node during the funding period that address the major network goals, activities and expectations described in this NOFO in Sections 1: Program Funding Opportunity Description and Section 2: Award Information. Objectives should be SMART (specific, measurable, attainable, realistic, and time-bound).
- Targets for each of the indicators listed in the table in the Purpose section of this NOFO.
- A description of activities and steps to achieve each of the project goals.
- An implementation schedule/timeline for the activities presented in a succinct manner, with a brief listing of responsible staff, specific milestones, and expected outcomes.
- Although you are not required to submit a logic model with your application, you should review the PECARN logic model

([http://www.pecarn.org/helpfulResources/documents/PECARN\\_Logic%20Model%2008.08.18.pdf](http://www.pecarn.org/helpfulResources/documents/PECARN_Logic%20Model%2008.08.18.pdf) ). Goals and objectives should be consistent with this logic model.

**Section III – Project Design: Methods and Evaluation** –Corresponds to Section V’s Review Criteria # 2 Response, # 3 Evaluative Measures, and #4 Impact.

A. **Methods:**

- Provide detailed descriptions of the methodology for accomplishing each of the specific goals, objectives, and activities.
- Describe how the health providers and/or researchers will function in partnership with the network in terms of study origination, design, execution, and administration.
- Describe plans to ensure clear roles, effective communication, and quality assurance across the node.
- Describe how prehospital to hospital data linkages will be established, and whether you plan to participate in the PECARN ED data registry, including the availability of adequate IT support, data use agreements, data storage, and allocated expertise and agreements.
- Describe plans and processes for engaging stakeholders (ED providers, EMS agencies, and other providers across the EMS continuum) in order to broaden the scope of Network research.
- Describe the process for generating and reviewing research ideas generated by the Research Node.
- Describe how research findings will be disseminated and adopted into clinical practice across the EMS care continuum.
- Include two Research Concepts as **Attachment 3**. A key aspect of successful participation in PECARN is the ability to generate research ideas and proposals. To demonstrate the ability to generate such ideas, two concept proposals must be submitted. At least one of these proposals must describe knowledge translation project that tests effective mechanisms to spread uptake of new clinical evidence into widespread practice. One concept proposal should be for the prehospital setting. These concept proposals should be no more than two pages each in length and address the following; (1) The topic’s significance, including how results will be readily applicable to improving clinical care; (2) Specific objectives; (3) Methods (study design, statistical sampling frame, and plan for evaluation); and (4) Funding Plan (identify potential plans to attain extramural funding for research projects). *Note: These concept proposals are a demonstration of ability only. Implementation of these ideas will need to follow applicable PECARN bylaws.*

B. **Evaluation:**

- Describe a plan for monitoring and evaluation that includes monitoring nodal processes and the progress towards achieving the project’s goals and objectives. This plan should also address the success of the RNC, HEDA sites, and EMS affiliate in enrolling patients in studies, contributing new research ideas to PECARN, writing grants to acquire extramural funding for specific PECARN studies, and timely publication of research findings.

- Discuss how the RNC will monitor HEDA and EMS affiliate site performance and include plans for assisting sites experiencing challenges or that do not meet performance targets.
- Describe potential problems and challenges that may arise in this project, and propose mechanisms for collaborative resolution among the Research Node participants.

**Section IV – Capability of RNC, HEDAs, and EMS Affiliate Sites** –Corresponds to Section V’s Review Criteria #2 Response and #5 Resources/Capabilities

A significant portion of the review criteria is focused on the ability to demonstrate historic success with conducting pediatric emergency medicine research and enrolling patients in interventional and observational studies. Applications must address the following:

- Document previous experience and demonstrable success in pediatric emergency care research and in enrolling patients in the ED and prehospital EMS settings in both randomized intervention trials and observational studies.
- Describe the availability of necessary infrastructure and staff with relevant experience to support both ED and prehospital research.
- Include letters of commitment from participating HEDAs and EMS Affiliates (**Attachment 1**)
- Include notation of access to an Institutional Review Board (IRB) or a Central IRB and experience with exemptions from informed consent. Describe procedures for obtaining IRB approval for PECARN research protocols. Include specific information on the frequency of IRB meetings and typical review times for study protocols at each HEDA site. Historical information for the amount of time needed to obtain IRB approval for the studies described above should be included.
- Highlight experience establishing electronic data collection system and data linkages for prehospital and hospital systems and with providing data to an ED Data Registry.
- For EMS affiliates, describe involvement of EMS affiliate leadership and the Medical Director in this collaboration. A Letter of Support should be included.
- Describe the proposed catchment areas covered by the HEDAs and the EMS affiliates. Explain how they will support research focused on improving care and outcomes across the EMS care continuum.
- Provide additional demographic data for the sites as described below:

**Category 1:** The following information must be included for each HEDA site:

- 1) Total number of pediatric ED visits at the HEDA site.
- 2) Characteristics of pediatric ED visits (demographics, percent trauma versus medical and other available statistics such as types of conditions).
- 3) Structure of each HEDA site that facilitates ED research (for example, resources available at the site such as electronic health records, presence of trained research personnel, trauma center designation, etc. that create a conducive environment to conduct research).
- 4) List of ED-based studies that the HEDA site has participated in during the past 5 years that enrolled pediatric patients. For each study, provide a table that includes the following information:

- a. Brief description of the study including study type (interventional versus observational);
  - b. Number of patients enrolled at the HEDA site. For multi-center studies: Percent of patients enrolled at the HEDA site (i.e., number of patients enrolled at the site divided by total patients enrolled across all sites).
- 5) Qualifications and experience of the HEDA PI (including the RNC PI if he/she is serving as the HEDA PI). The following specific items should be included (can be included in the biosketches- **Attachment 2**):
  - a. Major publications of the HEDA PI that involved a pediatric emergency medicine research study. Highlight noteworthy publications.
  - b. Noteworthy grants/contracts obtained by the HEDA PI to conduct pediatric emergency medicine studies.

**Category 1 and Category 2:** The following information must be included for each EMS affiliate site:

- 1) EMS agency demographics (total population served, total population under age 21, square miles in catchment area, number of annual EMS calls, number and percent of annual pediatric calls, types of conditions, highest level of care, number of paramedics).
- 2) Structure of each EMS affiliate site that facilitates EMS research.
- 3) List of EMS-based studies that the site has participated in during the past 5 years that enrolled pediatric patients. For each study, provide a table that includes the following information:
  - a. Brief description of the study including study type;
  - b. Number of patients enrolled at the EMS site. For multi-center studies, include percent of total patients enrolled at the EMS site (i.e., number of patients enrolled at the site divided by total patients enrolled across all sites).
- 4) Involvement in data collection and analysis (including activities related to quality improvement as well as research studies).
- 5) Qualifications and experience of the EMS affiliate scientific advisor (Category 1) or EMS Affiliate PI (Category 2), including major publications or grants to conduct pediatric emergency care research.

**Section V: – Organizational Information**—Corresponds to Section V’s Review  
Criterion # 5 Resources/Capabilities

- Provide a description of the organizational plan for management of the project, including an explanation of the roles and responsibilities of project personnel, project collaborators, and consultants.
- Include an organizational chart (**Attachment 4**) that describes the functional structure of the Research Node Center, HEDAs, and EMS affiliate personnel.
- Describe the Research Node operation and the relationship between the research, clinical practices, and administrative functional units within the Research Node.
- Describe the capability of the RNC PI to lead the Research Node and the responsibilities of all key personnel. Note: This section should focus on the ability of the RNC to serve as a coordinating node and of the PI of this application to provide leadership to the node and to PECARN; information provided about the RNC as a HEDA site in Section III does not need to be repeated.

- For competing continuation applications only, include a progress report (**Attachment 5**).

<b>NARRATIVE GUIDANCE</b>	
To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.	
<u><b>Narrative Section</b></u>	<u><b>Review Criteria</b></u>
Background and Significance	(1) Need
Goals and Objectives	(2) Response and (4) Impact
Project Design: Methods and Evaluation	(2) Response; (3) Evaluative Measures; and (4) Impact
Capability of RNC, HEDAs, and EMS Affiliate Sites	(4) Impact and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative (below)	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

### **iii. Budget**

See Section 4.1.iv of HRSA’s [SF-424 Application Guide](#). Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions included in the Application Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for funding, you will have a well-organized plan and by carefully following the approved plan can 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) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245), Division B, § 202 states, “None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.” See Section 4.1.iv Budget – Salary Limitation of HRSA’s [SF-424 Application Guide](#) for additional information. Note that these or other salary limitations may apply in the following FY, as required by law.

#### **iv. Budget Narrative**

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

In addition, the PECARN program requires the following:

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

- The nodal PI (the applicant) at a minimum of 20 percent Full Time Equivalent (FTE). The PI may also serve as the site PI for their HEDA site. The PI serving as Chair should anticipate an additional 5 percent FTE.
- A nodal administrator (NA) at each RNC with a minimum of 75 percent FTE to support the activities of the Research Node and PECARN administration.
- Funding at 10 percent FTE for a HEDA PI at each of the two HEDA sites and a scientific advisor for the EMS affiliate.
- A full-time (100 percent FTE) Research Coordinator (RC) for each HEDA and 50 percent RC for the EMS affiliate.
- Each recipient will be expected to contribute to the leadership of the network by chairing subcommittees or serving as the Chair or Vice Chair of the PECARN Steering Committee. Each recipient should plan to budget an additional 5 percent of time for the nodal PI or a HEDA PI to serve in this role. There are four major PECARN subcommittees and three Steering Committee leadership positions so each recipient should budget for 1-2 leadership positions.

**Travel:** The following travel is **required** to be budgeted:

- Travel expenses for the nodal PI, the HEDA PI, the EMS affiliate scientific advisor, the NA, and the RC (and other persons as needed) to attend up to two in-person Steering Committee meetings a year. At least one meeting will be held in the Washington, D.C. area and the other in a major U.S. city.
- Travel funds required for two individuals (the nodal PI and another individual with a designated role in the project, usually the NA) per site to attend the EMSC program's award recipient meeting (held on Years 2 and 4).
- Travel expenses for the PI and NA to attend one executive committee meeting a year in the Washington, DC area. For budgeting purposes, this meeting can be combined with the EMSC Award Recipient meeting listed above **by adding a day** to the EMSC Award Recipient meeting.
- There may be Steering Committee meetings in which the agenda includes information or training for RCs. Thus, at least one research coordinator from each site should be budgeted for travel twice a year for study related trainings.
- Travel for delivering presentations at scientific meetings should be budgeted as appropriate.

**Registration/Meeting Expenses:** Each Research Node should budget an estimated \$5,000 per meeting (total of \$10,000 per year) to cover PECARN meeting expenses such as room rental, audiovisual costs etc. The EMSC Innovation and Improvement Center (funded by a separate cooperative agreement from HRSA EMSC)<sup>15</sup> coordinates

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<sup>15</sup> Information is available at: <https://emscimprovement.center/>

the meeting logistics in partnership with PECARN and hotel meeting costs are invoiced to recipients.

**v. Program-Specific Forms**

Program-specific forms are not required for application.

**vi. Attachments**

Provide the following items in the order specified below to complete the content of the application. Unless otherwise noted, attachments count toward the application page limit. Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. You must clearly label each attachment

**Attachment 1: Letters of Commitment**

Provide a letter of agreement from each HEDA and EMS affiliate site that includes their agreement to participate in the project as outlined in this NOFO. Letters of commitment must be dated.

**Attachment 2: Biographical Sketches**

Include biographical sketches for the HEDA PIs, EMS affiliate Scientific Advisors, Nodal Administrator, and other key positions, not to exceed two pages in length each.

**Attachment 3: Concept Proposals**

Include two concept proposals that demonstrate the ability to generate relevant ideas. At least one proposal should describe a knowledge translation project that tests effective mechanisms for spreading uptake of new clinical evidence into widespread practice. Each concept proposal should be no more than two pages in length and address the components described in the Narrative guidance.

**Attachment 4: Organizational Chart**

**Attachment 5: Progress Report (FOR COMPETING CONTINUATIONS ONLY)  
(Counted in page limit)**

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

The progress report should be a brief presentation of the accomplishments, in relation to the objectives of the program during the period of performance. The report should include: (1) The period covered (dates); (2) Specific objectives - Briefly summarize the specific objectives of the project; and (3) Results - Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.

### ***Attachments 6-15: Other Relevant Documents***

You may provide additional attachments to complete the content of the application. Please note that these are supplementary in nature, and are not intended to be a continuation of the project narrative. Such additional attachments will count toward the 80-page application limit. Label each clearly. Examples of other attachments include:

- Letters of Support: Letters of agreement and support must be dated. They can be summarized or listed on one page and may be requested by the HRSA Project Officer at any time but may also be included in the application at your discretion.
- Tables, charts, or other materials to give further details about the proposal.
- Bibliography of published or accepted manuscripts that demonstrate involvement in multi-center trials.

### **3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management**

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

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

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

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

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

**UPDATED [SAM.GOV](#) ALERT:** For your SAM.gov registration, you must submit a [notarized letter](#) appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018. Read the [updated FAQs](#) to learn more.



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

#### **4. Submission Dates and Times**

##### **Application Due Date**

The due date for applications under this NOFO is *March 8, 2019 at 11:59 p.m. Eastern Time*. HRSA suggests submitting applications to Grants.gov at least **3 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**

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

See Section 4.1 ii of HRSA’s [SF-424 Application Guide](#) for additional information.

#### **6. Funding Restrictions**

You may request funding for a period of performance of up to 4 years, at no more than \$700,000 per year (inclusive of direct **and** indirect costs). If appropriate, a potential Chair site can request up to \$750,000. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project’s objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division B of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245) apply to this program. Please see Section 4.1 of HRSA’s [SF-424 Application Guide](#) for additional information. Note that these or other restrictions will apply in the following FY, 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 those for all other applicable grants requirements, the effectiveness of these policies, procedures and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at [45 CFR § 75.307](#).

## V. Application Review Information

### 1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review of applications 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. See the review criteria outlined below with specific detail and scoring points.

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 the objective review process except for the competing continuations' progress report, which will be reviewed by HRSA program staff after the objective review process. Unless otherwise stated, the criteria described below apply to both Category 1 and Category 2.

Review criteria are used to review and rank applications. The PECARN program has six review criteria:

- Criterion 1: NEED (10 points)
  - Criterion 2: RESPONSE (30 points)
  - Criterion 3: EVALUATIVE MEASURE (10 points)
  - Criterion 4: IMPACT (10 points)
  - Criterion 5: RESOURCES/CAPABILITIES (30 points)
  - Criterion 6: SUPPORT REQUESTED (10 points)
- TOTAL Points: 100

*Criterion 1: NEED (10 points) – Corresponds to Section IV's #I Background and Significance*

The extent to which the application:

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

*Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's # II Goals and Objectives and # III Project Design*

**Sub-criterion: Goals and Objectives (10 points)**

The extent to which the application:

- Effectively responds to program purpose, goals, and expectations described in described in this NOFO in Sections 1: Program Funding Opportunity Description and Section 2: Award Information.
- Includes clear and comprehensive goals and objectives that clearly align with the proposed project activities, including the extent that stated objectives are SMART

(specific, measurable, attainable, realistic, and time-bound) and consistent with the PECARN logic model.<sup>16</sup>

- Includes activities described in the application that are effective and feasible and capable of addressing the problem(s) and attaining the project objectives.
- Includes a feasible and complete implementation schedule for the activities.

### **Sub-criterion: Project Design Methods (20 points)**

The extent to which the application:

- Includes a detailed and effective methodology.
- Describes how the health providers and/or researchers will function in partnership with the network and includes a plan to ensure clear roles, nodal communication, and quality assurance.
- Describes a feasible plan to implement data linkages between the EMS Affiliates and the ED/hospital and if appropriate, participate in the ED Data Registry.
- Describes effective strategies to engage stakeholders across the EMS continuum in research generation.
- Describes a clear and feasible process to generate and review research ideas generated in the Research Node.
- Describes an effective plan to disseminate research findings and support adoption within clinical practice across the EMS care continuum.
- Demonstrates research capacity as evidenced through two quality research concepts with the required components, with at least one concept describing a knowledge translation study and one designed for the prehospital EMS setting.

### *Criterion 3: EVALUATIVE MEASURES (10 points) – Corresponds to Section IV's # III Project Design:*

The extent to which the application:

- Proposes appropriate and realistic targets for each of the indicators of Program Outcomes established in the Purpose section of this NOFO.
- Proposes effective methods to monitor and evaluate progress towards the goals and objectives.
- Identifies an effective continuous monitoring plan for ensuring success of the HEDA sites and EMS affiliates in enrolling patients in studies, contributing new research ideas to PECARN and writing grants to acquire extramural funding for specific PECARN studies and timely publication of research findings.
- Includes a feasible strategy for remediating sites not meeting performance metrics.
- Identifies potential challenges and mechanisms to address them, which reflect a collaborative approach to resolution.

### *Criterion 4: IMPACT (10 points) – Corresponds to Section IV's # II: Goals and Objectives and # III: Project Design*

The extent to which the application:

- Proposes clear objectives, activities and an infrastructure that effectively demonstrates the ability to conduct successful pediatric emergency care research and determine optimal clinical care.

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<sup>16</sup> [http://pecarn.org/helpfulResources/documents/PECARN\\_Logic%20Model%2008.08.18.pdf](http://pecarn.org/helpfulResources/documents/PECARN_Logic%20Model%2008.08.18.pdf)

- Proposes objectives and methods that will directly fill gaps in clinical evidence in order to define optimal pediatric emergency care.
- Describes effective methods to support dissemination of research findings and accelerate their adoption to clinical practice across the EMS care continuum.

*Criterion 5: RESOURCES/CAPABILITIES (30 points) – Corresponds to Section IV's # IV Capability of RNC, HEDA, and EMS Affiliate Sites and # V Organizational Information*

**Sub-criterion: Capabilities and Resources (20 points)**

The extent to which the application:

- Highlights relevant previous experience and demonstrable success in pediatric emergency care research and in enrolling patients in the ED and prehospital EMS settings, including in both randomized intervention trials and observational studies.
- Demonstrates an effective infrastructure to support both ED and prehospital EMS research.
- Includes required letters of commitment from each HEDA and EMS Affiliates, describing clearly the nature of the collaborative relationship.
- Includes information on access to an IRB or central IRB and experience with exemptions from informed consent.
- Discusses credible involvement of EMS affiliate leadership and the Medical Director in this collaboration and includes Letter of Support.
- Includes an appropriate description of how an electronic data collection system and data linkages will be established and, if applicable, participation in the ED Data Registry.
- Includes the required demographics and other components in the description of the catchment areas for the HEDAs and EMS affiliates that demonstrate an infrastructure for research and the extent to which the data are complete.
- Includes experience with leading pediatric emergency medicine research through successful grant applications and publications.

**Sub-criterion: Organizational Information (10 points)**

The extent to which the application:

- Provides an effective description of the organizational plan for management of the project, including an explanation of the roles and responsibilities of project personnel, project collaborators, and consultants.
- Includes an organizational chart that clearly describes the relationship between the research, clinical practices, and administrative functional units within the Research Node.
- Describes appropriate capability of the RNC PI to coordinate and provide leadership for the node as well as the responsibilities of key personnel.

*Criterion 6: SUPPORT REQUESTED (10 points) - Corresponds to Budget and Budget Narrative*

The extent to which the application:

- Provides a detailed budget request and justification for each year of the 4-year period of performance and includes a budget for required travel.

- Outlines costs in the budget and required resources sections, which are reasonable given the scope of work.
- Provides key personnel with adequate time to devote to the project to achieve project objectives, and reflects the recommendations in the NOFO.

## **2. Review and Selection Process**

The independent review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors below in award selection.

### **Funding Priorities**

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

- Progress Report (3 Points). HRSA program staff will grant up to 3 funding priority points to competing continuation applications based on the degree of successful progress described within the Progress Report (Attachment 5).

See Section 5.3 of HRSA's [SF-424 Application Guide](#) for more details.

## **3. Assessment of Risk and Other Pre-Award Activities**

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.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the [Federal Awardee Performance and Integrity](#)

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

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

#### **4. Anticipated Announcement and Award Dates**

HRSA anticipates issuing/announcing awards prior to the start date of September 1, 2019.

## **VI. Award Administration Information**

### **1. Award Notices**

HRSA will issue the Notice of Award prior to the start date of September 1, 2019. 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](#).

#### **Data Rights**

All publications the cooperative agreement recipient develops or purchases with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the cooperative agreement recipient owns the copyright for materials that it develops under this cooperative agreement, 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 cooperative agreement 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 other researchers. If applicable, the specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the Notice of Award (NOA). Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

#### **Human Subjects Protection**

Federal regulations ([45 CFR part 46](#)) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the

subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks. Some PECARN studies may include Exemptions from Informed Consent (EFIC) if approved by an Institutional Review Board.

### **Requirements of Subawards**

The terms and conditions in the Notice of Award (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. See [45 CFR § 75.101 Applicability](#) for more details.

### **3. Reporting**

The Discretionary Grant Information System (DGIS) reporting system will continue to be available through the Electronic Handbooks (EHBs). HRSA enhanced the DGIS and these improvements are available for recipient reporting. The agency will communicate with recipients and provide instructions on how to access the system for reporting. HRSA will also provide technical assistance via webinars, written guidance, and one-on-one sessions with an expert, if needed.

The updated and final reporting package incorporating all OMB-accepted changes can be reviewed at:

<https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection> (OMB Number: 0915-0298 Expiration Date: 06/30/2019).

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

- 1) **Progress Report(s).** The recipient must submit a progress report to HRSA on an **annual** basis, which should address progress against program outcomes, including any expected outcomes in the first year of the program. Further information will be available in the award notice.
- 2) **Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.
- 3) **Performance Reports.** HRSA has modified its reporting requirements for Special Projects of Regional and National Significance projects, Community Integrated Service Systems projects, and other grant/cooperative agreement programs 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). GPRA 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.

**a) Performance Measures and Program Data**

To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are at [https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/U03\\_2.HTML](https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/U03_2.HTML) and below.

<b>Forms</b>			
<ul style="list-style-type: none"> <li>• Form 1, Project Budget Details</li> <li>• Form 2, Project Funding Profile</li> <li>• Form 4, Project Budget and Expenditures</li> <li>• Form 6, Maternal &amp; Child Health Discretionary Grant</li> <li>• Form 7, Discretionary Grant Project</li> <li>• Products, Publications, and Submissions Data Collection Form</li> </ul>			
<b>Updated DGIS Performance Measures, Numbering by Domain</b> <i>(All Performance Measures are revised from the previous OMB package)</i>			
<b>Performance Measure</b>	<b>New/ Revised Measure</b>	<b>Prior PM Number (if applicable)</b>	<b>Topic</b>
<b>Core</b>			
Core 1	New	N/A	Grant Impact
Core 2	New	N/A	Quality Improvement
Core 3	New	N/A	Health Equity – MCH Outcomes
<b>Capacity Building</b>			
CB 5	Revised	3, 4	Scientific Publications
CB 6	New	N/A	Products

**b) Performance Reporting Timeline**

Successful applicants receiving HRSA funds will be required, within 120 days of the period of performance start date, to register in HRSA’s EHBs and electronically complete the program-specific data forms that are required for this award. This requirement entails the provision of budget breakdowns in the financial forms based on the award amount, the project abstract and other grant/cooperative agreement summary data as well as providing objectives for the performance measures.

Performance reporting is conducted for each year of the period of performance. Recipients will be required, within 120 days of the budget period start date, to enter HRSA’s EHBs and complete the program-specific forms. This requirement includes providing expenditure data, finalizing the abstract and grant/cooperative agreement summary data as well as finalizing indicators/scores for the performance measures.



**c) Period of Performance End Performance Reporting**

Successful applicants receiving HRSA funding will be required, within 90 days from the end of the period of performance, to electronically complete the program-specific data forms that appear for this program. The requirement includes providing expenditure data for the final year of the period of performance, the project abstract and grant/cooperative agreement summary data as well as final indicators/scores for the performance measures.

- 4) **Integrity and Performance Reporting.** The Notice of Award will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

**VII. Agency Contacts**

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

Bria Haley  
Grants Management Specialist  
Division of Grants Management Operations, OFAM  
Health Resources and Services Administration  
5600 Fishers Lane, Mailstop 10SWH03  
Rockville, MD 20857  
Telephone: (301) 443-3778  
Email: [bhaley@hrsa.gov](mailto:bhaley@hrsa.gov)

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

Diane Pilkey, RN MPH  
Nurse Consultant, EMSC  
Maternal and Child Health Bureau  
Health Resources and Services Administration  
5600 Fishers Lane, Room 18N52  
Rockville, MD 20857  
Telephone: (301) 443-8927  
Email: [dpilkey@hrsa.gov](mailto:dpilkey@hrsa.gov)

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

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

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

HRSA Contact Center

Telephone: (877) 464-4772

TTY: (877) 897-9910

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

## **VIII. Other Information**

### **Technical Assistance**

HRSA has scheduled the following technical assistance:

#### *Webinar*

Day and Date: Tuesday January 8, 2019

Time: 2 p.m. ET

Call-In Number: 1-866-917-4660

Participant Code: 68594605

Weblink: [https://hrsa.connectsolutions.com/pecarn\\_nof/](https://hrsa.connectsolutions.com/pecarn_nof/)

An archive recording of the call will be available within a week of the call at:

<https://mchb.hrsa.gov/fundingopportunities/>.

### **Tips for Writing a Strong Application**

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

## Appendix - Additional PECARN Background

### *Activities of the PECARN Chair*

- Serve as liaison and provide assistance to HRSA;
- Coordinate and manage the PECARN Steering Committee meetings;
- Organize network communications across the network sites and the Data Coordinating Center;
- Represent PECARN at national committees and meetings including the annual HRSA Maternal and Child Health Bureau's Research Network meeting;
- Provide briefings and presentations to national organizations;
- Oversee and update PECARN policies and procedures;
- Update all PECARN members on new/ongoing activities; and
- Oversee the activities of the PECARN Secretary (the Nodal Administrator at the Chair site).

### *Research Site Monitoring Reporting Requirements to the DCC*

As part of the externally funded research grant monitoring activities of the DCC, the HRSA award recipients agree to furnish the following information to the DCC to ensure the efficiency and productivity of the network and implemented studies:

The PI of the Research Node agrees to implement and adhere to an adverse event tracking system operated by the DCC.

1. Grant Protocol-Specific Reports: Recipients are required and agree to provide periodic reports of protocol-specific projects as requested by HRSA directly or through the DCC. At a minimum, the Research Node must provide timely enrollment information in a format and according to a schedule defined by the DCC and/or the HRSA PO for all HEDAs and participating EMS affiliate sites. Other protocol-specific reports, such as adverse event reports and other reports needed to monitor the safety and clinical effectiveness of drugs, treatments, or other interventions under investigation will be required in order to allow HRSA and the PECARN Steering Committee to monitor the research projects undertaken in the PECARN.
2. Investigational New Drug (IND) Reports: For projects involving IND, recipients are required and agree to provide reports according to regulations and guidelines established by the Food and Drug Administration (FDA).
3. Manuscript Analysis Request Form (MARF): A publication plan and manuscript analysis request form will be submitted to the PECARN Steering Committee for each planned primary or secondary manuscript as early as possible in the study planning process and before enrollment ends.
4. Final Publications: Prompt and timely presentation and publication in the scientific literature of findings resulting from research undertaken in the PECARN is required. A primary publication from the research should be published no later than 2 years after the last patient has been enrolled or data collection completed. Investigators must agree to abide by HRSA and PECARN policies concerning all publication of PECARN studies. Prior to the submission of manuscripts for publication, recipients agree to submit publications to the PECARN Steering Committee for internal peer review and approval. The publication policy is included in Appendix A. HRSA's Office of Communications will be consulted in advance of publication in order to

coordinate announcements of new HRSA-supported research results with other HRSA dissemination activities.

#### *Quality Control and Monitoring*

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

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

#### *Subject Safety/Oversight*

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

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

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

#### *Adverse Experience Reporting*

The PI of the Research Node agrees to implement and adhere to an adverse event tracking system operated by the DCC.

#### *Data Confidentiality*

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

personal identifiers and other identifying or identifiable data will be restricted and safeguarded.

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

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