STANDARD OPERATING POLICY AND PROCEDURE FOR DEVELOPMENT AND APPROVAL OF RESEARCH CONCEPTS AND PROTOCOLS

Initial Draft: February 2014 Version No.: 5 Revised:	Development and Approval of CHaMP Research Concepts and Protocols in PECARN	Original Steering Committee Approval: February 2015 Revised Steering Committee Approval:

1. PURPOSE

1.1. The purpose of this policy is to provide guidance for CHaMP investigators and others involved in PECARN research regarding the development, submission and approval process of a research concept and a research protocol for the CHaMP node.

2. POLICY

2.1. This document describes the approved method of initiating a CHaMP research project. Any changes to this process must be approved by the CHaMP Steering Committee.

3. SCOPE

3.1. This document applies to all investigators, nodal administrators and others involved in CHaMP-related research and to all participating sites.

4. DEFINITIONS

4.1. CHaMP Nodal Principal Investigator: Investigator named on the HRSA Notice of Award

4.2. EMSA: Emergency Medical Services (EMS) Agency that participates in CHaMP

4.3. E-RNC: EMS Research Node Center; a node of PECARN (e.g. CHaMP) that focuses on EMS-related research. The E-RNC utilizes the "E-RNC committee members" to make critical decisions for CHaMP and vote on approval of research concepts.

4.4. E-RNC Members: Comprised of the Nodal Principal Investigator, Field Provider Advisory Committee members, the EMSA Principal Investigators and the EMSA Academic Advisors.

4.5. PECARN: The Pediatric Emergency Care Applied Research Network, the federally funded multi-institutional network for research in pediatric emergency medicine in the United States.

5. RESPONSIBLE PARTIES

5.1. The Study Principal Investigator is responsible for preparing the initial draft of the concept or protocol, in conjunction with the CHaMP E-RNC members, subcommittees, subject matter experts, the DCC, biostatisticians, information technology/database experts, and others, as appropriate.

5.2. The Study Principal Investigator who initiates the concept or protocol is responsible for assuring that the concept or protocol meets all regulatory requirements, and is ethically

and scientifically sound.

6. PROCEDURES

6.1. Research Concept

6.1.1. The Study Principal Investigator will develop an initial description of the potential project. Initial descriptions will follow PECARN guidelines for research concepts in terms of length and format. The research concept presentation at the PECARN Steering Committee meeting is outlined in part 6.2.4 of the PECARN policy "Development and Approval of Research Concepts and Protocols." Guidelines and sample documents can also be found at http://www.pecarn.org/helpfulResources/pecarnTraining.html.

6.1.2. The Nodal PI may identify a mentor, subject matter expert or consultant as necessary to further develop the concept. The Nodal PI's role is to oversee the nodal review of the concept and to:

- Determine, in consultation with the Federal Project Officer, the general feasibility of conducting the proposed study within PECARN
- Assist the investigator in refining the science of the concept
- Assist the investigator in navigating the PECARN protocol development process

6.2. Concept Submission, Presentation and Review

6.2.1. The Academic Advisors and the Nodal Principal Investigator will provide assistance in the process of developing the concepts. The FACs at any or all of the EMSA's can also be consulted for assistance in concept development. The concept paper should address: the importance of the topic to EMSC, why the study requires the PECARN network involvement, and a brief overview of the background, specific aims, methodology, subject population, and sample size requirements.

6.2.2. Once the concept is complete, it should be submitted electronically to the CHaMP Nodal Administrator at least 2 weeks prior to the first PECARN due date. No budget is necessary at this step.

6.2.3. The E-RNC members will be sent a copy of the concept for review via email. They will then be asked to vote on the concept moving forward through the development process. Votes will be conducted electronically. E-RNC members vote by determining if the concept is feasible and relevant to prehospital care. During the vote E-RNC members will also provide feedback to the study PI on how to improve the concept.

6.2.4. Concepts that receive E-RNC member approval from at least 75% of all E-RNC members will be submitted to HRSA for evaluation. HRSA-approved concepts will then be sent to PECARN for review as outlined in PECARNs policies and procedures. If there is less than 75% approval from E-RNC members, the concept is returned to the PI for revision. A concept can return for a revote up to two times, after which it will not be reconsidered.

Nodal concepts will be presented to PECARN and receive feedback. Concepts that involve other PECARN sites (PECARN-wide) will follow the PECARN process including the required vote of approval from the PECARN Steering Committee (see "Development and Approval of Research Concepts and Protocols").

If there are more concepts ready for submission than allowed by PECARN, E-RNC members will vote on priorities and the top priority will be submitted first.

6.3. Protocol Development

6.3.1. Once a concept is approved to move forward, the Study Principal Investigator will develop a protocol.

6.3.2. The protocol should follow PECARN guidelines and must contain sufficient detail about the proposed study such that it may be assessed for scientific merit and feasibility. The essential elements of a protocol are described in (*Protocol Template: A Guideline for Writing a Clinical Protocol for PECARN*). If the protocol is PECARN-wide, investigators are required to discuss study design, protocol development and statistical methods with the DCC. For nodal studies this is encouraged but not required.

Throughout the rest of this policy, the word "protocol" is used with the understanding that the format to be submitted can be either in IRB-type protocol format or in grant format.

6.3.3. The protocol should also contain a preliminary budget and budget narrative. The investigators must work with CHaMP's Steering Committee and Nodal Administrator to develop the draft budget. For PECARN-wide protocols, investigators are also required to consult FAB, and strongly encouraged to consult other PECARN subcommittees.

6.3.4. Once the protocol is complete, it should be submitted electronically to the CHaMP Nodal Administrator at least 2 weeks prior to the first PECARN due date.

6.3.5. The E-RNC members will be sent a copy of the protocol for review via email at least two weeks prior to the first PECARN submission deadline. Votes will be conducted electronically. The E-RNC members will be asked to vote on whether the proposal is feasible in their EMS system and scientifically valid. The Principal Investigator will work to ensure that logistics are considered throughout the development process, but this review will be a final opportunity to ensure that no proposal is put forth that is not going to be successfully implemented. During the vote E-RNC members will also provide feedback to the study PI on how to improve the protocol.

6.3.6. Protocols that receive E-RNC member approval from at least 75% of all E-RNC members will be submitted to HRSA for evaluation. HRSA-approved protocols will then be sent to PECARN for review as outlined in PECARNs policies and procedures. If there is less than 75% approval from E-RNC members, the protocol is returned to the PI for revision. A protocol can return for a revote up to two times, after which it will not be reconsidered.

Nodal protocols will be presented to PECARN and receive feedback. Protocols that involve other PECARN sites (PECARN-wide) will be require a vote of approval from the PECARN Steering Committee and be subject to PECARN rules (see sections 6.4-6.6 of 'Development and Approval of Research Concepts and Protocols').

6.3.7. Once a nodal protocol receives feedback from PECARN or a PECARN-wide protocol receives approval from the PECARN Steering Committee, the E-RNC will assist the investigator with finding a funding source and submitting an application.

6.4. Grant Application

6.6.1 Following approval of the protocol, unless the protocol will be implemented with internal resources, the study principal investigator prepares a grant application.

6.6.2 The CHaMP Steering Committee and the FACs are available, as are all the PECARN subcommittees, to help develop and rigorously review the grant application following protocol approval.

6.5. Approval of Grant Application

6.5.1. Submission of the grant proposal to an external agency requires prior approval by a vote of the CHaMP SC, with at least 75% approval. The grant application must be submitted electronically to the CHaMP Nodal Administrator to distribute to the CHaMP SC for voting at least two weeks before the external grant application deadline. If the grant proposal involves PECARN sites, applications are due to the CHaMP Nodal Administrator at least one week before the first PECARN deadline. It must be sufficiently complete that changes made during the weeks following approval are not scientifically or fiscally substantive.

6.6. Protocol Development: Expedited Review Process

6.6.1. At the discretion of the CHaMP Steering Committee proposals may move through an expedited review process in exceptional circumstances such as pressing grant deadlines. A minimum of 75% of E-RNC members must approve of a fast track request made by the Study's Principal Investigator.

6.6.2. E-RNC members should be given a one-week turnaround to review a concept or proposal that has been fast-tracked. E-RNC members will vote on approval following the same criteria outlined above.

6.6.3. In exceptional circumstances, parts of this process may be obviated, as will be determined and resolved by the Nodal PI and Federal Project Officer.

6.7. Handling of Material

6.7.1. All E-RNC members will consider material distributed for voting confidential and will not share those documents under any circumstances.