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

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

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
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 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 Prot

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.

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- Development and Approval of Res

6.3.7. Once