



## How Studies Are Created and Monitored



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The Pediatric Heart Network (PHN) is a cooperative effort between participating medical centers, a data coordinating center, an independent Network chair, and the *National Heart, Lung, and Blood Institute (NHLBI)*  staff. All entities work together to:

- propose pertinent and timely research ideas
- develop protocols
- conduct research studies
- monitor patient safety and data
- disseminate the research findings

## Study Proposals

 = glossary definition

Principal Investigators and affiliated investigators propose new areas of research to the PHN *Steering Committee*  for review and consideration as Network studies. New ideas emerge from formal and informal discussion among the PHN Steering Committee members, co-investigators at participating institutions, and may also come from outside investigators. A written proposal is composed by the investigator(s) and is presented to the Steering Committee. Issues such as selection of a meaningful study endpoint, feasibility of proposed study procedures, availability of adequate numbers of patients, clinical center support and clinical relevance of the study are discussed extensively. Study proposals approved by the PHN Steering Committee are then developed into a full study protocol.

## Protocol Development



The protocol development team consists of one investigator from each participating center, at least one nurse/study coordinator, a biostatistician and project manager as well as NHLBI. Protocol development includes primary and secondary endpoints, the study procedures, data collection and analysis. Once the protocol is written it goes back to the Steering committee for a full review for approval or additional revisions.

## Protocol Review Committee (PRC)

The protocol is then reviewed by the PRC. The PRC is an independent group appointed by NHLBI and made up of experts within the fields of pediatric cardiology, pediatric cardiothoracic surgery, pharmacology, clinical trial design and analysis, ethics and genetics. The responsibility of the PRC is to provide scientific peer review of protocols developed within the Network.

The PRC may recommend that a protocol be approved as written, request certain changes to the protocol, or recommend that the concept not be considered for further development.

## Data Safety and Monitoring Board (DSMB)

After approval by the PRC, the protocol, model consent form(s) and data collection forms are reviewed by the *DSMB* . The purposes of this NHLBI-appointed board are to ensure the safety of study subjects and to provide advice on the ethical and safe progression of studies conducted by the PHN. Modifications to the study protocol may be requested by the DSMB. Once the final study protocol is approved by the DSMB, the protocol is ready to be reviewed by *the Institutional Review or Research Ethics Boards*  at the individual clinical centers.

## Monitoring Patient Safety

### Institutional Review Board (IRB)/Research Ethics Board (REB)

Each clinical center submits the protocol, consent forms, patient education materials, advertising materials and other required documentation to their *IRB/REB*. These boards are chosen by an institution to review and approve new research studies and to provide on-going review of the conduct of these studies. Their primary purpose is to assure the protection of human subjects.

### Ongoing Review by the Data Safety and Monitoring Board (DSMB)

The *DSMB* reviews each study on a regular basis to make sure that participants are safe and that the study data is reliable. The PHN DSMB meets at least every six months to:

- Assess how well each clinical site is performing.
- Review adverse events.
- Suggest possible early termination of the study because of lack of attainment of study objectives, safety concerns or poor recruitment.
- Recommend possible modifications to the protocol.

## Accountability at Research Sites

### Training/Certification

One or more training sessions are held for the research staff (study coordinators, technicians, PIs) prior to the start of any study. Each center must complete specific certification requirements including familiarity with study procedures, methods of endpoint measurement, use of the database system and designation of study staff responsibilities.

### Site Visits

Site visits are routinely made to assess the medical center's proficiency in executing the study protocols, to assess data quality and completeness, and to provide consultation in identifying and solving problems. The site visit team will generate a formal written report of the site's areas of excellence and recommendations for improvement. Problem areas will be identified and timelines will be given to the clinical site for documentation of improvement.

Is a Clinical Study Right For Your Patient? 

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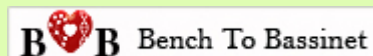
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