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 = glossary definition

Ensuring Safety in PHN Studies





A *clinical trial*  is planned to study a medicine, treatment or device to improve human health and medical care. The Pediatric Heart Network (PHN) develops studies to improve health in people with *congenital heart defects*  or *acquired heart disease* . Studies also help doctors and nurses make better decisions about using certain medicines and treatments. It is very important to the PHN nurses and doctors to keep patients safe in clinical studies. See the video and read the information on the [Children and Clinical Studies](#) website about "[Safety and Precautions](#)".

Study Design

Pediatric heart researchers suggest studies that they feel will answer important questions about how best to treat patients. Researchers will write a protocol to describe what will be learned from the study and how it will be done. It must also describe how safety will be maintained during the study.

Studies are reviewed for safety by many groups



There are several steps a study has to go through before it starts and patients can be enrolled:

1. The protocol is reviewed and discussed in detail by members of the PHN. The members have a wide variety of training and experience in nursing, medicine, statistics, special technologies and managing clinical trials. Changes are made to create the best and safest study possible.
2. The study protocol is then sent to a specially qualified, independent group appointed by the *National Heart, Lung, and Blood Institute (NHLBI)* . This group is called a Protocol Review Committee or PRC. It is their job to review the study protocol and make suggestions about how to best carry out the study.
3. Once additional changes have been made, the protocol is sent to a second independent review committee called the *Data and Safety Monitoring Board (DSMB)* . The DSMB may also suggest changes to the protocol or consent form to ensure the safety of the study subjects.
4. The protocol and *consent form*  that has been reviewed by the PHN members, the PRC and the DSMB, will then go to a review board at each hospital that will enroll patients in the study. These boards are called different names such as *Institutional Review Boards (IRB)* or *Research Ethics Boards (REB)* . These boards are chosen by a hospital to review and approve a study before it starts and then at regular times, at least once each year. The primary purpose is to assure that the patients who participate in studies are protected.

Special training on patient safety is required

Each member of the research team must complete special training on how to protect subjects in clinical trials. Additional training is given to the research team on how to safely conduct each PHN study. No one may contact a patient or family or participate in these studies unless there is proof that this training has been taken.

Dealing with adverse events


Each *research team*  must collect and report side effects (also called *adverse events* ) to their IRB or REB, the Pediatric Heart Network, then reported to the DSMB. Not all adverse events will occur because of the study but may occur as a result of the condition of the study participant. Adverse events are followed closely by the doctors and nurses doing the study and they will decide what to do as soon as the adverse event is known. Serious adverse events are reviewed by the medical monitor and the NHLBI staff within a few days of the report.

Ongoing review for safety

It is the job of the DSMB and IRB or REB to review the study regularly to make sure that participants are safe and that the study data is reliable. They will meet as often as necessary to:

- Assess how well each hospital is performing.
- Review adverse events.
- Suggest ending the study early if results show that the treatment is effective or not or because of safety concerns.

All of the steps described above are taken to protect people who are enrolled in PHN studies.

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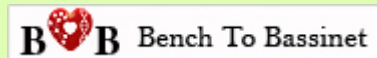
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