

What is a Clinical Study?

A clinical study is a carefully designed look at the effects of a medication, medical treatment, or a device on a group of volunteers. Clinical studies are an important step in making new medications available. They measure the drug's ability to treat a condition, its safety, and its possible side effects.

Each study has specific requirements of the volunteers such as age, sex, or medical condition. Each physician who is conducting the research reviews each volunteer's medical history to determine if they are eligible to participate based on the specific criteria.

Who can be in a Clinical Study?

Healthy people, as well as people with the condition being studied, can volunteer to participate in a clinical study. Before a volunteer can participate in a clinical study, he/she must read and sign an informed consent.

What is Informed Consent?

Informed consent is a process intended to give volunteers as much information as possible about a study, including known and unknown risks and discomforts that may occur during participation during the study. This process allows the volunteer to ask questions and exchange information regarding the study before deciding to participate.

The physician conducting the study is responsible for ensuring that each volunteer is informed and consented before any research related activity is done.

What is an Institutional Review Board/Institutional Ethics Committee? (IRB/IEC)

An Institutional Review Board/Institutional Ethics Committee (IRB/IEC) is a group of people that include healthcare professionals, scientists and non medical people from the local community. This group carefully reviews the study. The IRB's/IEC's primary responsibility is to ensure the safety and rights of each participant and some have patient advocates to answer questions.