Frequently Asked Questions - Clinical Trials

What is a clinical trial?

Clinical Research projects, also known as clinical research studies and clinical trials, are research studies that measure the safety and effects of new treatments and procedures in human volunteers.

Why participate in a clinical trial?

Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

Who can participate in a clinical trial?

All clinical trials have guidelines about who can participate.. The criteria is based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study.

How are clinical participants protected?

Federal guidelines and codes of ethics are designed to protect clinical research volunteers from harm. In addition, a panel of professionals and community members is responsible for monitoring study safety and safeguarding volunteer rights in every clinical research project.

What happens during a clinical trial?

The clinical trial process depends on the kind of trial being conducted . The clinical trial team includes doctors and study coordinators (nurses) as well as other health care professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch after the trial is completed.

Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. For all types of trials, the participant works with a research team. Clinical trial participation is most successful when the protocol is carefully followed and there is frequent contact with the research staff.

What is informed consent?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and study coordinators involved in the trial explain the details of the study. The research team provides an that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in theinformed consent document . The participant then decides whether or not to sign the document.

Informed consent is not a contract, and the participant may withdraw from the trial at any time.

What are the benefits and risks of participating in a clinical trial?

Benefits

Clinical trials that are well-designed and well-executed are the best approach for eligible participants to:

Play an active role in their own health care. Gain access to new research treatments before they are widely available. Obtain expert medical care at leading health care facilities during the trial. Help others by contributing to medical research.

Risks

There are risks to clinical trials.

There may be unpleasant, serious or even life-threatening side effects to experimental treatment. The experimental treatment may not be effective for the participant. The protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.