about clinical research studies

Clinical research studies are an important part of the development of medical treatments. Clinical research studies are designed to test investigational treatments so that the regulatory agencies in your country can determine if they are safe and effective. Clinical research studies also help those agencies – and their counterparts in other countries – decide whether to license these investigational treatments so that doctors may prescribe them for their patients.

To do this, investigational treatments may be compared with the current standard of care, a placebo (a treatment designed to have no effect on health), or with some other form of treatment. People only participate in clinical research studies if they want to, and they can stop participating at any time.

Clinical research studies are sometimes referred to as "clinical studies" or "clinical trials," or collectively as "clinical research," "medical research," or "research studies." As well, sometimes the word "study" or "studies", or "trial" or "trials" is used as a short-hand term. The information in this pamphlet applies equally, regardless of which term is used.

Who can participate in a clinical research study?

All clinical research studies have guidelines about who can participate. The researchers use very specific inclusion and exclusion criteria based on age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. A potential participant must meet these criteria before joining a clinical research study. These criteria help researchers identify appropriate participants, while ensuring that the researchers will be able to answer the questions they plan to study.

Why should I participate?

If you choose to take part in a clinical research study, you may:

- Have access to an investigational drug.
- Receive medical care and monitoring of your disease or condition during the course of the research study.
- Help others who have your disease or condition in the future by contributing to medical research.

How am I protected?

Regulatory agencies have strict and specific rules for conducting clinical research studies. For example, all clinical research studies must be approved and monitored by an ethics committee, whose role is to protect all participants in a clinical research study. Ethics committees must:

- Ensure that appropriate steps are taken to protect the rights and welfare of people who participate as volunteers in clinical research studies.
- Review and approve the research study protocol, informed consent forms, methods of recruitment, and all written information provided to participants.
- Monitor aspects of a clinical research study and require serious adverse events be reported.

A research study follows a carefully controlled protocol, which is a plan that details what researchers will do in that study. Researchers will also report the results of the study at scientific meetings, in medical journals, and to various government agencies. All participants' names remain confidential and will not be mentioned in these reports.

Participation in a clinical research study is always voluntary, and choosing not to participate will in no way affect the current medical care that you are receiving

The Four Phases of a Clinical Research Study

Clinical research studies can happen in one of four phases, depending on the status of the research on the treatment they are investigating.

- **A Phase I research study** is designed to determine the effects of an investigational drug in people. They are usually conducted on a small population of people to observe how the body absorbs, tolerates, distributes, and metabolizes the drug.
- **A Phase II research study** occurs after Phase I studies have been completed successfully. The investigational drug is tested for safety and effectiveness in a larger population of people who have the disease or condition for which the treatment was developed.
- **A Phase III research study** is the last round of pre-approval testing for an investigational drug. The drug is tested in comparison to the standard treatment for the disease or condition for which the drug is being researched. The results of these studies usually provide the information for the drug's package insert and label.
- **A Phase IV research study** occurs after a drug has been approved by the necessary regulatory agencies in your country. The drug may be compared to competitors, or may explore additional patient populations or study any side effects.

Common Terms Related to Clinical Research Studies

Blinding

The design of a clinical research study in which one or more groups involved in the study do not know which medication the participant is taking. Blinding is done to prevent the unintentional biases that can occur when treatment assignments are known.

Double-blind

The design of a research study in which neither the participant nor the investigator knows which medication (or placebo) the participant is taking.

Open-label

This is a research study in which everyone involved (patient, doctor, and study staff) is aware of the drug and dosing being given. In open-label studies, no one receives a placebo. These usually occur in Phase I and Phase II research studies.

Placebo

A placebo is an inactive substance designed to resemble the drug being tested. It is used as a control to rule out any psychological effects testing may present.

Randomization

Research study participants are often assigned to different treatment or control groups by chance (like flipping a coin). No particular criteria are used to assign a participant to a particular group, so all the groups in the research study will be equally comparable.

What happens if I decide to participate?

All patients must first go through the informed consent process. In this process, the research study – its purpose, duration, required procedures, key contacts, and any possible benefits and risks – is explained in detail in an informed consent form, and any questions are answered. This process ensures that patients understand what participation involves. As a potential participant, you must then decide whether or not you want to participate and sign the document. You may withdraw from the research study at any time.

The staff of a clinical research study may include doctors and nurses as well as social workers and other healthcare professionals. The clinical study staff checks your health at the beginning of a research study and monitors you throughout the research study. The clinical study staff provides specific instructions for participation and follows the research study protocol carefully in collaboration with the research staff. The procedures you may receive depend on the research study protocol and the disease or condition being researched.

Making Your Decision

Deciding whether to participate in a clinical research study is up to you. If you decide not to participate in a clinical research study, your decision will not have any effect on the care you're receiving now or in the future. If you decide to take part, you may withdraw at any time during the research study. If you have any questions, don't hesitate to ask the research study staff. They are there to help you.