

What is informed consent?

Informed consent is a process in which you learn the key facts about a clinical trial before you decide whether or not to participate. In addition to talking about these facts with the research doctor or nurse, they will be included in a written consent form that you can take home to read and discuss. The consent form will include details about:

- the study approach
- the intervention given in the trial
- the possible risks and benefits
- the tests you may have

This informed consent is part of a process that ensures a prospective participant in a clinical trial understands what known risks might be associated with the study, and whether there are potential, but as yet unknown, risks that may be associated with the product being studied. This information permits someone deciding whether or not to enter a clinical trial to make an informed decision about the level of risk they are willing to accept before they decide to participate. Do not hesitate to ask questions until you have all the information you need. While informed consent begins before you agree to participate in a trial, you should feel free to ask the health-care team any questions you have at any point. Informed consent continues as long as you are in the study. You can change your mind and leave the study whenever you want -- before the study starts or at any time during the study or follow-up period

What are the potential risks of clinical trials?

There are generally known and unknown risks associated with clinical trials, such as:

- New drugs and procedures may have side effects or risks unknown to the doctors.
- New drugs and procedures may be ineffective, or less effective, than current approaches.
- The treatment may not be effective for you.
- The protocol may require more of your time and attention than a standard treatment. (You may need to visit the study site on a regular basis, be subjected to additional tests, or get more treatments than are normally necessary).
- Even if a new approach has benefits, it may not work for you.

What's the role of FDA in approving new drugs & medical treatments?

The Food and Drug Administration's job is to make sure medical treatments are safe and effective for people. However, FDA does not develop new therapies, or conduct clinical trials to demonstrate safety and effectiveness. FDA staff members meet with researchers, and inspect clinical trial study sites to protect the rights of participants and to verify the quality and integrity of the data.



Should I Participate in a Clinical Trial?

Information for Potential Study Subjects

Where can people find out about clinical trials?

People can find information about clinical trials now being conducted by going to www.clinicaltrials.gov. ClinicalTrials.gov is an interactive online database, managed by the National Library of Medicine. It provides information on federally-funded and privately supported clinical research in human volunteers.

Should I join a Clinical Trial?

As a volunteer in a clinical trial, you are participating in the development of medical therapies—therapies that may offer better treatments and even cures for life-threatening and chronic diseases.

People volunteer to participate in a clinical trial for a number of reasons. You may get involved in a trial because you simply want to help in the advancement of science. Or you may be suffering from a disease for which a good treatment does not currently exist. You may join a clinical trial hoping to improve the medical care you receive. If you do not have health insurance, clinical trials are a way to receive study-related medical care.

Whatever your reason, you may have questions about clinical trials and drug research. This pamphlet attempts to answer some of your questions. You should also ask your physician and your research center's staff any questions you may have before you volunteer. It's important that you make an informed choice about volunteering for a clinical trial.

Why are clinical trials done?

Many clinical trials are done to see if a new drug or device is safe and effective for people to use. Clinical trials are also done for other reasons. Some compare existing treatments to determine which is better. The current, approved treatments are called the "standard treatments." Sometimes clinical trials are used to study different ways to use the standard treatments so they will be more effective, easier to use, and/or decrease side effects. Sometimes, studies are done to learn how to best use the treatment in a different population, such as children, in whom the treatment was not previously tested.

For most trials, researchers, doctors, and other health professionals administer the clinical trials according to strict rules set by the Food and Drug Administration (FDA). FDA sets the rules to make sure that people who agree to be in studies are treated as safely as possible.

The government requires researchers to give prospective participants complete and accurate information about what will happen during the trial. Participants must sign an "informed consent" document before joining the study indicating they understand that the trial is research, and that they can leave the clinical trial at any time.

What happens during a trial?

If you decide to participate in a clinical trial, you will work with a research team. Team members may include doctors, nurses, social workers, dietitians, and other health care professionals. They will provide your care, monitor your health carefully, and give you specific instructions about the study.

Participating in a trial may mean that you might have more tests and doctor visits than you would if you weren't in the study. Team members also may continue to stay in contact with you after the trial ends. To make the trial results as reliable as possible, it is important for participants to follow the research team's instructions. That means having all doctor visits and tests, taking medicines on time, and completing logs or answering questionnaires.

Are clinical trials safe?

The FDA works to protect participants in clinical trials and to ensure that people have reliable information as they decide whether to join a clinical trial. The federal government has **regulations and guidelines for clinical research** to protect participants from unreasonable risks.

Although efforts are made to control the risks to clinical trial participants, some risks may be unavoidable because of the uncertainty inherent in medical research studies involving new medical treatments.