

What is a Clinical Trial?

A clinical trial is the term for any test or study of an investigational drug, device, or other medical treatment in human subjects. Some clinical trials may test already approved (on the market) medications or devices.

Researchers are constantly looking for better or new ways for treating illness and disease. Clinical trials are designed to determine whether the investigational drug, device or treatments are safe and effective for people to use. Clinical trials attempt to show that the investigational treatment is better than, as good as, or not better than the standard treatments available.

Why do people volunteer?

There are several reasons why people volunteer for clinical trials but for most, it is the possibility to help themselves and to help others who may benefit from developing a new medication or treatment.

Who conducts clinical trials?

Clinical trials are sponsored by government agencies such as the National Institutes of Health (NIH), foundations such as the American Cancer Society and the Kidney Foundation, pharmaceutical companies, device manufacturers, research institutions, individual physicians, and other health organizations. The sponsor is responsible for designing a protocol, which is the study plan that the investigator follows. Only trained investigators (doctors, nurses and medical researchers) actually conduct the study.

How are volunteers protected?

Your study doctor and the research team are concerned about your health and safety. If you have any questions or think you are having a study related problem, you should contact them right away.

Federal regulations require that you be given complete information about the trial before you agree to participate. This is known as informed consent. You will be told:

- That the trial involves research
- The purpose of the research
- How long the trial is expected to take
- What will go on in the study and which parts are experimental
- Possible risks or discomforts
- Possible benefits
- Other alternatives that are available instead of the research treatment
- That the FDA and others may inspect the study records, but the records will be kept in a confidential manner
- Whether medical treatments may be available if you have side effects, what the treatments are, where you can get them and who will pay for them
- Who you can contact with questions about the trial, your rights as a research subject, and injuries related to the research
- That being in the trial is voluntary and that you can quit at any time without otherwise affecting your treatment or the services you receive

How are volunteers protected? (continued)

Before you can be in the trial, you must sign a consent form showing that you have been given this information and that you understand it. So make sure you understand all the information first and ask the person giving you the information to explain anything you do not understand.

Clinical trials, by law, must be approved and monitored by an institutional review board (IRB). The IRB checks to see that there is the least possible risk to volunteers and that the risks are reasonable in relation to any expected benefits. The IRB reviews the plan for volunteer selection for fairness and that informed consent is obtained correctly.

Who can participate?

Every clinical trial has guidelines about who is eligible. There are certain requirements about your health, medical condition, medications, age and other things.

What can I expect?

More than anything else, you have the right to expect complete information about the trial. You should not participate in a clinical trial unless all your questions have been answered in a way you can understand. You should also understand your commitment to the trial. You will need to follow the investigator's instructions carefully.

Volunteering for a Clinical Trial

*Important information you
need to know*



What are the risks?

There may be side effects or adverse reactions to the medications or treatments. Because the treatments being studied are new, the doctors do not always know what the side effects will be. While it is possible that some side effects could be permanent or life threatening, most are temporary and can be treated or go away when the treatment is stopped.

Many studies require that neither the subject nor the doctor know whether the subject is receiving the experimental treatment, the standard treatment or a placebo (an inactive substance that looks like the drug being tested).

What are the benefits?

There may or not be a direct benefit to you if you volunteer for a clinical trial. Your health or your health condition may get better as a result of your participation, it may stay the same or it may even get worse. No one can completely predict the outcome of a clinical trial or how it might effect you. The study may result in information that will help others in the future.

What kinds of questions should I be asking?

Here are some questions to ask the doctor to help you decide if you want to take part in a clinical trial:

- What is the study trying to find out?
- Who is sponsoring the study?
- What kinds of tests and exams will I have to take while I am in the study? How much time do these take? What is involved in each test? Are these extra tests?
- How often does the study require me to go to the doctor or clinic?
- Will I be hospitalized? If so, how often and for how long?
- What are the costs to me? Will my health insurance pay for it?
- Will there be follow-up?
- What happens at the end of the study?
- What are my other treatment choices? How do they compare with the treatment being studied?
- What side effects can I expect from the treatment being tested? How do they compare with side effects of standard treatment? How long will they last?

Questions, concerns, or feedback about human research at the University of Rochester, can be directed to a Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Ave., Rochester, NY 14642-8315; Telephone: 585/276-0005; for long-distance, call toll free: 877/449-4441.