



Clinical Trials: for Volunteers

Understanding Clinical Trials

What is a clinical trial?

A clinical trial is a research study to determine whether new drugs or treatments are safe and effective in humans. Carefully conducted clinical trials are the fastest and safest way to find treatments that work.

Here are some terms that you need to know as you learn about clinical trials:

Placebo A placebo is an inactive (or “dummy”) pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment’s effectiveness.

Control Group In many clinical trials, one group of patients will be given an experimental drug or treatment, while another group, the control group, is given the conventional treatment.

A Blind Study A blinded study is one in which participants do not know whether they are in the experimental or control group in a research study.

A Double-Blind Study A double-blinded study is one in which neither the participants nor the study staff know which participants are receiving the experimental treatment and which ones are getting a standard treatment. These studies are performed so neither the patients’ nor the doctors’ expectations about the experimental drug influence the outcome.

Side Effects Side effects are any undesired actions or effects of a drug or treatment. Such effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental treatments must be evaluated for both immediate and long-term side effects.

What are clinical trial phases?

Clinical trials of experimental drugs proceed through four phases:

- Phase I clinical trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- Phase II clinical trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
- Phase III studies, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- Phase IV studies are done after the drug or treatment has been approved for marketing. These studies continue testing the study drug or treatment to collect information about its effect in various populations and any side effects associated with long-term use.

Who sponsors clinical trials?

Clinical trials are sponsored by government agencies such as the National Institutes of Health (NIH), pharmaceutical companies, individual physician-scientists, health care institutions and organizations that develop medical devices or equipment. Trials can take place in a variety of locations such as hospitals, universities, physicians' offices or community clinics.

Who can participate in a clinical trial?

At SUNY Upstate Medical University, our researchers conduct hundreds of clinical trials for a wide range of drugs and treatments each year. Researchers encourage the participation of men and women from all gender, ethnic and racial groups. Choosing to participate in a clinical trial is an important personal decision. In addition to the information provided here, you may find it helpful to talk to your health care provider, family members or friends before deciding to join a trial.

All clinical trials have guidelines about who is eligible for the study. Guidelines are based on such factors as age, type of disease, medical history and current medical condition. Before volunteering for a clinical trial, volunteers must qualify for the study. Some research studies seek volunteers with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Healthy volunteers may participate in Phase I trials, vaccine studies, and trials on basic science studies on preventive care for children or adults.

What is a protocol?

Protocol The protocol of a clinical trial describes the study, including what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial,

volunteers are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

What happens during a clinical trial?

Participants work with a research team that may include doctors, nurses, social workers and other health care professionals. They will check the participants' health at the beginning of the trial, give them specific instructions for participating in the trial, monitor them carefully during the trial, and stay in touch with them after the study.

Participation is most successful if the participant follows the protocol carefully and stays in contact with the research staff. Some terms that will clarify what happens in a trial are defined at right.

How are clinical trial volunteers protected?

The government has strict guidelines and safeguards to protect people who choose to participate in clinical trials. Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and the benefits are as great as possible.

The IRB is involved to make sure that the study is performed ethically and that volunteers are protected.

Informed consent Informed consent is the process of learning the key facts about a clinical trial before you decide whether to participate.

These facts include:

- Why the research is being done.
- What the researchers want to accomplish.
- What will be done during the trial and for how long.
- What risks are involved in the trial.
- What benefits can be expected from the trial.
- What other treatments are available.
- The participant's right to leave the trial at any time.

If a person is considering volunteering for a clinical trial, the Upstate research staff provide informed consent documents that include the details about the study. If English is not the person's native language, the volunteer can ask for the consent documents in other languages. Volunteering for a clinical trial is an important decision. Therefore, volunteers are encouraged to ask questions about the study and the consent forms before they make a decision.

What are the benefits of participating in a clinical trial?

- You gain access to new treatments that may not be available to the public.
- You help others by contributing to medical research.
- You take an active role in your own health care

What are the risks of participating in clinical trials?

- There may be side effects or adverse reactions to medications or treatments.
- The treatment may not be effective for you.
- The protocol may require a lot of time for trips to the study site, treatments, hospital stays or complex dosage requirements.

What should I know before I join a clinical trial?

You should know as much as possible about the research study. It is important for you to feel very comfortable asking questions and the staff should answer them in a way you can understand.

Some questions you might ask about the research include

- Why is this research being done?
- What is the purpose of the study?
- Who is sponsoring the study?
- Who has reviewed and approved this study?
- Why does the research team think the treatment, drug, or medical device will work?

Some questions about participation in the study include

- Where is the study site?
- Are there transportation and parking costs?
- How often will I have to go to the study site?
- What kinds of therapies, procedures, and/or tests will I have during the trial?
- Will they hurt? If so, for how long?
- How will the tests in the study compare to tests I would have outside the study?
- How long will the study last?
- Who will provide my medical care after the study ends?
- Will I be able to take my regular medications during the trial?
- What medications, procedures, or treatments must I avoid while in the study?
- What are my responsibilities during the study?

- Will I have to be in the hospital during the study?
- Will the study researchers work with my doctor while I am in the study?
- Can anyone find out that I am participating in a study?
- Can I talk to other people in the study?
- Will I be able to find out the results of the trial?

For more information, contact:

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