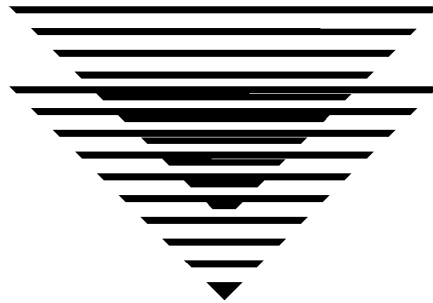


Volunteering for a Clinical Trial



***Your guide to participating in
an important research study***

INTRODUCTION

Over the past several years, a large and growing number of people want to learn more about clinical research and how to participate in a study. This brochure provides information about the clinical trials process and what it means for you to volunteer to participate in a clinical trial.

WHAT IS A CLINICAL TRIAL?

A clinical trial is a carefully designed study that is done with people like you who volunteer to receive investigational treatments under close supervision by a physician and other research professionals. Pharmaceutical, Device and Biotechnology companies have developed these treatments. These companies have then selected physicians, also called investigators, who are qualified to conduct clinical trials. It is through these trials that investigational drugs, devices and new treatments may show their benefits.

The clinical testing of an investigational drug, device or procedure is a step-by-step process that ensures you receive careful medical attention. All clinical trials are reviewed by the U.S. government's Food and Drug Administration (FDA) and Institutional Review Boards (IRBs). IRBs are independent committees whose job is to make sure your rights are fully protected and that you are not exposed to any unnecessary risks. IRBs also are responsible for ensuring you sign a consent form before agreeing to participate in a trial.

In a clinical trial, a volunteer is usually assigned a specific study group. Volunteers will receive an investigational treatment, study drug/device, or they will receive a placebo or a treatment already available. A placebo is an inactive product used to compare the results of the study drug. You, your physician and your research staff may not know who is receiving a placebo and who is not. In this way, volunteers in a clinical trial can be observed by the physician and research staff more fairly. Whether you receive the placebo or the investigational product, the level of medical attention and care that you receive is the same.

HOW ARE EXPERIMENTAL DRUGS/ DEVICES TESTED IN HUMANS?

Before a company can initiate testing in humans, it must conduct extensive preclinical or laboratory research. This research typically involves years of experiments in animal and human cells. If this stage of testing is successful, the company provides this data to the Food and Drug Administration (FDA), requesting approval to begin testing in humans. This is called an Investigational New Drug application (IND) or Investigational Device Exemption (IDE).

The clinical testing of experimental drugs/devices is normally done in three phases, each successive phase involving a larger number of people. Once the FDA has granted a New Drug Approval (NDA) or Investigational Device Exemption (IDE), sponsoring companies also conduct post marketing or late phase three/phase four studies.

Phase I Study

Phase I studies are primarily concerned with assessing the drug/device's safety. This initial phase of testing in humans is done in a small number of healthy volunteers (20 to 100), who are usually paid for participating in the study. The study is designed to determine what happens to the drug/device in the human body, how it is absorbed, metabolized, and excreted. A phase I study will investigate side effects that occur as dosage levels are increased. This initial phase of testing typically takes several months. About 70 percent of experimental drugs pass this initial phase of testing.

Phase II Study

Once a drug/device has been shown to be safe, it must be tested for efficacy. This second phase of testing may last from several months to years and involve up to several hundred patients. Most Phase II studies are randomized trials (like flipping a coin). One group of patients will randomly receive the experimental drug, while a second “control” group will randomly receive a standard treatment or placebo. Often these studies are “blinded” – neither the patients nor the researchers know who is getting the experimental drug. In this manner, the study can provide the company and the FDA comparative information about the relative safety of the new drug/device and its effectiveness. Only about one-third of experimental drugs successfully complete both phase I and phase II studies.

Phase III Study

In a phase III study, a drug/device is tested in several hundred to several thousand patients. This large-scale testing provides the company and the FDA with a more thorough understanding of the drug’s effectiveness, benefits, and the range of possible side effects. Most phase III studies are randomized (like flipping a coin) and blinded trials. Phase III studies typically last several years. Seventy to ninety percent of drugs/devices that enter phase III studies successfully complete this phase of testing. Once a phase III study is successfully completed, a company can request FDA approval for marketing the drug/device/treatment.

Post-Marketing – Late Phase III / Phase IV Studies

In late phase III/phase IV studies, companies have several objectives:

1. To compare a drug/device with others already on the market;
2. To monitor a drug/device’s long-term effectiveness and impact on a patient’s quality of life; and
3. To determine the cost-effectiveness of a drug/device therapy relative to other traditional and new therapies.

WHO PAYS FOR CLINICAL RESEARCH?

Funding for clinical research comes from both the federal government (through the National Institute of Health) and private industry (pharmaceutical, device and biotech companies). The sponsor of the research hires physicians, who may work in a wide variety of health-care settings, to conduct the clinical trial. Physicians are typically paid on a per-patient basis. The medical care is often provided free to the patient. Patients may also be paid a small fee to participate in a clinical trial to cover additional expenses like mileage and parking.

SHOULD YOU PARTICIPATE IN CLINICAL RESEARCH?

People volunteer to participate in clinical research for a variety of reasons.

- As a volunteer in a clinical trial, you help in the development of medical therapies – therapies that may offer better treatments and even cures for life-threatening and chronic diseases.
- People who volunteer for phase II and phase III trials might receive promising drugs/devices long before these compounds are approved for the marketplace.
- People participating in clinical research receive the highest level of comprehensive cardiovascular care available, emphasizing compassion and a commitment to excellence.
- Typically, people who participate in clinical research receive study-related medical care at no cost to the patient.

The patient's rights and safety are protected in two important ways:

- First, any physician awarded a research grant by a sponsoring company or the NIH must obtain approval to conduct the study from an Institutional Review Board. The review board, which is usually composed of physicians and lay people, is charged with examining the study's protocol to ensure that the patient's rights are protected, and that the study does not present an undue or unnecessary risk to the patient.
- Second, anyone participating in a clinical trial in the United States is required to sign an "informed consent" form. This form details the nature of the study, the risks involved, and what may happen to a patient in the study. The informed consent tells patients that they have a right to leave the study at any time.

It is important that you make an informed choice about volunteering for a clinical trial. Before you agree to participate, you should discuss the following questions with your physician or your research center's staff:

- How long will the trial last?
- Where is the trial being conducted?
- What treatments will be used and how?
- What is the main purpose of the trial?
- How will patient safety be monitored?
- Are there any risks involved?
- What are the possible benefits?
- What are the alternative treatments besides the one being tested in the trial?
- Who is sponsoring the trial?
- Do I have to pay for any part of the trial?
- What happens if I am harmed by the trial?
- Can I opt to remain on this treatment, even after termination of the trial?

WHAT CAN I EXPECT?

Once you have enrolled in a study, you may receive a physical examination. Your study physician or a research staff member will review your medical history as well. A detailed description of your specific clinical trial and what is expected of you will be outlined in your consent form.

Physicians and healthcare professionals who conduct clinical trials are committed to providing you with quality patient care and medical attention. You should feel free to discuss your medical treatment with your physician investigator or any research staff member at any time during the course of your clinical trial.

Your safety is the number one priority in a clinical trial. Therefore, it is important that you comply with all procedures and take all your medication as prescribed, that you keep all of your scheduled visits, and that you answer your investigator's questions regarding how you feel and whether you have been taking your medication at the scheduled times.

Many study volunteers appreciate the medical attention that they receive when they participate. Your study investigator needs to record any symptoms no matter how minor they may seem to you. If you miss your medication or you have not taken it on schedule, tell your physician or research staff. Your input is valuable and important.

When you participate in a clinical trial, your privacy is protected. Your medical records are confidential. The trial data that is provided to the company and the FDA will not include your name or the names of other individuals participating in the study.

As a volunteer, you have the right to leave your study at any time, and for any reason.

WHAT HAPPENS AFTER THE TRIAL?

After a study is complete, all of the information is collected and analyzed. This information determines whether a study drug/device/treatment is working, whether it is safe and whether it has any side effects. FDA medical advisors and specialists closely review this data before approving any new drug/device/treatment.

Even after approval, companies will continue to conduct studies that compare the new drug/device/treatment – in terms of its safety, effectiveness and cost – to other drugs/devices/treatments already on the market. Other research studies may determine if a therapy can be administered to children or special populations. Some studies assess the long-term effectiveness and its impact on the quality of a person's life.

Every volunteer in a clinical trial is extremely valuable and important. Without volunteers, there would be no new drugs/devices/treatments to fight diseases and ailments. By participating in a clinical trial, you are helping yourself and others like you live longer and healthier lives now and long into the future.

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