Clinical Trials of Medical Treatments: Why Volunteer?

What Is A Clinical Trial?

"Clinical trial" is the scientific term for a test or study of a drug or medical device in people. These tests are done to see if the product is safe and effective for people to use. Doctors and other health professionals run the tests 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 the studies are treated as safely as possible.

Why Volunteer?

By taking part in a clinical trial, you can try a new treatment that may or may not be better than those that already exist. You can also help others better understand how the treatment works in people of different races and genders.

Why Should Minorities and Women Participate In Clinical Trials?

In the past, most drug testing had been done on white men. This means that some groups, such as African Americans, Hispanics/Latinos, American Indians, Asians, Pacific Islanders and women, had not always been included in the tests done on drugs. But sometimes drugs work differently in these people than on white men. So FDA wants people from many different groups included in these studies.

What Happens in a Clinical Trial?

Clinical trials are done to test whether new products are safe and work against disease. Study products are tested to see how they compare to standard treatments or to no treatment if there is not presently one.

Many studies require that neither the patient nor the doctor know whether the patient is receiving the study treatment, the standard treatment, or a placebo (an inactive substance that looks like the drug being tested). In other words, some people may be getting no treatment at all.

Studies are done in phases to find different kinds of information. Usually, Phase 1 studies include only a few healthy people. Here, scientists find the best way to give a new treatment and how much they can safely give.

Phase 2 studies include more people than Phase 1 studies, and the people have disease that the product is going to treat. Now scientists try to see how well the product works against the disease. If the product works, the study moves into Phase 3. Here large numbers of patients with the disease are included to see if the new treatment works as well as the standard treatment.

What Are the Risks?

Some treatments that are being tested have side effects that can be unpleasant, serious or even life-threatening. Because the treatments being studied are new, doctors don't always know what the side effects will be. Many side effects are temporary and go away when the treatment is stopped. But others can be permanent. Some side effects appear during treatment, while others may not show up until after the treatment is over. The risks depend on the treatment being studied and all known risks should be fully explained to you by the researchers.

How am I Protected?

Informed Consent

To help you decide if you want to be in a study, FDA requires that you be given complete information about the study before you agree to take part. This is known as informed consent. FDA requires that people be told:

* that the study involves research of an unproven drug or device
* the purpose of the research
* how long the study will take
* what will happen in the study and which parts of the study are experimental
* possible risks or discomforts
* possible benefits
* other procedures or treatments that you might want to consider instead of the treatment being studied
* that FDA may look at study records, but the records will be kept secret
* whether any medical treatments are available if you are hurt, what those treatments are, where they can be found, and who will pay for the treatment
* the person to contact with questions about the study, your rights, or if you get hurt
* you can quit at any time.

Informed consents must be written so you can understand it. If you don't, be sure to ask the doctor or other medical person to explain it. Make sure you understand all of it before you agree to be in the study.

Before you can be in the study, you must sign the informed consent form, showing that you have been given this information and understand it. The informed consent form is NOT a contract and you can leave the study at any time, for any reason.

Other Ways Volunteers Are Protected

Institutional Review Boards (IRBs)

Scientists, doctors and other people from the local community serve on IRBs to review and monitor their hospital's or research institution's medical research involving people. They monitor studies to help make sure that there is the least possible risk to volunteers and that the risks are reasonable in relation to the expected benefits. IRBs make sure volunteer selection is fair and that informed consent is done correctly.

Data Monitoring Committees

These committees are used mainly when one treatment is being compared with another. These committees are particularly important in tests of treatments for serious or life-threatening disease. These experts review information from studies to make sure they are being done in a way that is safest for the volunteers. During a study, if the committee finds that the treatment is harmful or of no benefit, it will stop the study. If a study shows that one treatment works better than another, the committee stops the study and all volunteers are offered the better treatment.

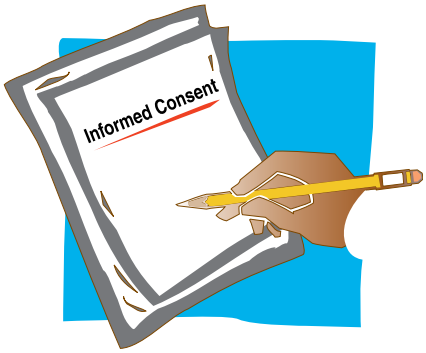
FDA Inspections

FDA inspects records and various scientists, clinics, and other research sites involved in a study. The agency does this to make sure volunteers are being protected and studies are being done correctly. From time to time such inspections are done in response to complaints.

What Questions Should I Ask?

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

* What is the study trying to find out?
* What kinds of test and exams will I have to take while I'm in the study? How much time do these take? What is involved in each test?
* 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?
* What follow-up will there be?
* What will happen 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 the study last?

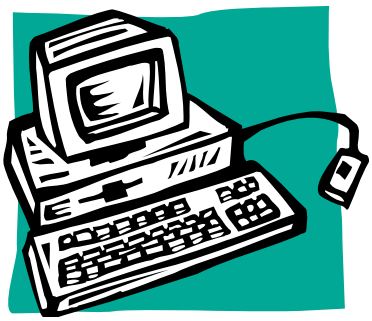


Points to Remember

* Clinical trials are tests of medical treatments to see if they are safe and if they work.
* Before you agree to take part in a study, you must be given complete information about the study, including possible side effects and benefits.
* You should ask lots of questions to be sure you understand the study.
* You must sign a special agreement called "Informed Consent" before taking part in the study.
* The Informed Consent is not a contract. You can leave the study at any time.

How Can I Find Out About Clinical Trials?

One good way to find out if there are any treatments in clinical trials that might help you is to ask your doctor. Other sources of information include:



For cancer, call 1-800-4-CANCER (1-800-422-6237) or visit this World Wide Website: *cancertrials.nci.nih.gov/*

For AIDS and HIV, call 1-800-TRIALS-A (1-800-874-2572) or visit this World Wide Website: *www.actis.org*

For general information about clinical trials, call FDA's Office of Special Health Issues at 301-827-4460 or visit this World Wide Website: *www.fda.gov/oashi/home.html*

For other clinical trials of other diseases, visit this World Wide Website: *www.clinical trials.gov*

The Food and Drug Administration is an agency of the U.S. Department of Health and Human Services that makes sure blood transfusions and medicines for HIV, AIDS, and other illnesses work and are safe.

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