FDA Office of Women's Health

Clinical Trials

CLINICAL TRIALS

What is a clinical trial?

A clinical trial is a study carried out in human volunteers to help doctors learn more about the human body and the many diseases that attack it. It may also be used to answer health questions about new medicines and treatments. The information gained from a clinical study is added to the results from lab and animal testing. This helps researchers find out if these products are safe for humans to use and if they work the way they are supposed to work.

What can I gain from joining a clinical trial? You will:

- Take a more active role in your own health care.
- Try new treatments that are not offered to the public. They may work better than the treatments that are offered now.
- Get free care at some of the best hospitals and clinics in the country.
- Help to expand science and research.

What are some risks of being in a clinical trial?

- Since treatments are new, doctors don't always know what the side effects may be.
- Some treatments may cause problems or side effects that are unpleasant and or serious.
- The study may take more time than getting a regular treatment. You might need to make lots of visits, have lots of tests, or stay in the hospital.
- The treatment may not work for you.
- Your regular health insurance may not cover the costs of treating any side effects you have during a clinical trial, or after the clinical trial is over. Check with your health plan before joining any clinical trial.

What questions should I ask if I am thinking about a clinical trial?

If you want to take part in a clinical trial, the law says that you must first see papers that tell you all about the benefits and risks of the trial. It must tell you the reasons for the study and how it will be done. These papers are called "Informed Consent". Informed Consent protects your health while taking part in the clinical research. After reading it, you should be able to go over the information with the study doctors and ask questions about anything you do not understand. For example:

- Why is this study being done?
- How might the study help?
- What other treatments are available, besides the treatment that is being studied?
- How long will the study take?
- What will happen in the study?
- What problems or side effects could happen?
- Are there treatments for people who have side effects or problems? What are they? Who will pay for them?

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Afterwards, you will have to sign the Informed Consent form saying that you got this information and that you understand it. It's your choice to be in the study and you can quit at any time.

What is a "placebo"?

Usually, clinical trials compare a new treatment to a treatment that is already offered to the public. Researchers want to see if the new treatment works as well or better than the old one. In some studies, volunteers may get a placebo. A placebo is often called a "sugar pill". It looks like the product that is being tested, but it doesn't do anything. Using a placebo can be the fastest and surest way to see if the new treatment really works.

Placebos are not used if a patient has a serious illness that needs treatment, All people are told before they join a trial if placebos are going to be used in the study.

Who can be part of a clinical trial?

- Every study has its own rules about who can take part.
- Some studies need volunteers with a certain disease.
- Other studies need healthy people who have no diseases.
- Some studies want just men or just women, or people who are a certain age.

To Learn More...

Food and Drug Administration Office of Special Health Issues
Phone: 1-301-827-4460
www.fda.gov/oashi/clinicaltrials/default.htm

National Institutes of Health
www.nih.gov/health/trials/index.htm

FDA Office of Women's Health
www.fda.gov/womens