FDA Office of Women's Health

Clinical Trials for Medical Treatments

A "clinical trial" is a test or study of a drug or medical device on people. Clinical trials are done to see if the drug or device works and is safe. They are the best tool we have to find treatments that will help everyone's health. The FDA sets strict rules so people who enter these studies are treated as safely as possible. The rules also protect the rights of people in the study.

Why should women and minorities take part in clinical trials?

- In the past, women, African Americans, Hispanic Americans, Native Americans, and Asian Americans have often been left out of research.
- Sometimes drugs work differently in these groups. FDA wants the best treatments for all people who will be using a product after it is approved.
- It is important for everyone to participate in clinical trials.

What are the risks?

- In many studies, the patient and the doctor do not know what the patient is getting. The patient may get the experimental treatment, the standard treatment, or a placebo. (A placebo looks like the drug being tested, but it doesn't do anything.) In other words, some volunteers may be getting no treatment at all.

  Placebos are *not* used when:
  - doctors already have treatments that work or
  - getting no treatment could put the patients at risk.

- Some treatments may have side effects that are unpleasant, serious, or could even put your life in danger.
- Since treatments are new, doctors do not always know what the side effects will be.

What about my health insurance?

- Health insurers do not always cover all the costs of side effects during a research study. Make sure to contact your health plan before taking part in a study.

What are the benefits?

- You *may* get a treatment that is better than other treatments available right now.
- You will get free screenings and exams.
- Information from the study could improve your health and the health of future generations.
- The study will keep a close record of your health care and any side effects.

What else do I need to know?

- Talk about the study with your own doctor to help decide if it is the right choice for you.

What is informed consent?

FDA wants to inform people who take part in clinical trials. Before taking part in a study, you must be told certain things.

- This 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
- Possible risks or discomforts
- Possible benefits
- Other treatments you may want to consider other than the one being studied
- Whether any treatments are available if you are hurt, what those treatments are, and who will pay for them
- Before you start the study, you must sign a written "informed consent" form showing that you have been given the information and understand it.
- Being in the study **is your choice** and **you can quit at any time**.

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CLINICAL TRIALS

Clinical Trials for Medical Treatments(cont.)

To Learn More…

FDA's Website: www.fda.gov
OWH (Office of Women's Health) Website: www.fda.gov/womens

FDA's Office of Special Health Issues:
Call 1-301-827-4460

Or visit:
www.fda.gov/oashi/home.html
www.nih.gov/health/trials/index.htm