

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.
- Help to expand science and research.

What are some risks of being in a clinical trial?

- Since treatments are new, doctors do not always know what the side effects may be.
- Some treatments may cause problems or side effects that are unpleasant, serious, or life threatening.
- The study may take more time than getting a regular treatment. You might need to make many visits, have many tests, or stay in the hospital.
- The treatment may not work for you.

What about my health insurance?

- 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.



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What is informed consent?

Informed consent is the process of learning key facts about a clinical trial before deciding to take part. Before joining, you must be told certain things:

- This study involves research of an unproven medical device or product such as a drug or medical device.
- The purpose of the research.
- How long the study will take.
- What will happen in the study.
- Which parts are experimental.
- Possible risks or discomforts.
- Other treatments you may want to think about.
- Who will have access to your study records.
- Whether any treatments are available if you get hurt, and who will pay for them.
- The person to contact with questions about the study, your rights, or if you get hurt.
- **Being in the study is your choice. You can quit at any time.**

FDA Office of Women's Health <http://www.fda.gov/womens>

To Learn More:

FDA Office of Special Health Issues

Phone: 301-827-4460

<http://www.fda.gov/oashi/clinicaltrials/default.htm>

National Institutes of Health (NIH)

<http://www.nih.gov/health/trials/index.htm>