



Clinical Trial Research

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What is a Clinical Research Study?

Before a new medication can be approved and sold as a treatment for an illness, it must be proven to be safe and effective in research studies, which are also clinical trials. A clinical trial is a research study in human volunteers that is designed to answer important questions about investigational medication, including:

- Does the investigational medication work?
- Which dose works best?

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People participate in clinical research studies for a variety of reasons. Some people participate in clinical research studies because they want to contribute toward developing medical knowledge, to gain access to investigational medications, and to help researchers understand if and how an investigational medication works. There are also known and unknown risks associated with participating in a clinical research study, such as side effects resulting from the investigational medication and the potential that the medication does not work for the participant.

Choosing to take part in a clinical research study is an important decision. This brochure provides information that may help you decide if you would like to take part in clinical research studies.

What Can I Expect My Experience to Be?

- You will be *randomly assigned*, like flipping a coin, to receive a real drug or a placebo (harmless pill).
- You have an *equal chance of receiving a placebo or real drug* during the study.
- *You and the study staff will not know which study drug you are getting* until the study is complete (this is called 'double blind').
- Most drugs being tested do not help everyone who takes them.
- You can have a change in your symptoms even if you are taking the placebo (harmless pill).
- Your symptoms may or *may not get better* from the treatment you receive in a study.

What is Expected of Me in a Clinical Trial?

- *Give accurate information* about your symptoms.
- Honestly report when you have *no change* in symptoms.
- Honestly report if your symptoms get *better* or *worse*.
- Think of yourself as a consumer-goods product tester. This is like a blind taste test comparing foods to see which brand tastes better.
- You are **NOT** expected to report that your symptoms got better, just report how you feel each day.

How Do Clinical Trials Help?

When some people take a drug at the same time that other people take a placebo (harmless pill), we can find out:

- If the drug works at all.
- If the drug works better than the placebo.
- If the drug works the same the placebo.

Both "over-the-counter" and prescription medicines, like cough syrup or pain killers, were once tested in clinical trials. They now help thousands of people every day.

What is a Placebo?

Placebos do not contain any medicines. The placebo will look, smell, taste, and feel like the real drug being tested. Sometimes participants taking a placebo experience side effects or their symptoms might get better. Many people assume this means they are taking the real drug. Although this is possible, you might experience changes in your symptoms because you:

- Use other treatments or medicines.
- Are hopeful about the study.
- Feel worried about side effects.
- Want to help the research staff.