

# What is a Clinical Trial?

A clinical trial is the term for any test or study of an investigational drug, device, or other medical treatment in human subjects. Some

Clinical trials may test already approved (on the market) medications or devices. Each clinical trial is reviewed and conducted under the guidance of the Food and Drug Administration (FDA).



## Who conducts clinical trials?

Clinical trials are sponsored by government agencies such as the American Cancer Society and the Kidney Foundation, pharmaceutical companies, device manufacturers, research institutions, individual physicians and other health organizations. The sponsor is responsible for designing a protocol, which is the study plan that the investigator follows. Only trained investigators (doctors, nurses and medical researchers) actually conduct the study.

## How are volunteers protected?

Your study doctor and the research team are concerned about your health and safety. If you have any questions or think you are having a study related problem, you should contact them right away. Federal regulations require that you be given complete information about the trial before you agree to participate. This is known as informed consent.

Before you can be in the trial, you must sign a consent form showing that you understand it. Clinical trials, by law, must be approved and monitored by an institutional review board (IRB). The IRB checks to see that there is the least possible risk to volunteers and that the risks are reasonable in relation to any expected benefits. The IRB reviews the plan for volunteer selection for fairness and that informed consent is obtained correctly.

## Who can participate?

Every clinical trial has guidelines about who is eligible. There are certain requirements about your health, medical condition, medications, age and other criteria.

38135 MARKET SQUARE, ZEPHYRHILLS

**813.780.8368**



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## What are the risks?

There may be side effects or adverse reactions to the medications or treatments. Because the treatments being studied are new, the doctors do not always know what the side effects will be. While it is possible that some side effects could be permanent or life threatening, most are temporary and can be treated or go away when the treatment is stopped.



## What are the benefits?

There may or not be a direct benefit to you if you volunteer for a clinical trial. Your health or your health condition may get better as a result of your participation. It

may stay the same or it may even get worse. No one can completely predict the outcome of a clinical trial or how it might effect you. The study may result in information that will help others in the future.

## What kind of questions should I ask?

- What is the study trying to figure out?
- Who is sponsoring the study?
- What kinds of tests and exams will I have to take while I am in the study? How much time do these take? What is involved in each test? Are these extra tests?
- 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?
- Will there be follow-up?
- What happens 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 the side effects of standard treatment? How long will they last?

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