

*Meridian Health offers clinical trials in cardiology, oncology, infectious disease, medicine, women's health, rheumatology, endocrinology, surgery, pediatrics and other therapeutic areas.*

### What questions should I ask about clinical trials?

- What is the purpose of the study?
- Who is going to be in the study?
- Have other clinical trials been done using this study's treatment method and if so, what were the results?
- Why do researchers believe the new treatment being tested may be effective? Has it been tested before?
- What kinds of tests and treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Will hospitalization be required?
- Will my insurance cover the costs of participating in the study?
- How long do I have to decide about enrolling in this trial?



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# RESEARCH

## Understanding Clinical Research





## What is clinical research?

The purpose of clinical research, or clinical trials, is to find a better way to detect, prevent, control, or cure a disease or disorder. Some trials test the effects of treatment on disease, some aim to prevent disease; others study the effect of the disease itself on the quality of life, costs, and comfort.

Clinical trials involve people and are primarily designed to test the effects of a new or existing treatment on an illness or disorder. The treatment can be a drug, a biological agent, a medical device, or a behavioral change, but it needs to have shown some promise in treating or preventing the health problem before it can be treated in a clinical trial.

## Why is clinical research important?

Advances in medicine and science result from new ideas or approaches developed through research. Clinical trials help identify how safe and effective a treatment is for its intended use. In the U.S., new drugs or devices must be shown to be safe and effective in clinical trials of certain patients before the Food and Drug Administration (FDA) can approve them for use. Until then, they are considered investigational.

## Who qualifies for clinical trials?

Not everyone with a specific disease or condition is eligible. Type and extent of disease, age, and health status can determine your eligibility. Inclusion and exclusion criteria are used to identify appropriate participants. The criteria help ensure that researchers will be able to answer the questions they plan to study.

## What are some of the risks of participating in a clinical trial?

- The treatment given in a clinical trial may not help a participant more than standard of care.

- Side effects of treatment may be different or worse than those of standard of care for participants on a clinical trial.
- Health insurance does not always pay for all your costs in a study. Each insurance policy and study is different and your care team will be able to tell you what to expect.

## What are some of the benefits of participating in a clinical trial?

- Participants in clinical trials will receive either standard of care or a promising new treatment that doctors hope will be better than standard of care. The new treatment may be available only to those who join the trial.
- If a new treatment is proven to be effective, participants in clinical trials who are taking it may be among the first to benefit.
- In many clinical trials, study medication, medical care, and laboratory services may be provided to you free of charge.
- In most cases, your own doctor provides your care in your own community where access is often more convenient.
- Although there may or may not be a direct medical benefit to you, doctors will learn as much as possible to help future patients.

## What is the process?

Before you enroll in a clinical trial, a doctor or nurse will explain why the study is being done, how it relates to your care and what will happen during the study. You are encouraged to ask questions.

You will be given a consent form that explains what will happen before, during, and after your participation in the clinical trial, what side effects are possible, and how your daily life will be affected.

You can take as much time as you need to make your decision. If you decide to take part in the clinical trial, you will sign the consent form. Even if you sign the consent form, you can change your mind and stop participation in the trial at any time.

## How are my rights protected?

Clinical trials are reviewed and monitored by health authorities and medical experts at both a national and local level. Another important group is called the Institutional Review Board (IRB) at Meridian Health. Its job is to review each clinical trial to make sure it is safe and fair. The board includes Meridian Health doctors, nurses, pharmacists, and representatives from the community.

## Do I have to participate in a clinical trial if it is offered to me?

NO — taking part in a clinical trial is your choice. It is always a good idea to discuss all of your treatment options with both your doctor and your family. Get all the information you need to feel comfortable about your decision.

Meridian Health provides an exceptional patient experience through its hospitals and partner company programs and services.

To learn more about clinical trials at Meridian Health, talk to your doctor or call the **Office of Clinical Research** at **732.776.2953**. You can also visit any of our hospitals online and find us under the **'Health Information'** Tab or E-mail us at **Clinicaltrials@meridianhealth.com**.