

Frequently Asked Questions About Clinical Trials

Your doctor may have asked you to participate in a clinical trial. The following FAQs are provided to help answer some questions you may have about what to expect if you decide to join a clinical trial. We encourage you to discuss your treatment options with your doctor.

What is a clinical trial?

Clinical trials are typically defined as health-related research studies in human beings that follow a pre-defined protocol. There are 2 basic types of studies: observational and interventional. Observational studies are those in which individuals are observed and their outcomes are measured by the investigators. Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured.

Why participate in a clinical trial?

By participating in a clinical trial, you may gain access to new research treatments before they are widely available, play a more active role in your own health care, and help others with similar conditions by contributing to medical research.

Who can participate in a clinical trial?

To help produce reliable results, all clinical trials have guidelines about who can participate. Factors that allow someone to participate in a clinical trial are called “inclusion criteria” and those that may prevent someone from participating are called “exclusion criteria.” These may include age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. The criteria help ensure that researchers will be able to get the answer to the questions they plan to study, as well as ensure participant safety.

What happens during a clinical trial?

Each clinical trial is different, as the clinical trial process depends on the type of trial being conducted. The research team includes doctors and nurses as well as social workers and other health care professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and maintain contact after the trial is completed.

What is informed consent?

It's important for participants to understand key facts about a clinical trial before deciding whether or not to participate. To help someone decide whether or not to participate, doctors and nurses involved in the trial explain the details of the study. This is known as informed consent. Then the research team provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

What are the benefits and risks of participating in a clinical trial?

The benefits of clinical trial participation include the opportunity for participants to gain access to new research treatments before they are widely available, obtain expert medical care at leading health care facilities during the trial, help others by contributing to medical research and play an active role in their own health care.

Risks may involve the potential for unpleasant, serious, or even life-threatening side effects associated with an experimental treatment, or lack of effectiveness of the experimental treatment for the participant. Another important factor to consider is that being part of a trial may take more time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays, or complex dosage requirements.

What are side effects and adverse reactions?

Side effects are any undesired actions or effects of the experimental drug or treatment, for example, headache, nausea, hair loss, skin irritation, or other physical problems. These may occur right away or over a period of time.

How is the safety of the participant protected?

The safety of trial participants is protected by ethical and legal codes that govern medical practice and clinical trials. Additionally, most clinical research is federally regulated with built-in safeguards to protect the participants. Individual participants' names will remain confidential and will not be mentioned in trial reports.

What should people consider before participating in a trial?

People should know as much as possible about the clinical trial and feel comfortable asking the members of the health care team questions about it, the care expected while in a trial, and the cost of the trial.

The following questions might be helpful for the participant to discuss with the health care team. Some of the answers to these questions are found in the informed consent document.

- What is the purpose of the study?
- What risks and benefits have been associated with the experimental treatment?
- What time commitment will be expected if I participate?

In the US, each clinical trial must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures that a clinical trial is ethical and the rights of study participants are protected.

Does a participant continue to work with a primary health care provider while in a trial?

Yes. Most clinical trials do not provide extended or complete primary health care, focusing instead on short-term interventions related to a designated illness or condition.

Can a participant leave a clinical trial after it has begun?

Yes. A participant can leave a clinical trial, at any time.

What is a placebo?

A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the experimental treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or experimental treatment.

What is a control or control group?

A control is the standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.