Participating in research is a choice

Joining a research study is an important personal decision. Before you join, researchers will talk with you about the goals of the study, and the possible risks and benefits. They will also explain the rules they follow to protect your safety and privacy. Ask for help if you don't understand something or have questions.

You should never feel rushed or pressured to make a decision. Being part of a research study is completely voluntary – it's your choice.

After you understand the study, if you decide to take part you will be asked to sign a document called an "informed consent form." You can change your mind at any time, for any reason, even after you sign.

Where can I find out more about clinical trials?

Your healthcare provider may be able to help you find more information about clinical trials. You can also sign up for a research registry to learn more about clinical trials. For more information, check out our Research Registry brochure.

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Questions to ask

You have the right to ask questions about a clinical trial before you decide whether to participate. Below is a list of some questions you might want to ask before you agree to take part in a clinical trial.

- What is the purpose of the clinical trial?
- Who is paying for the trial?
- What makes me eligible to participate in the trial?
- What will I be asked to do as part of the trial?
- How long will the trial last?
- How many times will I need to be seen or be asked to provide information?
- What are the potential benefits and risks if I participate?
- What are my alternatives to participating?
- Will you share my test results with me? Will I be told the results of the study?
- Will I know or be able to find out which treatment I receive? If so, when will I be told?
- Will I be compensated for participating in the clinical trial?
- If I develop any problems from the trial, will the study pay for my medical care?

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CLINICAL TRIALS

Participating in research is your choice. Be informed. Ask questions. Get answers.

A clinical trial is a type of research study that includes human research participants (also called "research volunteers" or "research subjects"). In a clinical trial, researchers observe the effects an intervention may have on participants. The researcher collects data (information) about how the intervention affects participants' health.

What is a clinical trial?

A clinical trial is a type of research study that includes human research participants (also called "research volunteers" or "research subjects"). A research study is done to answer a scientific question, and a doctor or scientist who is conducting research is called a "researcher." In a clinical trial, researchers observe the effects an intervention may have on participants. An intervention may be a medical drug or device or procedure; it might also be a behavior change that participants agree to try. The researcher collects data (information) about how the intervention affects participants' health.

Why do we need clinical trials?

Clinical trials are needed to develop or test new drugs, devices, treatments, and procedures and help answer questions such as:

- Does it work?
- Does it work better than other treatments?
- What amount is safe and effective?
- What are the side effects?

Who can participate?

People of all ages may participate in clinical trials. Some participants have a disease or condition that the researchers are studying; other participants are healthy volunteers. For each clinical trial, there are requirements regarding who can participate (inclusion criteria) and reasons why someone might not qualify to participate in the trial (exclusion criteria).

How are clinical trials developed?

1. First, researchers decide what question(s) they want to answer.
2. Then, researchers develop a research study plan (called a "protocol"). The protocol describes how the researchers intend to answer the question(s) and the role of research participants in the study.
3. Next, a research ethics committee must review and approve the protocol. In the U.S. this committee is called an institutional review board (IRB). The IRB considers the scientific benefits and potential risks of the study, and how research participants will be affected by taking part.
4. After it has all the necessary approvals, the researcher can start the clinical trial.

What are the phases of clinical trials?

In Phase I trials, researchers test an intervention in a small group of healthy volunteers. They want to learn if the intervention is safe, the correct dosage, and if volunteers have any reactions to or side effects from the intervention. In Phase II, III, and IV trials, researchers learn more about the safety of the intervention and how well it works in larger groups of participants.

Who pays for clinical trials?

Trials may be paid for by government agencies, pharmaceutical companies, or nonprofit organizations.

How do clinical trials work?

For most clinical trials a participant is assigned to either an intervention or a control group.

Intervention Group: Participants in this group receive the intervention that is being tested.

Control Group: Participants in this group do not receive the intervention. Instead they might receive the standard treatment for the disease or condition, or they might receive a "placebo". A placebo looks or feels like the intervention, but it is not an active medicine or treatment. The control group helps the researchers understand the effects of the experimental intervention.

Research participants are often assigned randomly to a group. This means your group assignment happens by chance (like tossing a coin). If you take part in a clinical trial, you might not get the experimental treatment that is being tested. In some cases, you won't know the group to which you are assigned.

Potential benefits and risks may include:

Benefits:

- Having access to experimental treatments that are not yet available to the public
- Helping others by contributing to the development of new medical treatments or procedures

Risks:

- Receiving an experimental treatment when its effects are not yet fully understood
- Experiencing unpleasant, serious, or even life-threatening side effects or complications