

SHOULD I BE A RESEARCH PARTICIPANT?



YOUR GUIDE TO UNDERSTANDING THE CLINICAL RESEARCH PROCESS

The term “clinical research” describes studies that collect new information on human health and disease. Clinical research involves research participants to test new drugs, procedures, or devices, or to better understand how the human body works.

Why Volunteer in Clinical Research?

- > The development of new medical treatments and cures would be impossible without the help of research participants.
- > By volunteering in a study, you will help others by contributing to medical research.
- > You could also help researchers to learn about a disease or condition.
- > In some cases, you can try a new drug, procedure, or device before it is available outside of research studies; however, they may not work better than the ones that are already available.

Questions to Ask Before Participating in a Study:

- > Why is the study being done?
- > What will happen if I agree to join?
- > Could the study help me? Could it help others?
- > Could I get hurt during the study?
- > Will I be paid to participate in the study?
- > Will I have to pay for anything if I am in the study?
- > How will my personal information be protected?
- > What happens if I get hurt in the study?
- > How long will the study last?
- > Can I leave the study at any time?
- > Who should I call with questions about the study?

Research Participant Bill of Rights

As a research participant, you have the following rights:

- > To be treated in a caring and polite way.
- > To be told what the study is trying to find out.
- > To understand every form you are asked to sign or fill out.
- > To understand what will happen during the study, and what makes it different from standard medical care.
- > To be told about possible side effects or discomforts that might happen during the study.
- > To be told about any benefits from being in the study.
- > To be told about other treatment options, and how they might be better or worse than the study treatment.
- > To be told what treatment is available for you if any medical problems arise while you are in the study.
- > To ask any questions about the study.
- > To take your time when you are deciding if you want to be in the study.
- > To be told about new information that comes up during the study that could affect your decision to stay in the study.
- > To refuse to be in the study, or to change your mind about being in the study after it has started.
- > To receive a copy of the consent form you sign if you decide to join the study.



Common Misunderstandings about Clinical Research

The doctor or research team would not suggest a study unless it is best for me.

This is not true! We do research to find out which treatment is better. No one can guarantee that the treatment being studied will be better than the standard available treatment.

If the doctor asks me to participate, I really should say yes.

You can decide whether or not you want to join a study. It is your personal decision, and if you say no, your care at the hospital or your relationship with your doctor will not change.

Once I decide to be in the study, I cannot change my mind.

You are free to stop participating in any study at any time.

If I agree to take part in drug research, I will get the new drug.

Not necessarily. Many studies of new drugs include a “control” medication. This could be a drug that is already approved as a treatment, or a fake pill (called a placebo). In most studies, participants are assigned to the new drug or placebo by chance. Neither you nor the researcher can choose what you get.

What is Clinical Research?

The term “clinical research” describes studies to collect new information on human health and disease. Clinical research involves research participants to test new drugs, procedures, or devices, or to better understand how the human body works.

There are several types of clinical research studies:

- > **Genetic studies** find the role of genes in different diseases.
- > **Prevention studies** test ways to prevent specific diseases.
- > **Behavioral studies** test how people act in different situations.
- > **Physiological studies** increase understanding of how the human body works.
- > **Clinical trials** are studies of a drug, procedure, or medical device used in healthy participants or people who have a specific disease.

Clinical trials of new drugs are done in different phases to answer different questions.

- > **Phase I studies** test a new drug for the first time in humans to see if it is safe.
- > **Phase II studies** include more people to see if the new drug works.
- > **Phase III studies** are done in large groups of people to see if the new drug works better than what is already available.
- > **Phase IV studies** are done after the drug is approved by the U.S. Food and Drug Administration (FDA) to find out more information.

How Am I Protected if I Participate in a Research Study?

Researchers design studies that keep the risks to participants as small as possible. There are also laws to protect participants.

- > All clinical studies have a very detailed study plan called a “protocol” spelling out how the study will be done.
- > A group of doctors, nurses, researchers, and members of the community looks carefully at each protocol. This group is called an Institutional Review Board or IRB. They make sure that the study is conducted fairly, with as little risk for participants as possible.
- > When you enroll in a study, you will receive the contact information of the person in charge of the study, along with a phone number of the IRB, for any issues and questions related to safety.
- > Some more risky studies also include another review group called a Data and Safety Monitoring Board (DSMB). A DSMB is made up of doctors who are not part of the study. They make sure that the risks of participating in the study are as small as possible.

What are the Risks?

There may be risks when participating in research. Some drugs or procedures can have unpleasant or serious side effects, including life-threatening ones. Sometimes, there may be side effects that researchers do not know about. New drugs or procedures are not always better than what is already available. Talk to the research team about the risks in the study.