

Why Volunteer in Clinical Research?

- > The development of new medical treatments and cures would be impossible without the active participation of research volunteers.
- > 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 treatment before it is available outside of research studies; however, these new drugs, procedures, or devices may or may not be more effective than the ones that are already available.

10 Questions to Ask Before Enrolling in a Study:

- > Why is the research being done?
- > What is expected of me if I agree to participate in the research?
- > How will I benefit from the research?
- > Could the research hurt me?
- > What will the researcher do with my information?
- > Will the research cost me anything?
- > Who pays if I'm unexpectedly injured in the study?
- > How long will the study last?
- > What happens if I decide to leave the study early?
- > Who should I call if I have a question about the research?
- > Could my tissue or cell line(s) made from my tissue be transplanted into others?

Research Subject Bill of Rights

As a research subject, 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 be informed what will happen, and whether any of the procedures, drugs, or devices are different from what would be used in standard medical care.
- > To be told about possible side effects or discomforts that may happen during the study.
- > To be told if you can expect any benefit from being in the study and, if so, what the benefit might be.
- > To be told of other choices for treatment you have, and how they might be better or worse than being in the study.
- > To be told what sort of treatment is available if any medical problems arise.
- > To be allowed to ask any questions about the study both before agreeing to be involved and during the course of the study.
- > To be free from pressure when deciding if you want to be in the study.
- > To be told about new information learned during the study that might affect your safety or your willingness to continue to take part in the study.
- > To refuse to be in the study, or to change your mind about being in the study after it has started. This decision will not affect the care you receive at the hospital.
- > To receive a copy of a signed consent form.

Learn more:

guides.library.harvard.edu/healthresearch



Health Research

SHOULD I BE A RESEARCH SUBJECT?



YOUR GUIDE TO UNDERSTANDING THE CLINICAL RESEARCH PROCESS

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

This brochure contains general information for educational purposes and is not intended to provide medical advice. Talk with your own doctor or the research team for advice about your personal situation and health concerns.

Questions? Call us at



Common Misunderstandings in 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 be changed in any way.

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

You are always free to stop taking part in any study at any time.

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

Not necessarily. Frequently, studies of new drugs include a “control” medication. It could be an already approved drug or a fake pill (called a placebo). In most studies, volunteers are assigned to the new drug or placebo by chance, like tossing a coin. Neither you nor your doctor 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 volunteers to test new drugs, procedures, or devices; or to better understand how the human body works.

There are several types of clinical research studies, including the following:

- > **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 functions.
- > **Clinical trials** are studies of a drug, procedure, or medical device used in healthy volunteers or people who have a specific disease.

Clinical trials of new drugs are done in different phases:

- > **Phase I studies** test a new drug for the first time in humans to see if it safe.
- > **Phase II studies** are done in more people to see how effective the new drug is.
- > **Phase III studies** are done in large groups of people to see if the new drug works well, has side effects, and how it compares to other drugs
- > **Phase IV studies** are done after the medication is approved by the U.S. Food and Drug Administration (FDA) to get additional information.

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

Investigators design studies that keep the risks to subjects as small as possible. These are also safeguards (protections) that are required by law. Some of these safeguards are:

- > All clinical studies have a very detailed “protocol”, (study plan) spelling out how the study will be done.
- > The Institutional Review Board (IRB), a committee of doctors, nurses, researchers, and members of the community, reviews each protocol. The IRB makes 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 phone number of the doctor 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 committee called a Data and Safety Monitoring Board (DSMB). A DSMB is made up of doctors who are not part of the study. This Board regularly looks at the results during the course of the study. The DSMB makes sure that the risks of taking part in the study are as small as possible, and can stop the study if new concerns about safety come to light.

What are the Risks?

There may be risks for research volunteers. Some tests or procedures can have unpleasant or even serious side effects, including life-threatening ones. The new drugs, procedures, or devices under study can have side effects that are not well known. New treatments are not always better than the standard care to which they are being compared.