

WHAT IS DIFFERENT ABOUT RESEARCH AT THE NIH?

The NIH is a Federal Government agency dedicated only to health-related research. Health-related research is different from healthcare. **This means that doctors and other healthcare providers at the NIH cannot evaluate your health or care for you unless you are enrolled in a research study at NIH.**

If you decide not to participate in a study, the doctor at NIH may be able to help your regular doctor find a specialist who can assist in your regular care.

WHAT IS THE INSTITUTIONAL REVIEW BOARD?

The NIH IRB includes people with a variety of backgrounds, such as:

- Scientists (e.g., doctors, nurses)
- People who are not scientists
- People who understand the perspective of research participants
- People who are not connected to the NIH

HOW DOES THE IRB HELP YOU AS A RESEARCH PARTICIPANT?

By reviewing a study before it starts, the IRB makes sure the study is ethical, fair, and as safe as possible for you to take part in it.

The IRB also looks at the **informed consent form** to make sure that it is written in a way that is understandable. It also makes sure that you get the information you need to decide whether or not you want to join the research study.

While the study is happening, the IRB reviews it to make sure that it continues to be safe and ethical for you to take part in. For example, the IRB reviews changes to the research, or problems that may happen during the research.

If there is new safety information about the study, the IRB will ask the researcher to give you the new information, so that you can decide if you want to stay in the study.

Contact the office below if you have questions about this pamphlet or your rights as a research subject.

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS (OHSRP)

Email: irb@od.nih.gov

Phone: (301) 402-3713

Website: <https://irbo.nih.gov/research-participants>



ARE YOU THINKING ABOUT JOINING AN NIH RESEARCH STUDY?



JOINING AN NIH RESEARCH STUDY IS
YOUR CHOICE

BE INFORMED. ASK QUESTIONS.
GET ANSWERS

WHAT IS A RESEARCH STUDY?

A **research study** is a group of activities that are done to answer a specific scientific question. Studies are designed to increase our knowledge and understanding about health and disease. All studies must follow a detailed plan that outlines who is eligible to join and what will happen during the study.

When you join an NIH research study, you help researchers learn about health-related conditions or behaviors. There are many different types of research studies. For example, some studies look at new drugs or medical devices and test whether it is safe to use them in humans. Some studies look at whether a new drug or device works better or is safer than treatments that you might get in a regular doctor's office. Other types of studies follow people with specific diseases over time to learn more about the disease. Other studies look at healthy people to better understand normal human health.

HOW IS RESEARCH DIFFERENT THAN MEDICAL CARE?

It is important to understand that enrolling in a research study is very different than seeing your regular doctor. For example, if you are in a study that is testing a new drug or medical device to treat a disease that you have, it may not help you in any way. Researchers often do not know if the new drug or device will work or how safe it is which is why the study is being done.

After a study ends, researchers may share the results in a medical journal, at a conference or in a news article. They may also share it with the people who were in the study.

What questions should you consider asking NIH researchers when you are deciding whether or not to join a study?

Here are some questions you might want to ask before you agree to take part in a study:

- How are the activities (procedures) and medicines in this study **different from the healthcare** I am able to get from my regular doctor?
- **Why am I being invited to join** this research study?
- **What do researchers expect me to do** in this study?
- What parts of the study would someone get during **regular medical care**? What parts of the study will be done that is **only for the research**?
- Could being in the study **improve** my symptoms or condition? Could being in the study make my symptoms or condition **worse**?
- If I join this study, will it **prevent** me from getting other treatments or procedures for my condition that are not part of this study from my medical doctor?
- Are there other treatments or procedures I could get from my medical doctor if I **don't join** this study?
- **How often** will I need to visit the NIH? How long will the study **last**?
- Is there anything I need to know if I am **pregnant** or plan to become pregnant soon?
- Could I have **side effects**, or could there be other risks from being in the study?

- Will the results of my study tests **be given to me**?
- Will being in the study **cost me** anything (for example, travel, lodging or medications)?
- Will my insurance **be billed** if I am in the study?
- Will my blood samples, information collected on the study, or any other personal information about me be **used or shared** with anyone outside the study?
- Can anybody **find out** that I am in the research study?
- Will I be able to **get the drug or device** being studied after I complete the study?
- If I join the study, can I later **decide to stop** being in the study?
- What do I need to know if I **leave the study**?
- When the study is complete, how will you **share** what you learned from the study? Will you share the study results with me **personally**?

