

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 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, you can agree to take part by signing a document called an “informed consent form.” You can change your mind at any time, for any reason, even after you sign.

What are the risks of taking part in drug research?

Taking part in drug research may involve some risks for research participants. This is because being in a research study is not the same as getting regular medical care. Instead, the researchers are trying to answer a question.

A research drug might work the way researchers think it will, or it might not. Research drugs can have side effects (unwanted effects of taking the research drug) that are not well known. Specific risks and benefits will be described in detail in the informed consent form. Make sure you understand the risks before you agree to take part in a study.

Questions to ask

You have the right to ask questions about a research study before you decide whether to take part in it. Below is a list of questions you might want to ask before you agree to take part in a drug research study.

- > What is the purpose of this research study?
- > Will I get the research drug? Will the research staff know if I have been given the research drug or a placebo?
- > Do I have to go to the research site? If yes, how often? What if I miss a visit?
- > What are the potential risks and benefits of being in this study?
- > What are the expected side effects?
- > Do I have to pay for the research drug? Will my insurance company be billed for any visits and medication I receive for this research study?
- > Will my participation in the research study be added to my medical records? Will my primary care physician be informed of my participation in this study?
- > How long will the study last? What happens if I decide to leave the study early?
- > Can I get the research drug without being in the study?
- > If the research drug works, can I get it after the study ends?
- > Who should I call if I have questions about the study or research drug?



WHAT IS INVOLVED IN A DRUG RESEARCH STUDY?



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

Researchers are interested in how drugs can help prevent, diagnose, or treat diseases and conditions. They are also interested in how some drugs can improve general health. A chemical that researchers are studying is called a “research drug.”

What is drug research?

Clinical research is the process of developing and testing new medical drugs and other medical treatments. A drug is any chemical that can change the way your body works. Drugs can come in many forms such as a liquid or a pill. Researchers are interested in how drugs can help prevent, diagnose, or treat diseases and conditions. They are also interested in how some drugs can improve general health. A chemical that researchers are studying is called a “research drug.”

Steps in drug research

Researchers first test drugs in the laboratory and in animal studies. If a research drug meets certain safety standards and might be an effective new treatment, researchers then test it in humans.

Drug research happens in **3 major steps**:

1. **Drug discovery:** Researchers look for chemicals that could have positive effects on the human body.
2. **Preclinical studies:** Researchers test the research drug on cells in a laboratory or on animals. They do this to learn what the research drug might do in the human body.
3. **Clinical Trials:** Researchers test the safety of a research drug, look for side effects, learn the right amount (dosage) of the drug for people to take, and determine how well it works. Clinical trials involve research participants (also called “research volunteers” and “research subjects”). In clinical trials, researchers usually compare a research drug with a drug that is already approved to treat the disease or condition they are studying. They might also compare it with a placebo. A placebo is a pill or treatment that looks like the drug being tested but does not contain the actual research drug.

What does it mean to take part in drug research?

When you participate in drug research, you help researchers answer questions about a research drug. Clinical trials are divided into four phases. Each phase helps scientists answer different types of questions, and each phase may involve different responsibilities for research participants.

- > In **phase I** trials, researchers test a drug in a small group of healthy research participants. They want to learn if the drug is safe, what amount is safe, and if research participants have any side effects.
- > In **phase II, III, and IV** trials, researchers keep learning about the safety of the research drug. They learn how well it works in larger groups of research participants. Some research participants have the disease or condition the drug is designed to help.

It’s important to know that if you take part in drug research, you might not get the research drug. Instead, you might get the usual treatment or you might get a placebo. Researchers often assign research participants to different drugs at random (by chance). In some studies, the research team might not be able to tell you if you received the research drug. It is also possible that no one in the study, including you, the researcher, and the study staff, will know what drug you get or who gets the research drug. Sometimes the team might not be able to share your test results with you.

Who takes part in drug research?

Drug research studies can involve hundreds or thousands of research participants. Adults and children can both take part in drug research.

They can be:

- > Healthy research participants, or
- > People with a disease or condition researchers are studying

Why do researchers do drug research?

- > To find a chemical or combination of chemicals that has a good effect on the human body
- > To learn if a research drug is safe and effective in treating a disease or condition
- > To find the best dosage of a research drug
- > To learn how different people react to a research drug – including children, adults, patients with a certain disease or condition, and others
- > Regulatory agencies, such as United States Food and Drug Administration (FDA) use the information from drug research to determine if a research drug should be approved and made available to the public as a treatment.

