

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.

Giving information is also a choice

The research team will review with you a list of information they will collect and share as part of the research study. Be sure to tell them if there are certain pieces of information that you do not want to share. It's best to tell the research team about this as soon as possible. If you can, tell them before you start the research study, so they do not collect any information that you are uncomfortable sharing. Researchers may need specific information to do the study, and you may need to provide it if you want to be in the study. If you choose not to share that information, you may not be able to take part in the research study.

If you have questions about sharing your information, ask a member of the research team.

Questions to ask

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

- > What information will you collect about me?
- > Who will have access to my research data?
- > Are my research data placed in my regular medical records?
- > How will you store and protect my research data?
- > Will you share my research data with others? If so, how will they protect it?
- > If you take my name off my research data, can someone still identify me?
- > What will happen to my research data when the study ends?
- > How long will you store my research data?
- > Even if my data will be deleted, will it be permanently erased and removed from all the places it was shared or stored?
- > What types of research might be done with my research data in the future?



Health Research

RESEARCH DATA: HOW IS MY INFORMATION PROTECTED AND USED?



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

If you take part in a research study, researchers may collect information about you as part of the study. Researchers call this information "data." Before you decide to take part in a research study, make sure you understand how information about you will be collected, stored, and shared. This brochure tells you what researchers do to keep your data protected.

Questions? Call us at



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

What are research data?

Research data are pieces of information that are collected, observed, or created for researchers to review as part of a research study. If you take part in a research study, researchers may collect from you information on the research topic as well as personal information, such as your age and address.

What are the differences between research data and medical information?

Your doctor collects medical information from you to provide you with medical care. The medical information goes into your medical records.

A research study is not intended to provide you with medical care. Researchers collect and look at research data to help answer a scientific question. Research data are stored in a secure study file, and some data might also go into your medical record.

Does my research data become part of my medical records?

It depends. Research data are kept in the study file, separate from your medical record. However, some information might go into your medical records, where your doctor can see it. For example, researchers might send your doctor a list of allergies or the results of blood tests performed as part of the research. If you have questions about what information might go into your medical records, or be sent to your doctor, ask a member of the research team.

How are my research data protected?

Researchers work to make sure only people who should see your research data are able to. Each study protects research data in different ways.

Research teams often:

- > Lock paper records in a file cabinet or room
- > Store electronic information behind a firewall or on a secure computer
- > Use a password or encryption (an electronic code) to protect research data

Can researchers guarantee my research data will stay protected?

Researchers work hard to protect research data. They must follow laws and rules to secure your information. United States law requires some organizations to keep the following types of information private:

- > Information that identifies you
- > Information about your physical and mental health

There is no absolute guarantee your research data will be protected. If your research data are incorrectly shared, the research team will work to fix this problem.

Who will see my research data?

The research team for your study can see your research data in the study file, but they may not be able to match this information with your identity.

Researchers may separate information that can be used to identify you (for example, your name) from the rest of your research data. Sometimes they use a code (such as numbers and letters) so that this information can be connected again later, if needed.

Members of the committee that make sure the study is done correctly might need to see your information. This committee is called the “ethics review committee” or the “institutional review board,” also called the IRB. People who supervise or help with the research study, such as government agencies, lawyers, or data storage workers, might also need to see this information.

Your research data may be saved after the study ends so that researchers can use it in the future. If your information is included in future studies, you may have little or no control over who will see it or how it will be used.

If you have questions about who will see your research data now or in the future, ask a member of the research team.