

Human Research Protections

UT Southwestern is committed to protecting the rights, safety and welfare of people who voluntarily participate in research. This commitment is carried out through the Human Research Protection Program (HRPP).

The HRPP is a network of components such as Institutional Review Board (IRB), Compliance, Safety Committees, Privacy, Grants and Contracts, Conflict of Interest, and other Institutional offices and committees designed to oversee how research is carried out.

Institutional Review Board (IRB)

The Institutional Review Board (IRB) is a critical part of the HRPP. The IRB is responsible for ensuring rights and welfare of participants are protected and that research meets ethical standards as required by law.

UTSW has four IRBs, each meeting twice per month to review research. Each IRB includes scientists, nurses, doctors, non-scientists and people from the community. The IRBs meet and review all studies to make sure the risks in the study are as low as possible, and that benefits of the research justify the risks to participants.

All human research must be approved by the IRB before starting any research activities.

HRPP Office (HRPPO)

UT Southwestern has established an office to coordinate of Human Research Protection Program. The HRPPO supports research by overseeing the IRBs, ensuring communication between HRPP components and by providing guidance, education , and compliance oversight for studies involving human participants.

Questions, Concerns or Comments

If you are participating in a research study, contact the research team first, especially if you are having medical problems.

If you have questions about research, need answers about your rights as a research participant, need to voice concerns or complaints, or cannot contact the research team, you can contact:

Human Research Protection Program

UT Southwestern Medical Center
5323 Harry Hines Boulevard
MC 8843
Dallas, Texas 75390

Phone: 214-648-3060
E-mail: HRPP@UTSouthwestern.edu

Human Research Participant Information

*What do you need to know
about participating in
research studies?*

*Human Research
Protection Program*

UT Southwestern
Medical Center



What is Research?

Research may be referred to as a clinical trial, protocol, survey, or experiment. Research is what scientists do to answer questions.

Research studies are essential to making discoveries, like a new medication, that improves health care for all people.

Often, research is a test or study of a drug or medical device. Tests must be done to see if the product is safe and effective for people to use. If you volunteer for a research study, you may be asked to take a medication, have tests completed or complete a task. The research team will collect information about you and combine it with information from other participants in the study to answer the research questions.

There is no guarantee that you will benefit from participating in a research study, but the researchers hope the information learned in the study will benefit other people in the future.

Research vs. Treatment

The goal of **research** is to learn new things in order to help groups of people in the future. Researchers follow the same plan for all participants and usually do not make changes for each individual participant. You may not receive any benefit from participating in a research study.

The goal of **treatment** is to help you get better or improve your quality of life. Your doctor may change your care to give you the best chance to get better or improve your quality of life.

The Consent Process

The research team will give you information about the research to help you decide if you want to participate. You may be given a consent document containing all information about the study.

You should read the consent document and ask the research team any questions you may have. You may also want to , discuss the study with family, friends, and your doctors.

If you agree to participate, the researchers may ask you to sign the consent document. If you do not understand what will take place in the study or if do not wish to participate, you do not have to sign the consent.

You or your legal representative must give consent before any research activities begin. If the research is for your child, your child may also be involved in the consent discussion and should agree to participate according to his/her understanding.

Research Participant Rights

If you are asked to participate in a research study at UTSW, you have the right to:

1. Learn what the research study is about
2. Understand what you will be asked to do and how much time it will take
3. Learn about any benefits you might expect and what new things may be learned
4. Receive a description of any discomforts or risks you could experience from participating
5. Learn about the risks and benefits of all treatment options outside of the research study, including drugs, devices, or other treatments
6. Understand what will happen if you have any problems because of participating in a research study
7. Ask questions about the study and receive answers before and after you decide to participate
8. End your study participation at any time without affecting your care at UTSW
9. Learn about where to look for information about what was learned from the research study when the study is over
10. Receive a copy of the consent document or information sheet

