

What are your rights if you decide to participate in a research study?

If you volunteer to participate in research studies you should understand what is being asked of you and why the research is being done. It is also important that you know your rights, which include:

- Being told what the study is trying to find out.
- Being told what will happen to you and whether any of the procedures, drugs or devices differ from what would be used in standard practice.
- Being told about the frequent and/or important risks, side effects or discomforts you may encounter during the study.
- Being told whether you can expect any benefit from participating and, if so, what that benefit might be.
- Being told about other choices you may have and how they may be better or worse than being in the study.
- You may ask questions about the study before you agree to participate and during the course of the study.
- Being told what medical treatment is available if complications arise.
- You may refuse to participate or change your mind about participating after the study has started.

Questions you need to ask, or think about before deciding to participate in a research study.

- Am I feeling pressure or obligation to participate in this study?
- How long does my participation in this study last?
- When does this study take place?
- Is the study anonymous or confidential?
- How is my privacy being protected?
- Would I be able to quit without harming my relationship with the researcher or the university?
- Who can I contact if I have questions or complaints?
- Is the study safe?
- Am I going to learn anything from participating?

QUESTIONS, CONCERNS, COMPLAINTS

If you have any questions about your rights as a research subject or if you have concerns or complaints about the research study in which you are participating, please the IRB at (605) 677-6184. All calls will be confidential and, if you choose, anonymous.

**Office of Human Subjects Protection
Phone: (605) 677-6184**

Human Subject Research



What you should know before deciding to participate in a research study.



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What is human subject research?

Researchers utilize human subjects to answer a specific question or find information that may benefit people. . These studies can involve a wide variety of procedures, ranging from filling out surveys and questionnaires to taking experimental drugs or even surgical procedures. Some studies last a few minutes while others last for many years.

Who does research at USD?

Research studies are conducted by students, staff, and faculty of the university. Research studies can be conducted by students to fulfill an educational requirement such as a thesis or dissertation, or by a faculty member searching for the answer to a medical or social, behavioral or educational question.

The researcher in charge of the study is called the Principal Investigator (PI). The PI has the ultimate responsibility for the management of the study and for protecting the rights, welfare and safety of the human subject.

Are there any benefits to being in a research study?

Not everyone who participates in a research study will benefit personally. Sometimes, your participation will benefit humanity by helping researchers learn more about a disease or condition. In other studies, you may benefit if the experimental drug or device makes your disease stop progressing or lessens its effect on you.

Who determines if the researcher has approval to do his or her research?

The University of South Dakota requires that all research involving human subjects be reviewed and approved by the Institutional Review Board (IRB) before the research can begin.



What is the IRB?

The IRB is a committee of people charged with assuring, both in advance and by periodic review that appropriate steps are taken to protect the rights and welfare of people who participate as subjects in research studies.

The IRB is comprised of faculty, physicians and staff from disciplines that conduct human subject research at the university. IRB membership also includes a Native American representative, and a community representative who is not affiliated with the university.

The USD IRB reviews non-clinical research as well as medical research that is conducted by the Medical School and the Sioux Falls, Black Hills, and Fargo, ND Veterans Administration Hospitals.

What are the risks of being in a research study?

Research studies may involve some degree of risk. A study that asks you to anonymously fill out a survey usually has only minor risks, such as the discomfort or fatigue that may follow filling out the survey. For other studies, risk can be much greater; for example, having a bad reaction to a drug.

Researchers are required to explain the risks of being in a study to you before you decide whether or not to participate.

Participation in a research study is voluntary and you may choose not to participate at any time. Your decision will in no way affect your relationship with USD.

Withdrawal from a study will not result in any penalty or loss of a benefit to which you were otherwise entitled.

What should you do if you have more questions?

If you have any questions regarding a specific research study, the PI will provide you with a way to contact them. You may contact them at anytime during the study. If you cannot reach the investigator or you wish to talk to someone other than the PI about the study you may call the Office of Human Subjects Protection at (605) 677-6184.