Participant Rights

What is research?

Research is an organized way of collecting information to help understand problems and test ideas for the benefit of society. Sacramento State faculty, students and staff do research in many different areas. Humans might participate in research about things like:

- how people behave or make decisions
- the ways groups and societies are organized
- what people think or believe
- how people learn
- the best ways to provide social services or healthcare

What do participants do?

Participants help researchers in many different ways. Depending on the goals of the research, participants might be asked to do things like:

- Take part in interviews (sometimes as part of a group)
- Complete questionnaires, tests or special tasks
- Allow access to private information (such as medical records or school records)
- Let researchers observe behavior
- Complete physical, psychological or other kinds of examinations
- Give samples of blood, saliva or other materials
- Use experimental medical devices

What is the Institutional Review Board (IRB)?

CSUS's IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted by CSUS faculty, staff, or students. CSUS's IRB is composed of 12 members representing University faculty and staff, as well as the local community. The IRB reviews research which involves human subjects to ensure that two broad standards are upheld: first, participants are not unnecessarily exposed to risk; second, they willingly give, without undue influence or coercion, informed consent to participate in the research. A project is first reviewed in its proposal stage - even before participants are recruited. An IRB can require changes to research, or even not allow research, to protect participants. When an IRB approves a researcher's protocol, the researcher must follow that plan exactly. If a researcher wants to change the plan, an IRB has to review and approve the changes first (unless changes are needed right away to protect participants from harm). When issues arise, researchers must report those problems to the IRB. Each approved study is re-evaluated at least annually. The Department of Health & Human Services (HHS) Office for Human Research Protections (OHRP) oversees the operation of the IRB, and the Food and Drug Administration (FDA) enforces regulations for the use of experimental drugs and devices.

Who can volunteer to be a research participant?

Anyone can volunteer. People who volunteer for research come from all walks of life. Volunteers can be healthy or they may have a specific condition. Volunteers can be younger or older adults as well as children. Everyone, regardless or gender, age, or ethnicity may volunteer for research.

Can children participate in research too?

Yes, children can participate in research studies. However, there are additional protections for children. For example, the parent(s) or legal guardian(s) must provide their permission for the child to participate. In addition, if a child is old enough to understand what the study is about, the child may also be asked to give his/her agreement or assent to participant in the research.

What rights do I have as a participant?

It is your decision whether or not you want to participate. In most cases you do not have to decide right away. You have the right to make this decision without any pressure. There will not be any consequences if you refuse.

To help you make an informed decision, you have the right to receive information about the study. Information will almost always be given to you in writing (written study information is called an "informed consent form" or "study information sheet"). The information must always be in a language you can understand. If you do not understand something, the study team must explain it for you in a way that you can understand. You have the right to ask questions at any time and to have your questions answered. If you decide to participate, you will be asked to sign and date the informed consent form if the study is not exempt from this requirement. In many cases, a signature is not required because the research is low risk and your signature may be the only thing linking you to the research.

You also have the right to leave the research at any time. If you leave the research, your decision will not affect your relationship with CSUS or any rights or benefits to which you are otherwise entitled. You simply need to tell the research staff that you have changed your mind.

What information should the researcher give to me?

The researcher will usually give you the information listed below. Some of the information below will only be given to you for medical studies.

- Why the research is being done
- Why you are being asked to participate
- How long your participation will last
- What will happen during the research (what you will do)

- How the research is different from your usual medical care, if applicable (research is not the same as treatment)
- Any expected risks or discomforts that you might experience
- How information about you will be protected
- Any expected benefits
- Who can help you with problems or give you more information about the study or your rights

If you are concerned about any issue or you do not feel like you have enough information, tell the researcher at any time before, during or after the research.

What will happen if I participate in research at CSUS?

You will be presented with information about the study. This is called the informed consent process. Members of the study team, including the researchers, will discuss this information with you. They will usually ask you questions to make sure that you understand the information.

Once you understand the information and decide to participate, you will be asked to sign the consent form. In low risk studies, you may not be asked to sign the form to ensure complete anonymity of participants. You might also be asked to sign other documents, such as a form giving permission to use your medical records.

Before you go through informed consent, the researchers might ask some basic questions about you. This is to see if you might qualify to participate.

If you answer questions before giving informed consent, the researchers might still need more information about you after you give informed consent. This will be done to make sure that you qualify. If you are in medical research, this might include a physical examination, blood tests or other procedures.

In some cases, researchers can accept anyone who volunteers. In other cases, researchers can accept only a certain number of people or only people who fit exactly what they are looking for. If you do not qualify, it means the researchers are looking for other specific qualifying characteristics or the study was already full.

If you qualify for a study, you will go through the exact steps of the approved research plan. What you undergo during the research should be exactly what is described in the consent form.

What will happen (and for how long) depends on the goals of the research. Sometimes researchers will be able to work around your schedule. In other studies, visits might have to happen at very specific times. All of this should be explained to you during the informed consent process.

What are the benefits of participating?

Researchers are searching for new information and new answers to problems. Because of this, most research is not intended to provide you with direct benefits. Research can also have serious risks. When you participate in research, you are mostly contributing to scientific progress and helping society.

Research is not the same as treatment. In clinical research, many of the devices and procedures being tested are experimental. This means that they have not been proven to work. There may be unknown risks. Although being in a clinical study might help you, nobody can guarantee a direct benefit for you.

Will I be paid for participating?

Most studies do not have the resources to pay you. Payment will be explained to you during the informed consent process. Other studies might pay you for the time and effort it takes to participate. The money is usually only enough to cover expenses (parking, transportation, meals, etc.) and maybe for some of the time you spend away from work.

The payment should not be enough to convince you to take risks that you normally would not take.

If you leave before the end of the research, you will usually be paid for that portion of the research you complete.

How do I protect my rights if I participate?

The most important thing to do is take an active role and communicate with the study team before, during and after the research. You should always ask questions if you are not clear about something, if you are curious about something, or if it seems like the research plan is different from what you were told. You have a right to have your questions answered. Take your time making decisions about whether or not to participate. You should seek the advice of trusted family members, friends or healthcare professionals before and during the research.

If you feel uncomfortable with what you are doing, or if you think you might be experiencing changes in your health (whether good or bad), let the study team know. Always keep in mind that participation in research is voluntary. If you feel like you are being pressured to join or stay in a study, you can always say no. You can leave the research at any time for any reason, and you do not have to explain your decision.

You can also contact our office with questions about your rights, or any problems or complaints about your experience with research at CSUS.

Confidential Reporting

If you would like to report activity that you believe to be non-compliant with federal regulation, state and local law, or university policies and you would like to submit this confidentially, please

contact us at irb@csus.edu. The information you submit is confidential and will be maintained to the highest level permitted by law.