If You Are Planning to Conduct Research with Humans as Participants. . .

. . . this brochure will help guide you through the process to assure that your research is approved as required by federal regulations and by Sonoma State University.

Read this brochure closely if you are among Sonoma State University faculty, staff, or students doing research with human participants.

SSU has regulations in place that follow federal guidelines and govern the use and protection of humans as research participants.

SSU and U.S. federal regulations require that researchers have their research projects reviewed and approved by the campus Institutional Review Board before the research begins.

This brochure explains the background and purpose of the regulations and the process for requesting and receiving approval.

Heather Smith, Chair
Institutional Review Board
Sonoma State University

For more information, please contact:

Office of Research and Sponsored Programs
1040 Salazar Hall
1801 East Cotati Avenue
Rohnert Park, CA 94928
Phone: 707-664-2066
E-mail: irb@sonoma.edu

Visit our website:
http://orsp.sonoma.edu/research-compliance/human-subjects

SONOMA
STATE UNIVERSITY

Working with Human Subjects in Research

Background

Protecting human participants in research is mandated by federal law for institutions applying for federal funding. It is a high priority for Sonoma State University. The University's policy, available online at https://www.sonoma.edu/policies/human-subjects-research, is modeled on the basic ethical principles detailed in the 1979 Belmont Report. These principles — respect for persons, beneficence, and justice — are designed to be integrated into research projects that involve human participants. This integration ensures that participants in research conducted at SSU know that their rights, personal safety, psychological security, and dignity are protected. SSU's policy on the use of human subjects in research extends the same commitment to human participants of all research whether or not projects are federally funded.

The Institutional Review Board (IRB)

Federal regulations stipulate that SSU organize an Institutional Review Board (IRB) to review and approve projects that involve human subjects before research begins. As required by law, SSU's IRB is composed of faculty, staff, and a member of the local community and is diverse and balanced in its membership.

What is "research"?

According to federal mandates, which can be found in the Code of Federal Regulations at 45CFR46, "research means a systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge" (46.102.(d)). This means that any study involving human subjects, including one that evaluates the effectiveness of a program by surveying the participants, should be submitted for review. If in doubt as to whether you should submit an application, please contact the Office of Research and Sponsored Programs at irb@sonoma.edu.

Levels of Review for Research Projects

There are three levels of review conducted by the IRB:

Exempt from Full IRB Review
Research that presents less than minimal risk to the participants and may include educational tests, surveys, interviews, etc. is exempt from full IRB review. Only the IRB, not the researcher, can make the judgment as to whether research is exempt.

Expedited Review
Research projects involving only minimal risk—which may include recording data through audio or video technology, or the use of external physical sensors, surveys, observation of behavior, etc.—receive an expedited review performed by the IRB Chair.

Full Review
Research projects involving greater than minimal risk to participants including vulnerable populations receive a full Board review. A full review requires the IRB to convene a quorum and may require adjustments consistent with safeguarding the rights of human subjects.

SSU Policy and Procedures

The IRB Compliance Officer , employed by the Office of Research and Sponsored Programs, serves as the contact liaison between the Institutional Review Board and the researchers. This person provides administrative support to the review process.

If you plan to have human participants in your research, you should review the steps listed below and incorporate them into your research project design.

- Contact the IRB Compliance Officer, for assistance in applying to the IRB to have your research evaluated and approved.
- Ask questions of the IRB Compliance Officer, your peers, or your faculty colleagues or advisor and include their suggestions in your research plan.
- Complete the application for the use of human participants. The application is available on the Office Research and Sponsored Programs web site: http://orsp.sonoma.edu/forms
- Complete "**CITI IRB Training"** provided by Collaborative Institutional Training Initiative (CITI), at https://citiprogram.org/. All Applicants, Co-Investigator(s) and Faculty Advisor(s) must submit a Certificate of Completion for IRB training. Certificate of Completion is valid for five years.
- Submit the application to the IRB Compliance Officer for processing and review. The IRB may ask for more information from you during the review process.
- Begin your research project **only after receiving approval from the IRB.** Research approvals expire on the date indicated on the application, unless an extension is requested and approved.
- Submit any proposed modifications to your research project to the IRB for approval.

Application for Use of Human Subjects

The application for the use of human participants in research is not complicated. You will be asked to briefly summarize the following aspects of your research:

- Scientific rationale for your research
- Subject pool (population, recruitment, selection, and expected number)
- Data collection procedures, including setting, equipment or questionnaires used; and procedures for protecting the confidentiality of the data
- Risks, if any, to participants and how these risks will be minimized
- Benefits, if any, to participants and/or to society at large
- Informed consent procedures.

Timeline

SSU policy requires you to **submit your application to the IRB Compliance Officer at least 30 days prior to your proposed start date**. It is a policy violation to commence research without IRB approval.

What Is Informed Consent?

The human participants in your project must receive adequate information in advance about your research project and voluntarily decide to participate. Essential information described on any informed consent form should include the following:

- Purpose of the research
- Benefits to the participant, or to others, that may reasonably be expected from the research
- Risks or discomforts to the participants that are reasonably foreseeable
- Length of participation time with the project
- How participants information is being protected
- Right to withdraw from the study at any time, that participation is voluntary, and the reassurance that their refusal to participate will involve no penalty or loss of benefits
- A source for answers to questions related to the project, and their participation as a research participant; or a contact in case of an emergency.

Informed consent, whether oral or written, may not include language through which the participant or their representative waives any legal rights, or language that releases the researcher, the sponsor, the university, or its agents from liability for negligence.