



UNIVERSITY OF
SOUTH DAKOTA

Human Subjects Protection Program

Student Investigator Guide

Why does USD require all research involving human participants to have IRB approval?

The University has a Federalwide Assurance (FWA) with the Office for Human Participant Protections (OHRP) in the Department of Health and Human Services (DHHS). The FWA is a binding written agreement between USD and DHHS which binds USD to comply with all federal regulations.

Per this agreement, all research involving human participants must be reviewed and approved by the USD Human Subject Protection Program.

Do I need to obtain IRB approval if I am using a pre-existing data set with or without participant identifiers?

Yes, anytime you are conducting research that contributes to generalizable knowledge and is considered a systematic investigation you must obtain IRB approval. The application requires the PI to specify where the data was obtained, the data points that will be evaluated, and how the PI has access to the data.

Do I need to obtain IRB approval if I am just doing a pilot study and am not going to use the data I collect from participants?

Yes, all human subjects research conducted at USD must have IRB approval. If research begins before formal IRB approval is granted, it is a violation of university policy.

What are the different levels of IRB Review?

Exempt Review

Research that presents minimal risk to the participants and may include educational tests, surveys, interviews, etc. With very few exceptions, private identifiable information **cannot** be recorded by the investigator or the research team. Research participants **do not** sign a consent form, but in most instances, a consent statement or cover letter is required.

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.

Full Board Review

A full board review requires the IRB to convene under a quorum and vote on research projects involving greater than minimal risk to participants, including vulnerable populations.

- The study is reviewed at convened IRB meeting.
- When all questions, clarifications, and revisions are complete, a decision is rendered at either a convened IRB meeting or by an experienced member.