## What if I am Conducting Research at Sites Other than the University?

When research is conducting at sites outside of the University of South Dakota the IRB requires the investigator to obtain documentation that he or she has permission to conduct the study at that site. In some instances (e.g., when research is conducted in certain school districts or at other hospitals), the permission of an additional IRB may be required. Please be aware that obtaining these permissions may prolong the time needed for the USD IRB to review and approve a protocol.

## Do I and my Advisor need any type of training?

Yes. You and your advisor need to complete human subjects training (CITI). You will need to complete either the **Group 1 Biomedical Research Investigators and Key Personnel** module or the **Group 2 Social Behavioral Research Investigators and Key Personnel** module.

www.citiprogram.org

## 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. If the data does not have any participant identifiers most likely the study will fall into the exempt category, but that is the determination of the IRB. If the data contains identifiers, it falls under the expedited category. 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.

## What exactly do I need to do to submit my study?

1. Complete the CITI Training (Advisor too!)
2. Visit the IRB Website
3. Complete the appropriate IRB Application
4. Write Informed consent or consent statement or cover letter.
5. Obtain signatures of advisor and Dean.
6. Make sure IRB Submission contains (if appropriate)
    - Surveys, interview questions
    - Data collection forms or variables
    - Letters of permission
    - Informed consent or consent statement or cover letter
    - CITI Certificates
    - Consent waivers
7. E-mail IRB Application packet to IRB (HumanSubjects@usd.edu). Make sure to attach the signature page as a PDF or send the hard copy to the office
8. After the IRB receives your application check your e-mail frequently in case the reviewer has questions or revisions.

## I have never submitted a project to the IRB before, is there anyone to help me through the process?

Yes, the IRB office staff is always willing to help a new or experienced investigator with their IRB submission. You can call the office, e-mail, stop in, or make an appointment**.**

## What resources are out there to assist me?

IRB Website—IRB Forms

http://www.usd.edu/research/research-and-sponsored-programs/human-subjects-protection.cfm

**Office of Human Subjects Protection**
**Slagle 107C, USD Vermillion Campus**
**HumanSubjects@usd.edu 677-6184**

# The University of South Dakota Human Subjects Protection Program

# Student Investigator Guide to the Institutional Review Board (IRB)

## What is the IRB?

An IRB is an institutional committee charged with reviewing all research involving human participants. The primary purpose of the IRB review is to insure the safety, rights and welfare of human participants involved in research.

## How many IRBs does USD have?

The University of South Dakota has one IRB. The USD IRB reviews all social, behavior, educational, health science, and medical studies conducted by faculty, staff and students. USD IRB also serves as the IRB for the Sioux Falls VA, Fargo VA and Black Hills VA.

The board convenes the second Thursday of every month. The deadline for submissions for a Full Board review is two weeks prior to the meeting.

## Who are the IRB committee members?

The IRB is composed of University faculty and staff from multiple disciplines, as well as representatives from the local community, school districts, and the Native American community.

## 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 an IRB.

## What are the different levels of IRB Review?

***Exempt – Expedited - Full Board***

### *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 members of the research team
Research participants **do not** sign a consent form, but in most instances, a consent statement or cover letter is required.

- Exempt review is conducted by IRB experienced office staff on a first come first served basis.
- Review takes 1-2 weeks.

### *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.

- Project is reviewed by an experienced IRB member on a first come first served basis.
- Average review takes 1-2 weeks.

### *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.

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

## How does a reviewer review my study and what criteria do they apply?

1. Reviewer(s) read through entire application and all accompanying materials.
2. Reviewer(s) use detailed checklists to ensure that the study (1) provides adequate protection for the rights and welfare of the human participants and (2) has a sound research design.

The reviewer(s) focuses on:

- Purpose and methodology
- Risks and benefits to participants
- Informed consent document and consent process
- Confidentiality of the data
- Privacy and confidentiality of the participant
- Vulnerable populations

For more information on the review process or checklists used by the reviewers, refer to the IRB Policy and Procedures.
http://www.usd.edu/research/research-and-sponsored-programs/human-subjects-protection.cfm

## What can I do to get my project reviewed and approved quickly?

- Use IRB templates and forms located on IRB website.
- Be sure to obtain all appropriate signatures.
- Review your cover letter, surveys, and informed consent for typos, readability, soundness, and grammar.
- Use the informed consent checklist to ensure all elements of informed consent are present within your document.
- Cover, in detail, issues relating to confidentiality, privacy, and risks to participants.
- Respond quickly to IRB questions, requests, and clarifications.
- Make sure your IRB application can be a “stand alone” document, i.e. all the questions answered fully and completely in the IRB application.

## Do I have any responsibilities after my study is approved?

**You have several responsibilities once your study is approved.**

### Changes to the study

Any changes to your research plan must be approved prior to implementing those changes. For example, if you requested to interview 10 people and you decide you need more data and want to interview 20 additional subjects, you must first submit an amendment/project update form to the IRB and await approval.

### Report Unanticipated Events or Problems during the study

You are obligated to report any problems that arise during the conduct of the study. Examples include breeches of confidentiality (stolen or lost laptop computer that contained identifiable research data); a subject becomes unduly upset or ill during participation requiring referral to a healthcare professional; problem with the study or data collection site, or other such issues. If you are in doubt regarding whether to report something to the IRB or not, always call the IRB Office and ask.

### Continuing Review/Renewal

Expedited or Full Board studies need to be renewed. Your approval letter will have the dates of the approval period for your study. It is your responsibility to submit a renewal if you need to continue to work on any aspect of your study after the designated approval period.

### Study Approval and Closure

- Exempt Projects: Approval is indefinite. You may close the study after all data has been collected and you are no longer in contact with your participants.
- Expedited or Full Board Projects: IRB approval usually expires 1 year from the approval date (exceptions may occur). If you do not renew your project before the expiration date, your IRB approval expires and you must cease all research activity.