

## UNIVERSITY OF SOUTH DAKOTA OVERVIEW OF PROCEDURES FOR REVIEW OF RESEARCH PROJECTS INVOLVING HUMAN SUBJECTS

All research projects of University employees and students must be reviewed and approved if they involve the creation of generalizable knowledge about the intrinsic properties of human beings. A clear boundary between intrinsic and extrinsic properties does not exist, but the latter includes most information of which a person becomes aware as a result of the experiences of life. Most oral history, for example, is not human subject research. The requirement for project review bears no relationship to whether a project is or is not externally funded.

The research that is the concern of the federal regulations is defined as “a systematic investigation ... designed to develop or contribute to generalizable knowledge.” A human subject is “a living individual about whom an investigator ... conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures ... and manipulations of the subject’s environment ... for research purposes.” Interaction involves communication of information. It may be verbal or non-verbal, oral or signed, written or tape recorded. Project review is required when the above definitions of research and human subject are both met.

The project director bears the responsibility for determining if a project needs review. However, the definitions do not provide black and white distinctions. A flow chart is available at [Is it Human Subjects?](#) which may be helpful in your determination. If you are uncertain, it is best to contact the Office of Human Subject Protection in Vermillion (605-677-6184). It is the project director’s responsibility to make an informed judgment.

**A project, including pilot studies, may not proceed without approval.** The following is a summary of the steps by which a project receives approval.

1. All personnel conducting human subject research must complete the Collaborative Institutional Training Initiative (CITI) on-line human subject research course. Each discipline (clinical trial, social/psychological, health sciences) will be required to complete specific modules. You must submit your Certificate of Completion with your study proposal. The Principal Investigator or Project Director should ensure that all key personnel have completed the training prior to submitting the proposal or continuing review. The advisors will need to complete their training and turn in their certificate along with the student's certificate when they turn in the student’s proposal. You can register for the CITI course at [www.citiprogram.org](http://www.citiprogram.org)
2. Obtain or download from the web site the *Exempt Application, Non-Medical Application or Medical Application*. Completion of this form involves obtaining signatures including that of the dean of your school or college. The completed application is forwarded electronically to the Office of Human Subjects Protection at [humansubjects@usd.edu](mailto:humansubjects@usd.edu). The signed original signature page must be submitted, either by mail or a scanned and emailed pdf, before approval will be granted. Check lists, sample consent forms, and other guidance are also available at the web site.

3. Your project will be given preliminary administrative review and you may receive a telephone or e-mail response if this review indicates that revisions or clarifications will be needed to secure approval. There are three levels of review, exempt review, expedited review, and review by the convened board. The convened board is denoted as an Institutional Review Board (IRB), a less explicit but more common denotation.

4. Exempt review and approval are provided administratively. Expedited review and approval are provided by the IRB chair or another experienced IRB member. When a project involves more than minimal risk, it must be reviewed and approved by the convened board. Exempt review and approval is often completed in two or three days, expedited review in a week. The IRB meets monthly and full board proposals are due two weeks before the meeting. Approval within three weeks may be expected if all questions can be resolved as a result of one meeting.

5. When all required changes have been made and confirmed by the Chair or Primary/Secondary reviewer, a letter of approval is created and forwarded to the project director or to the advisor in the case of a student project. All research personnel are to await the formal documents before beginning any work on the project. Funding agencies may require copies of the approval documents.

6. Approval of a project can be for no more than a year. When a project will take more than a year, it must be given review for continuance. A continuation application may be found on the website, and is due 4-6 weeks prior to the expiration of the project approval. **When the approval period has expired, the project is no longer approved and may not proceed except as cessation would endanger subjects.** The Project Closure Form is used for filing the final report. The final report is best filed as soon as all subject contact is completed unless the data analysis may require re-contact of subjects.