

IRB APPROVAL OF STUDENT RESEARCH

Research, as defined in CFR Title 45, Part 46, is a systematic investigation (an organized, scientific way of collecting information, using a series of questions or observations) designed to develop or contribute to generalizable knowledge (i.e. knowledge shared by professionals in a given field which is designed to contribute to that field). Data is collected from a "human subject", who is a living individual about whom an investigator (a faculty member, staff or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

These definitions are important to remember when students (undergraduate and/or graduate) are contemplating to conduct independent class projects, senior or honor's theses, master's projects, doctoral dissertations, or participate in research methodology courses. Application and submission procedures for students to follow are described in sections A and B below.

Faculty advisors play an important role in the students' design and development of human participant research projects. Faculty advisors are ultimately responsible for the protection of the subjects, even if the student is the primary investigator (PI) and actually directs the project. Advisors shoulder the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

Faculty advisors and course instructors are required to review codes of ethics relevant to the discipline of study.

Student Research Category A

Independent class projects, senior or honor's theses, master's projects and doctoral dissertations

During the design of a project, faculty members instruct students on the ethical conduct of research and help them prepare applications for IRB approval. In particular, students:

- Complete the online NIH training for research with human participants and submit their completion certificates to the IRB**
- Complete the SUU IRB Submission form that includes the SUU Assessment of Risk and Vulnerability**
- Understand the elements of informed consent**
- Develop a readable consent form (templates are provided on the SUU IRB webpage)**
- Plan and document appropriate recruitment strategies for identifying subjects**
- Establish and maintain strict guidelines for protecting anonymity and confidentiality of research participants**
- Allow sufficient time for IRB review and completion of the project**

In short, submission procedures for research conducted by students (except for student research projects described in category B below) are identical to those followed by faculty or staff for the purpose of contributing to generalizable knowledge.

As assurance that the University's guidelines will be followed, the advisor or instructor is required to review and sign the student's application for IRB approval.

All IRB proposal or applications follow the monthly deadlines described in the IRB webpage.

After IRB approval, faculty members take an active role in ensuring that projects are conducted in accordance with the IRB's requirements. Meeting periodically with students to review their progress is one way to meet this responsibility.

Student Research Category B

Graduate and undergraduate research methodology courses: Abbreviated Review Procedure

The IRB recognizes that graduate and undergraduate research methodology courses are designed to teach students research skills through a combination of readings, lectures and research activities or projects. The purpose of such research projects is for the student to apply what is taught (i.e. use skills outside of the classroom) rather than to contribute to existing research literature in a field. Accordingly, the IRB has developed special guidelines for such **class** projects. **Students must discuss class projects with their instructors prior to initiating the project.**

An instructor who wishes to make use of this abbreviated review procedure must first diligently review each student's proposal to determine its acceptability and then submit according to the procedures described below.

NOTE: Students contemplating using a class-based project as part of an undergraduate senior/honor's thesis, master's thesis, doctoral dissertation, independent study project, or for submitting it for off campus publication or presentation must follow the standard IRB review procedures before commencing the project (see Student Research Category A, above)

Choosing an Acceptable Topic for Abbreviated Review Procedures

- 1) Only non-sensitive information may be collected from participants. No personal identifiers (e.g., name, social security number) may be included on any of the research materials. The following types of projects **CANNOT** be approved by instructors through this abbreviated review procedure:
 - Any project which tests one or more participants who do not belong to the SUU campus community
 - Any project involving greater than minimal risk (i.e. risks greater than those one can expect to encounter in the course of everyday life)
 - Any project which uses procedures which could cause physical pain/discomfort
 - Any project involving a vulnerable population (e.g. minors, prisoners, pregnant women, individuals with poor command of English, cognitive or physical disabilities, hospitalized or nursing home residents, individuals with learning disabilities)
 - Any project involving deception of participants, other than concealing the

precise details of the hypothesis to be tested.

- Any project in which participants could reasonably feel physically or psychologically threatened by the investigator or confederates (including use of weapons, verbal threats, or striking an intimidating pose)
 - Any project involving collection of information about participants' own:
 - sexual history (including AIDS, rape, date-rape, abuse, use of contraception, pregnancy, abortions)
 - religious orientation and views
 - illegal activities or criminal history
 - mental health history (including suicide ideation, depression, eating disorders, compulsive behaviors, treatment for psychiatric disorders)
 - the use and/or abuse of any illicit drug or the illegal use of a licit drug
 - war experiences
 - racial, ethnic biases or views
 - medical history or present medical conditions
- 2) Although students **may not collect personal information** of a sensitive nature from participants, they may ask participants to make judgments about behaviors of anonymous others. For example, participants may be asked to read about a crime and be asked to judge the appropriateness of the sentence as a factor of characteristics of the perpetrator.
- 3) Regardless of the project, students **may not use language** that is inflammatory (including racial, religious, or sexual slurs and obscenities).

Student Research Category B: Submission Procedures

Course instructors must submit a Class Project Research Application **each semester** the projects will be conducted. This application will include a descriptive title of each student project, the student investigator's name, and the type and estimated number of subjects who will be enrolled.

Submission of this application will certify to the IRB that:

- a) The instructor and all teaching assistants are fully aware of and agree to comply with the policies and procedures that regulate the SUU human research subjects protection program.
- b) The instructor and all teaching assistants have completed the online NIH training course and have submitted their completion certificate to the IRB. These can be submitted with the Class Project Research Application form.
- c) The instructor and teaching assistants have discussed the aspects of human research protection in their coursework and demonstrate this by submitting a syllabus indicating where such discussion occurs.
- d) The instructor and teaching assistants will provide supervision to students on all phases of their research projects to ensure that these are conducted in compliance with SUU IRB policies and procedures.

- e) The students enrolled in these classes have familiarized themselves with the requirements associated with the use of human subjects in research, such as maintaining confidentiality and obtaining proper informed consent before a project begins.

Instructors of these courses will be made ***ex-officio members*** of the IRB during the semesters when they are teaching research methods courses. Acting in this capacity, instructors will have the authority to review, approve, and submit proposed projects to the IRB for abbreviated review and acceptance. These projects must not involve any of the topics or procedures described above which are not acceptable for abbreviated review. Additionally, course instructors carry the responsibility that he or she is accountable for the design, conduct and oversight of all projects undertaken by students in these classes.

Students conducting research accepted through abbreviated review procedures must obtain informed consent from each participant. Do **NOT** have participants *sign* any informed consent document. Required elements of informed consent are described in the “instructions for IRB submission”, located on the SUU IRB website.

End of Semester Report Procedures for Student Research Category B

Course instructors are required to file a Class Research Project Report to their college’s IRB chair by the end of the semester providing the following information:

- a) The course name and number, a listing of all course instructor approved projects, and information on the students [name and contact info.] responsible for data collection associated with such projects. An abstract (100-250 words) of each project must accompany this report.
- b) Details must be provided about any problems occurring in connection with the administration of any of the projects. Note that these problems were to have been reported immediately to the IRB chairperson.
- c) An assurance is given that all elements of informed consent for minimal risk research were provided to each participant, and that each participant agreed to participate thereafter.

Submission of this report is due within two (2) weeks of the end of the semester.

Compliance with the Abbreviated Review Procedure

A failure to comply with any aspect of this procedure could result in the Instructor losing the privilege of serving as an ex-officio member of the IRB the next time he or she teaches any relevant research or methodology courses. If such occurs, projects from students will need to be submitted in the traditional manner (see student research category B)