

Oversight of Research Type Class Activities

This document is intended to assist SSU instructors in assessing whether class activities involving human participants may be excluded from IRB review.

According to the Code of Federal Regulations research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge . . ." 45 CFR 46. 102(d). Furthermore, a human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) Data through intervention or interaction with the individual, or 2) identifiable private information" 45CFR46.102(f).

Savannah State University (SSU) requires that all research involving human subjects conducted by students, faculty, or staff affiliated with the university, be reviewed and approved by the Institutional Review Board (IRB) prior to initiation.

The IRB further requires that a faculty member supervise all student research activities; however, some types of student based, *research type* activities may **not** require IRB review. These activities may include activities where students participate in data collection and reporting of data garnered from interaction with human subject participants for pedagogical purposes, as a part of assignments designed to teach students about research as opposed to "designed to develop or contribute to generalizable knowledge."

Learning how to conduct ethical research is a vital part of a student's educational experience, especially when human subjects are involved. To facilitate this process, and to ensure the ethical and safe treatment of human participants in these types of activities, the SSU IRB provides the following guidelines:

Class Activities

Class assignments or projects that are designed with the objective of providing students with training about and experience with human subject research may not meet the federal definition of research, and therefore *do not* require IRB review **if the following conditions are met:**

- 1) Data collection procedures present less than minimal risk to subjects; the probability and magnitude of harm are no greater than those ordinarily encountered in daily life (45 CFR 46.102).
- 2) The data are collected in a manner that subjects cannot be identified (e.g., no audio or video recording).
- 3) The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed.
 - a) Sensitive topics include any information that could place participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
- 4) The project does not involve vulnerable populations.
 - a) In regulatory terms vulnerable refers to a person that may have compromised autonomy, therefore additional protections may be required.
 - b) Examples include, but are not limited to prisoners, children, mentally or physically disabled individuals, and institutionalized individuals.
- 5) The project must involve the voluntary participation of individuals without any coercion or pressure from the student. Though not required, it is recommended that instructors/students consider providing a consent document to participants and fully informing them that the project is for class credit only and has not been subject to IRB review.
- 6) The results of the project will never be distributed outside the classroom and/or institutional setting or used for publication, although the results may be presented to instructors or peers for educational purposes or as part of a class assignment. If a presentation is to be delivered beyond the classroom (e.g., to a student club as an example of research in the discipline) explicit permission must be included in the waiver.

- 7) *If the possibility exists that either the instructor or the student would consider disseminating the data as generalizable knowledge (e.g., submit the data to a University, local, regional, or national conference), the research must be submitted for IRB review.*

Class projects that do not meet the criteria listed above require IRB review prior to subject recruitment and data collection.

Responsibility for Oversight of Student Projects/Class Activities involving human participants

At Savannah State University, the Chair of the IRB has the responsibility for assessing whether class activities involving human participants meet eligibility for exclusion from IRB review. Each activity must be submitted to the Chair of the IRB by a faculty member who will serve as **principle instructor** for the activity, oversee the activity, and assure that ethical principles will be adhered to in the conduct of the activities.

The **principle instructor** must complete all appropriate training for the activities, assignments, or projects they will be supervising and students (minimally) must complete CITI training for **Students conducting no more than minimal risk research**. IRB training certification at SSU is offered through the Collaborative Institutional Training Initiative (CITI) Program (CITIProgram.org).

With regard to class projects, faculty are encouraged to become fully familiar with each student's project(s). It is also important that instructors who teach research methods classes educate students regarding the existence of IRBs and discuss the relevant ethical issues surrounding the use of human subjects in research.

Class activities involving human participants must be submitted to the Chair of the IRB to obtain a waiver that confirms it meets the eligibility criteria for exclusion from IRB Review.

SSU Institutional Review Board Class Project Waiver Application

Instructor Name/Title		Department	
SSU Email		Office Phone Extension	
Campus Address		Course Number and Title	
Has this request been approved in previous semesters?	If yes, please indicate last semester approved		
Semester/Year			

Please Describe the Class Assignment:

Briefly describe the class assignment or attach syllabus or class handouts highlighting relevant information concerning class project.

Please describe procedures for maintaining confidentiality, minimizing risk, and monitoring the class project:

Waiver requirement checklist:

I understand there should be NO publication and NO presentation of the project outside the course for which the project is being completed. **This includes not presenting the project at the SSU Annual Research Conference**

I understand NO minors or vulnerable populations should be included as participants in the project.

(***)Exceptions include research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: research on regular and special education instructional strategies, or research on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods.)

Risk is not more than “minimal.”

“Minimal risk” is when “the probability and magnitude of harm or discomfort in the project are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

- No use of deception
- No video or audio recording
- The professor overseeing the class project has completed ethical training for conducting research with human subjects
- ALL students completing the project have completed ethical training for **Students conducting no more than minimal risk research**. IRB training certification at SSU is offered through the Collaborative Institutional Training Initiative (CITI) Program (CITIprogram.org).

-Please submit class roster with 915s for students who completed the CITI training in a different course.

-For students completing the CITI training in your course please submit the class roster plus certificates.

Principle Instructor Acknowledgements:

I accept primary responsibility for ensuring the rights and welfare of the human subjects and to:

- Train students in the proper protection of human subjects involved in research;
- Review Student projects to determine if each project qualifies for a waiver or requires a standard IRB application
- Ensure that students get written informed consent from subjects and assent from children;
- Review all methods and instruments used in each project
- Document that students receive permission to conduct the project at institutions other than Savannah State University
- Monitor each project and inform the IRB immediately of any significant problems that arise.

By checking this box, I certify that the information provided in this Classroom Project Waiver is complete and correct. As Principal Instructor I have the responsibility for the protection of the rights and welfare of the human participants and the overall ethical performance of the projects. Click or tap to enter a date.

Please email this form to irb@savannahstate.edu with syllabus or other relevant course materials.

For IRB office use *only*:

Approved: this signifies notification of IRB APPROVAL of the Classroom Project Waiver described above:

IRB Reviewer:

Date:

Approval subject to modifications listed: this signifies notification needed revisions to meet the requirements of the Classroom Project Waiver described above:

IRB Reviewer:

Date:

Rejected: this signifies notification of IRB Rejection of the Classroom Project Waiver described above for the following reasons:

IRB Reviewer:

Date: