

Request for Classroom Project Waiver of IRB Protocol

South College Institutional Review Board (IRB)

Submit completed protocol to: Ms. Brittany Galyon, IRB Coordinator, bgalyon@south.edu

Complete this form to request a waiver of an Institutional Review Board (IRB) Human Subjects Research protocol for a Classroom Project involving human subjects.

Attached at the end of this form are excerpts from the *South College Institutional Review Board (IRB) Policies and Procedures Manual for Human Subjects Research* that explain the distinction between a Classroom Project and Classroom Research. Classroom Research cannot be granted a waiver of an IRB Human Subjects Research protocol.

1. INSTRUCTOR INFORMATION

Instructor name:

Instructor academic title:

Department/School:

Campus mailing address:

E-mail:

Phone:

2. COURSE AND PROJECT INFORMATION

Course number and title:

Semester and year:

Name of student(s) working on project:

Describe the class project; be sure to provide sufficient details such as research objective, description of subjects being studied, data collection and analysis methods for classroom research project:

Describe procedures for maintaining confidentiality, minimizing risk, and monitoring the project:

3. WAIVER REQUIREMENT CHECKLIST

- a. I have read the Policies on Classroom Projects and Classroom Research Involving Human Subjects. True False
- b. I have completed Human Subjects Research Training (**attach CITI training completion report**). True False
- c. The activity is a requirement for a South College undergraduate or graduate course. True False
- d. The sole purpose of the activity is to give students a learning experience in the methods of research. True False
- e. I am aware of all aspects of the project and I will ensure that students adhere to ethical principles. True False
- f. I informed students and attest to the fact that the results may **never** be presented or published outside of South College. True False
- g. Students will obtain informed consent from all participants. N/A True False

If you indicated 'not applicable', briefly explain why:

- h. The project involves minimal risk to subjects. True False
- i. The project does not involve sensitive topics or confidential information. True False
- j. The project does not involve persons from vulnerable populations (e.g., children, prisoners, etc.). True False

If your project involves children, explain how it qualifies for the exception described in the Classroom Project Policy:

- k. The project involves the voluntary participation of subjects . N/A True False

If you indicated 'not applicable', briefly explain why:

- l. The project does not involve deception. True False
- m. The project does not involve any audio/video/photo recording. True False

If your project involves audio/video/photo recording, explain how it qualifies for the exception described in the Classroom Project Policy:

If you answered False to any question (and your project does not meet the exception for children in the classroom and/or audio/video/photo recording), your activity does not meet the description of a Classroom Project. A waiver cannot be granted and your research project will require the submission of a Human Subjects Research Protocol to the IRB before the research can begin.

4. CLASSROOM PROJECT INSTRUCTOR'S ASSURANCE

I accept the primary responsibility for ensuring the rights and welfare of the human subjects in this Classroom Project. I agree to follow all applicable college policies related to the protection of human subjects in Classroom Projects, as described in the *South College IRB Policies and Procedures Manual for Human Subjects Research*.

I verify that the information provided in this Request for Classroom Project Waiver of IRB Protocol is accurate and complete.

Signature of Course Instructor

Date

Typed name of Course Instructor

The following are excerpts from the *South College Institutional Review Board (IRB) Policies and Procedures Manual for Human Subjects Research*. The complete manual may be obtained from the South College IRB website.

WHAT IS HUMAN SUBJECTS RESEARCH?

Federal, state, and South College regulations require the IRB to review and monitor *human subjects research*. Several terms are defined below to help investigators determine if IRB review of a project is required. In support of South College's mission to protect human research subjects, and the regulatory consequences of not obtaining IRB review and approval, investigators should consult with the IRB office if they have any doubt about whether or not a study involves human subjects research.

Research: Federal regulations define research as: "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities." [45 CFR 46.102(l)]

For purposes of this part, the following activities are deemed not to be research:

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. [45 CFR 46.102(l)]

Human subjects: The DHHS regulations define a human subject as "a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." [45 CFR 46.102(e)]

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided

for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. [45 CFR 46.102(e)]

Coded private information or biological specimens: DHHS Office of Human Research Protection (OHRP) policy considers private information or biospecimens to be individually identifiable when they can be linked to specific individuals either directly or indirectly through coding systems. The IRB must determine if coded private information or biospecimens constitute research. Investigators do not have the authority to make an independent determination that research involving coded private information or biospecimens does not involve human subjects.

Clinical investigation: The Food and Drug Administration (FDA) defines clinical investigation as "any experiment that involves a test article and one or more human subjects and that either must meet the requirements for prior submission to the Food and Drug Administration... or need not meet the requirements for prior submission to the Food and Drug Administration... but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit." [21 CFR 56.102(c)]

POLICIES ON CLASSROOM PROJECTS AND CLASSROOM RESEARCH INVOLVING HUMAN SUBJECTS

The purpose of this section is to assist faculty and students in determining the difference between a Classroom Project and Classroom Research, and the IRB requirements for each type of activity. All South College instructors who supervise students in a Classroom Project or Classroom Research that involves human subjects are required to complete a web-based training program in the protection of human research subjects (see Section 8, Required Training for Human Subjects Research).

An important aspect of a college education is for students to engage in classroom activities designed to help them develop the knowledge and skills necessary to conduct research, which may involve human subjects. For the purposes of the South College IRB, these activities fall into two different categories with the following requirements:

Classroom Project

- a. Instructor **must** complete Human Subjects Research Training.
- b. Instructor **does not** need to submit a Human Subjects Research Protocol to the IRB if specific conditions are met (see below).
- c. Instructor **must** submit a Request for Classroom Project Waiver of IRB Protocol.

Classroom Research

- a. Instructor and student researchers **must** complete Human Subjects Research Training.
- b. Instructor and student **must** submit a Human Subjects Research Protocol to the IRB.

Classroom Projects: Definition. South College recognizes that some student classroom projects conducted to fulfill course requirements involve activities that might be viewed as research in another context. As a general rule, when classroom projects are conducted *solely* to fulfill a course requirement, an element of the definition of research is lacking, which is the intent to develop or contribute to generalizable knowledge. Classroom

projects with human subjects for which the sole purpose is a student learning experience in the methods and procedures of research do not require the submission of a Human Subjects Research Protocol to the IRB if **ALL** of the following conditions are satisfied:

- a. The activity is a requirement for a South College undergraduate or graduate course.
- b. The sole purpose of the activity is to give students a learning experience in the methods and procedures of research.
- c. The instructor is aware of all aspects of the project and takes responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of all project activities.
- d. There is no intent on the part of the instructor or student to produce generalizable knowledge and findings from the study will **NEVER** be disseminated beyond presentation to instructors or peers in a South College classroom setting. If the possibility exists that the instructor or student would consider disseminating the data as generalizable knowledge (such as presenting the results in a Master's thesis or Doctoral dissertation, poster or talk at an academic conference, publication, etc.), then the activity is a research project and a Human Subjects Research Protocol must be submitted to the IRB before any research activities are performed.
- e. The project involves minimal risk to subjects (i.e., when "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests").
- f. The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed. Examples include, but are not limited to:
 - Information relating to an individual's psychological well being or mental health.
 - Information relating to sexual attitudes, preferences, or practices.
 - Information relating to the use of alcohol or drugs.
 - Information relating to illegal behavior.
 - Information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation.
 - Information that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to social discrimination or stigmatization.
 - Genetic information.
- g. The project does not involve persons from vulnerable populations as participants. Examples include, but are not limited to:
 - Individuals under the age of 18 (Exception – Projects conducted in established or commonly accepted educational settings involving normal educational practices, such as: investigation of regular and special education instructional strategies, or investigation of the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods).
 - Prisoners
 - Pregnant women
 - Fetuses
 - Mentally challenged individuals
 - Individuals with impaired decision-making ability
- h. The project involves the voluntary participation of subjects without any coercion or deception.
- i. No audio/video/photo recording of subjects, except under the following circumstances:
 - Instructors are required to oversee the process and ensure permission is granted by the subjects before audio/video/photo recording is performed; and
 - Instructors must submit to the IRB a course syllabus with the Request for Classroom Project Waiver of IRB Protocol. The syllabus must state that all audio/video/photo recording gathered

as part of the classroom project remains the property of South College and will be forfeited to the course instructor at the end of the project; and

- The audio/video/photo recordings, and any other data produced in the project, are to be exhibited only in the classroom, in departmental or interdepartmental seminars designed to exhibit coursework or to continue the learning process related to presentations, or in the company/agency/organization from which the data were gathered.

Classroom Projects: Instructors are Required to Complete Human Subjects Research Training. All South College instructors who supervise students in a Classroom Project or Classroom Research that involves human subjects are required to complete a web-based training program in the protection of human research subjects. See Section 8, Required Training for Human Subjects Research, for instructions on completing the training. The training is good for a period of three years. A refresher course must be completed every three years.

Classroom Projects: Instructors are Required to Obtain a Waiver from the IRB. Instructors who supervise student Classroom Projects that involve human subjects are required to submit to the IRB a **Request for Classroom Project Waiver of IRB Protocol**. The form is available on the South College IRB website. The waiver is good for a period of three years as long as the same project is performed in the same course. If any aspect of the project is changed, if the instructor is changed, or if the project is conducted in a different course, a new waiver request must be submitted. A copy of the instructor's CITI training completion report must accompany the waiver request.

Classroom Projects: Disclosure to Human Subjects. All activities conducted under the Classroom Project policy **must** be preceded by a disclosure of the following information to the human subjects. If an Informed Consent Document is used, these points must be included in that document:

- a. The student identifies her/himself as a South College student who is performing the activity to fulfill a course requirement, and the course is specifically identified.
- b. The name and contact information for the supervising faculty member to contact for questions is provided.
- c. The persons who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/agency/organization).
- d. Subjects are informed that their participation is voluntary, that they can skip any questions they do not wish to answer (e.g., for surveys, interviews, focus groups, etc.), and that they can stop participating at any time.
- e. The disclosure should **not** state that the project has been approved by the South College IRB.

Classroom Projects: Important Considerations for Instructors. Classroom project data may never be shared outside of the classroom setting, such as in a thesis or dissertation, poster or talk at an academic conference, publication, etc. **The IRB cannot grant retroactive approval for a research project.** Therefore, it is very important that you give careful consideration to whether or not you may want to first submit a Human Subjects Research Protocol to the IRB before your students begin your project. For example, if a classroom project results in important findings and you or your students want to present the data at an academic conference, this will not be possible because the project did not receive review and approval from the IRB before the study was conducted. However, if you first submit a Human Subjects Research Protocol to the IRB for your project and it is approved before your students begin the research, then you and your students have the option of presenting or publishing the results.

Classroom Research: Definition. Classroom activities designed to teach students the knowledge and skills necessary to conduct research with human subjects, and that also contribute to generalizable knowledge, fit the

definition of human subjects research. In general, contributing to generalizable knowledge refers to the dissemination of study findings outside of the classroom setting.

Master's theses, Doctoral dissertations, other forms of publication, talks and posters at academic conferences, etc., usually contribute to generalizable knowledge and fit the definition of research.

All students and faculty performing classroom research involving human subjects must first complete human subjects research training. See Section 8, Required Training for Human Subjects Research, for instructions on completing the training. The principal investigator (PI) of a classroom research project must submit a Human Subjects Research Protocol to the IRB for review and approval before the research begins. See Section 11, Types of IRB Review, and Section 13, Steps in the IRB Application and Review Process for instructions on submitting a protocol to the IRB.

Student Research Projects

South College students may serve as the principal investigator (PI) on an IRB application for student-initiated research involving human subjects. However, student-initiated research involving human subjects, whether thesis, dissertation, or other research, must include a South College faculty member as the Co-PI. The South College faculty member will share full responsibility with the student for all aspects of the protocol and research. The only time that a South College IRB protocol will have a Co-PI is if the PI is a student.

The IRB must review and grant final approval to projects before any research activity or study procedures can take place. There is no retroactive approval for data previously collected for the current study. **Failure to seek approval for student research may invalidate the study and/or result in a delayed graduation.** If it comes to the attention of the IRB that IRB approval has not been obtained for student research prior to initiation of research involving human subjects, the IRB will refer the faculty member(s) and student researcher(s) to the appropriate Dean and/or Department Chair, and to the Institutional Official.

REQUIRED TRAINING FOR HUMAN SUBJECTS RESEARCH

South College policy requires all faculty, staff, and students who wish to perform human subjects research to complete a web-based training program in the protection of human research subjects. **Additionally, South College faculty who supervise student classroom projects that involve human subjects are required to complete a web-based training program in the protection of human research subjects.** The training is administered through the Collaborative Institutional Training Initiative (CITI). The CITI program is widely accepted as an industry standard among university and college IRBs, and by the federal government and other funding agencies. The IRB members are also required to complete CITI training. This policy assures that all individuals performing or reviewing human subjects research receive the training necessary for South College's compliance with federal regulations. The web-based training program allows individuals to complete the training at their convenience. Initial CITI training is valid for a period of three years. After the initial training period, a refresher course must be complete every three years. The document entitled **Human Subjects Research Training Instructions**, located on the South College IRB website, provides instructions on how to complete the required training.

The IRB will not grant approval of human subjects research applications until all investigators associated with the project have completed Human Subjects Research Training and provided the IRB with a certificate of completion.