



Division of Research

SUBJECT: University Students as Research Subjects	Effective Date: March 30, 2018	Policy Number: 10.3.8 Version 2
	Supersedes: October 20, 2014	Page 1 of 6
	Responsible Authorities: Vice President, Research Institutional Review Board Assistant Vice President, Research Integrity	

I. Background

Human subjects research in which university students will be asked to serve as research subjects is governed not only by fundamental regulations under [45 CFR 46](#), and [21 CFR 50 and 812](#) (for FDA regulated studies) but also the [Family Educational Rights and Privacy Act \(FERPA\)](#) and the Department of Education’s [34 CFR Part 97](#).

Title 34 provides the overall regulatory principles for human subjects research activities supported by the Department of Education. FAU must ensure it is in compliance with Title 34 for those studies funded by the Department of Education.

FERPA is a federal law that protects the privacy of personally identifiable information contained within a student’s educational record. FERPA applies to all schools (K-12 including postsecondary institutions) that receive funds under various programs from the U.S. Department of Education.

Where applicable, researchers may choose to apply principles of professional societies and organizations, when they provide protections above and beyond those of federal regulations.

II. Purpose

The purpose of this policy is to provide guidance on conducting research studies in which university students will be asked to be research participants within their educational setting.

III. General Statement

In some research situations, use of students is integral to a research protocol. This is particularly true of research into teaching methods, curricula and other areas related to the scholarship of teaching and learning. In the social and behavioral sciences course credit is commonly offered for research participation.

An underlying principle of the regulations governing use of human subjects in research is that the subject's participation is voluntary and based upon full and accurate information. The student-teacher relationship raises the issue of volunteer participation. For example, students may volunteer to participate in the belief that doing so will place them in a favorable situation with an instructor (e.g., better grade, good recommendation, employment possibilities), or that failure to participate will negatively affect their relationship with them (e.g. lower grade, less favorable recommendation, being "uncooperative and not part of the scientific community).

Instructors cannot mandate or require student participation and care should be taken to eliminate or reduce the risk that they may unduly influence or coerce student participation in research. Instructors are strongly discouraged from recruiting students they directly supervise or selecting subjects on such basis.

Alternative assignments must be provided to students who decline from participating in research. Students should be fully informed about the research requirements or alternatives and the compensation offered for their participation in either one.

IV. Policy

- a. **Students should be of the age of majority (18 years old in the State of Florida) in order to consent for themselves.** Research involving minors less than 18 years of age (even 17 year old college students) in most instances requires a signed parental consent, as well as an assent from the student. (See IRB policy on Children in Research) however some types of research may qualify for a Waiver of Parental Permission.
- b. **Researchers generally may not access classroom performance evaluations, grades, and information in a student's records without prior written permission** from the student, regardless of the access a researcher may have in his/her academic role.
- c. **If the instructor is also the researcher,** he/she should arrange to have the consents and/or data collected by an independent third party when he/she is not present, so that he/she does not know who participated and does not have access to the identifiable data or identity of participants for any purpose until grades have been assigned and entered. (A teaching assistant in the class in which the student is enrolled does not qualify as a "third party" for collecting the data on behalf of the researcher if they have a role in teaching and grading as well).
- d. **Whenever possible, researchers should avoid data collection during regular class meetings.** Unless the research is directly related to class material, or the study process is being used as a teaching opportunity, the IRB discourages the use of class time to recruit subjects or class time used to complete study instruments.

Loss of instructional time for both participants and non-participants may be considered a loss of benefits. Also, when research participation is expected during the same session at which participation is invited, students may be unduly influenced to take part due to peer pressure, perceived stigmatization from non-participation, or a sense of having otherwise wasted time by attending that day's class. The use of class time for research purposes must be justified.

- e. **When course credit or extra credit is given to students who participate in research, non-research alternative assignments should be provided to students who do not wish to participate in the research to ensure students are not unduly influenced into participating in the research study.**
 - Alternative assignments could include, for example, short papers, special projects, book reports, and brief quizzes on additional readings, research seminars, or completing a similar project.
 - The alternative assignment should require approximately the same time and effort commitment as research participation and **earn the same amount of credit.**
 - Instructors should make every effort to ensure that they do not exert undue influence on students to participate in research rather than the alternative assignment
 - The consent form and any recruitment material should clearly describe the alternative assignment in a way and at a time that allows the students to make an informed choice about which method they will use to earn credit.

- f. **Recruitment of student subjects for research must be done in a non-coercive manner.** To avoid undue influence, subjects should be recruited by a general announcement, central posting or announcement mechanism that should include a clearly written description of the project and a statement of the proposed student participation. Special precautions need to be taken to ensure that there is no undue coercion, and to ensure that student's don't feel that if they don't participate they will be punished or receive a lower grade. In addition to being provided with the traditional information and consent forms, the student should also be provided with the name and contact information of a neutral third party to contact should they feel coerced at any time during the process.

- g. **Since there are special risks of confidentiality in the close environment of the university, special attention should be given to full disclosure of these risks when obtaining the student's consent to participate.** The plan for handling research data should be designed to minimize the risk that confidentiality will be breached. When instruments call for the disclosure of information which participants may view as personal or sensitive, data should be collected in a manner that minimizes the chance of one participant learning the response of another. Procedures for data storage, data coding, retention, and security should be described in the protocol. If survey data collection is anonymous or if there is an intention to code the survey data, researchers should remove from the survey document's requests for the participants' names and significant identifying information. To the extent possible, PIs should limit the involvement and scope of multiple, junior level research assistants in projects involving sensitive topics. Student researchers are likely to have outside of research contact with their peers which may expand the potential for breach of confidentiality. Researchers should be sensitive to these issues when writing their research protocol.

- h. **Students must be allowed to withdraw from the study at any time.** The informed consent statement should make clear the consequences of withdrawing from a study prior to completion. In general it is favorable to give credit if the subject withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student.
- i. **If the research is one where data are collected from a group project or perhaps an audio- or videotape of the group interaction, each student's consent is necessary for the use of that data in the research.** If one student does not consent, the data may be used only if the non-consenting student's data can be effectively excluded. Special data storage considerations should be given to protecting the confidentiality of video and audio research data, including encryption measures and secure, locked physical storage locations.
- j. **Students have the right to full disclosure as soon as possible. Whenever possible a teaching opportunity in the form of an "educational debriefing" should be employed.** Students should know something about the rationale for the study, the process of data collection, and intent of the researcher. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the completion of data collection. In such cases, students must not be subjected to undue stress or embarrassment and must have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected. During the debrief students should be given an opportunity to decide whether the researcher(s) can use the data collected.
- k. **Research involving departmental units that maintain their own subject pools must be coordinated appropriately with the subject pool administrator.** In addition, use of the subject pool and provision of subject pool credits must be adequately described in the IRB protocol. To ensure that students are fully informed about the research requirements for a course and the compensation offered for their participation, the department should specify how many hours or units of research participation are required for the course, the alternative assignment that students can complete in lieu of the research, and the consequences of not showing up for or completing a research study.
- l. **Where applicable, researchers may choose to apply principles of professional societies and organizations** (e.g., American Psychological Association), when they provide protections above and beyond those of federal regulations.

V. Definitions

University student: Student of any age or enrollment status who is enrolled in an institution of higher education.

VI. Accountability

The Principal Investigator (PI) will be responsible for:

- Ensuring that the points addressed in this policy are taken into consideration when designing a research protocol that proposes to enroll university students as subjects.

- Coordinating as appropriate with the University subject pool coordinator and obtaining appropriate approvals.
- Obtaining letters of cooperation or other relevant permissions, as applicable, from cooperating university units that provide access to students and student data.
- Ensuring that co-investigators or any other person (including faculty, staff, students or agents) involved in the design, conduct, evaluation, participant care, and/or reporting for the proposed study adhere to the responsibilities included in or referred to in this policy, as well as those outlined in their study protocol.
- Ensuring that the student's participation is voluntary and not coerced and based upon full and accurate information.

The IRB will be responsible for:

- Ensuring that the points addressed in this policy are taken into consideration when reviewing research protocols that propose to enroll university students as subjects.

VII. Procedures

- The PI should become familiar with this policy prior to designing his/her research protocol.
- When completing the IRB application package, the PI should note on the IRB application whether the types of subjects will include either "students of PI or study staff" and/or "students to be recruited in their educational setting."
- The PI should ensure there is no undue coercion and take precautions to make sure there is no conflict of interest in using their own students in research. Options to remedy the situation are:
 - State in the consent form students will not have any penalty if they do not participate, and they will not make the teacher upset.
 - The study can be presented by a colleague or somebody not involved with the students.
 - The study can be completely anonymous.
 - The teacher can collect the data and not use it for research until after the class has been completed and grading is complete.
- The PI should obtain letters of cooperation or other relevant permissions, as applicable, from cooperating university units that provide access to students and student data. For example, if access to grades that are maintained in a central location (e.g. registrar) is required, the researcher should appropriate permissions from that university entity. (See template for Letter of Cooperation).
- The PI should coordinate as appropriate with the University subject pool coordinator and obtain appropriate approvals.

VIII. Policy Renewal Date

As needed

IX. References

45 CFR 46
21 CFR Part 50 and 812 (for FDA regulated studies)
Family Educational Rights and Privacy Act (FERPA)
34 CFR Part 97

POLICY APPROVAL

Initiating Authority

Signature: 

Date: 3/23/2018

Name: Daniel C. Flynn, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)