

Chapter 16

Student Research

This chapter describes the responsibilities of faculty advisors and students who conduct human subjects research. Additionally, other topics specific to student research are discussed including assistance provided by the IRB Student Mentor, international research considerations, mandatory reporting responsibilities, and subject pool policies.

16.1 Introduction to Student Research

In accordance with federal regulations, the IRB requires that all human subjects' research be prospectively reviewed by an IRB including master's theses, doctoral dissertations, and all student research projects involving human subjects. Under IRB policy, no UPC student research will be approved with a study design that includes administration of medications. For unique situations, this prohibition may be discussed with the UPIRB.

16.2 Classroom Assignments Involving Human Subjects

The University recognizes that some student projects are conducted to fulfill course requirements, and involve activities that might appear to be human subjects research. Classroom assignments **do not** require IRB approval. These projects typically fulfill a course requirement, are often completed in one semester, and are designed to teach research methods. Faculty members design these assignments to engage students in interaction with individuals, gather data about individuals, and/or illustrate concepts covered in the course. For the most part, they are not intended to create new knowledge or to lead to scholarly publication. The publication of classroom study results or poster sessions at a professional meeting does not make the project human subjects research. These classroom assignments do not meet the federal definition of [human subjects research](#). Additionally, library research or content analysis of public documents is **not** human subjects research. If students or faculty are uncertain if a classroom project must be reviewed by the IRB, they should contact the IRB.

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For projects that do not require IRB review, faculty may direct students to a practice IRB application through the iStar [Sandbox](#) Training application. This site allows students to familiarize themselves with iStar, the online application used for IRB submissions, and work on mock IRB submissions.

Additionally, it is recommended that students working on classroom projects complete the Collaborative IRB Training Initiative ([CITI](#)), the online human subjects education program. This training is **not optional** for projects required to undergo IRB review.

At USC, students involved in classroom assignments are encouraged to follow the University's Code of Ethics and policies when designing and conducting projects with human volunteers.

Faculty members assigning projects in research methods classes are expected to help students understand ethical obligations toward anyone with whom they interact to complete their assignments.

16.3 Requirements of Faculty Who Supervise Student Research

Faculty should determine whether an assigned project involving human subjects is defined as a course-related student project. Faculty is strongly encouraged to contact the IRB office for assistance in making this determination and for education on how to mentor students through the IRB and human subjects research process. Faculty should discuss general principles of research ethics with the class prior to the initiation of any project involving human subjects. It may be possible to bundle similar studies conducted under one faculty advisor, decreasing the number of submissions that need to be submitted to the IRB (please contact the UPIRB for further information). No IRB approval may be given after a classroom-assigned study is begun or completed.

Faculty Responsibilities for the Protection of Human Subjects

Faculty who supervise student research are responsible for the protection of human subjects and are required to:

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- Determine whether projects require IRB review and assist students with the process.
- Discuss research ethics with the students.
- Familiarize themselves and students with ethical and regulatory mandates for human subjects research
- Approving the student's IRB application and signing a Faculty Advisor Assurance outlining their responsibilities.
- Monitor student projects focusing on maintaining confidentiality, privacy, the level of risk, voluntary participation and withdrawal, and informed consent.
- Assure prompt reporting to the IRB of any event that requires reporting in accordance with the IRB policies and procedures for Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (refer to [Section 20.2 – Unanticipated Problems Involving Risks to Subjects or Others](#)).
- Complete CITI (On-line human subject protection training)

16.4 IRB Student Mentor

The IRB student mentor is a graduate assistant at the Office for the Protection of Research Subjects (OPRS). The IRB student mentor, like other graduate assistants at USC, contributes to the research and teaching activities of the University while pursuing academic degrees.

As a peer mentor, the IRB student mentor counsels USC student investigators on issues related to human subjects protection and the IRB application process through individual advising and group workshops. The IRB student mentor also works closely with the Executive Director of OPRS, the UPIRB office, and individual schools and departments on the University Park campus to continuously plan and implement outreach programs for the USC community. These programs educate faculty, students, and staff on important issues pertaining to human subjects protection in research activities.

The IRB student mentor serves as a liaison between USC students and OPRS, through whom OPRS develops a better understanding of students' needs and concerns as they relate to protecting research subjects.

For more information visit <http://oprs.usc.edu/education/mentor/>

16.5 International Research Conducted by Students

The following policy is specific to international research conducted by USC students and is not applicable to funded clinical trials.

International research involves projects that are conducted outside of the United States. Federal regulations acknowledge that local customs, norms, and laws where the research will take place may differ from U.S. regulations governing research. Funded student research is required to meet U.S. standards wherever it is conducted. For unfunded student research, USC IRBs may accept comparable standards depending on the risk level. It is the expectation that there will be a local contact and/or consultant for the student researcher who will provide information on local laws and cultural norms.

IRB Considerations

If an unfunded study involves less than minimal risk to participants, domestic IRB approval may be sufficient. Examples include surveys that compare use of social media in U.S. adults versus adults in another country or other questionnaires that do not collect sensitive information. Students and/or faculty should contact the UPIRB for additional information.

If a study involves more than minimal risk to participants, USC requires protocol review and approval by an outside IRB/Ethical Review Committee (EC), equivalent organization in the country where the research will occur or approval letter from local entity (refer to [Section 13.5 – USC Investigators Conducting Multi-Site Research](#)) in addition to USC IRB review, if applicable. Examples of these studies include surveys about high-risk behavior or questionnaires that ask questions about HIV status.

International studies will follow the same criteria for IRB review and approval as domestic studies. For example, a less than minimal risk study can receive an expedited review, whether the study is conducted within the US or abroad.

Research policies for studies conducted within the U.S. apply to international research wherever possible. In addition, international research protocols often include:

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- Explanations of cultural differences that influenced the study design and the consent process
- Rationale for conducting the study with an international population
- Information regarding the host country's IRB, Ethical Review Committee or equivalent organization and documentation of its approval of the research, if applicable
- A copy of the letter(s) of agreement on letterhead stationery with signatures from the local host Institution(s), and from government officials, as necessary, to cooperate in the proposed research
- A copy of the informed consent form, if used, in English, and a copy in the appropriate native language(s)
- Information regarding the literacy level of the expected subjects and how this may affect the informed consent process
- A description of the informed consent process, including methods for minimizing the possibility of coercion or undue influence in seeking consent and safeguards to protect the rights and welfare of vulnerable subjects
- A description of the processes for assuring anonymity and/or confidentiality of all data, and a description of the methods of transport and security of data to the United States, if applicable
- If data will be collected by someone other than the researcher, the curriculum vitae of the individual and letters of agreement should be included on letterhead stationery and with original signatures from the research collaborators
- If compensation is to be given to subjects, justification for the amount of money or goods should be provided and an explanation as to how this compensation is proportionate to the average annual income of people in the host country should be examined

Faculty Advisor Responsibilities

Faculty Advisors are expected to remain in contact with students conducting research at any foreign site to ensure safety and welfare of the participants and student. Faculty must

also prepare students for cultural differences they will encounter in an international setting. Faculty who supervise student researchers must be aware of their responsibilities and their role in the protection of human subjects. Refer to [Section 16.3 – Requirements of Faculty Who Supervise Student Research](#) for more information.

16.6 Students as Research Subjects

Consistent with an overall concern that no research subject should be coerced, researchers must take precautions to avoid the unintentional or subliminal coercion that can occur when potential research subjects are also students. For this reason, researchers should avoid using their own students as research subjects. Researchers who wish to use their own students must be able to provide a good scientific reason, rather than convenience, for selecting their own students as research subjects.

In instances where investigators can provide justification for using their own students in their research, the IRB generally requires that someone other than the investigator (instructor) obtain informed consent and collect the data. When this is not possible, the IRB will consider other methods for obtaining consent and collecting data that would not reveal to the instructor, whether or not a student participated in the research project until after final grades have been determined. The students should be informed of these procedures in the informed consent form. In addition, it is generally recommended that the investigator/professor provide a recruitment flyer or letter to the students, so that the students may be the initiators and contact the investigator/professor regarding the research study.

16.7 Student Researchers' Abuse Reporting Obligations

Mandated reporters are individuals who are obligated by law to report suspected cases of child and/or elder abuse and neglect. In general, any person who has contact with children or the elderly in a professional capacity is a mandated reporter, although laws vary from state to state, as does the legal entity to which reports must be made. For the California Penal Code definition of mandated reporter see [Elder Abuse and Dependent Adult Civil Protection Act Section 15630 \(a\)](#) and Child Abuse and Neglect Reporting Act Section [11165.7](#).

Only “mandated reporters” are required to make mandatory reports of child and elder abuse. If one is not a mandated reporter, he or she is not required to file.

Student Researchers’ Abuse Reporting Obligations

Although child or elder abuse may be disclosed or suspected in many research disciplines, research conducted in certain schools or departments (gerontology, psychology and social work) often provide situations in which evidence or disclosure of such abuse is more likely to be encountered. Abuse is defined as “non-accidental injury inflicted by others; sexual abuse; unjustifiable mental suffering (as in a young child witnessing domestic violence); neglect; cruelty; statutory rape (minor under 16 and other 21 or older, even if consensual); lewd and lascivious conduct (minor under 16 and other 10 years older, even if consensual); consensual sexual contact between minors (where one is 14 years of age and the other is under 14 years of age)”. In the event that a student researcher becomes aware of, or reasonably suspects, that a study subject has been the victim of child or elder abuse, the student should follow these procedures:

If student researcher’s faculty advisor is a mandated reporter, the student researcher should notify that mandated reporter of the suspected abuse. A mandated reporter is legally obligated to follow up.

Even when the student’s faculty advisor is *not* a mandated reporter, the student researcher should notify the faculty advisor and/or the department of their concerns.

If one is not a mandated reporter, he or she need not make a mandated report however, students have an ethical obligation to report their suspicion to a faculty member for further action. Guidance for student researchers who are not mandated reporters who encounter or suspect child/elder abuse may be found at

http://oprs.usc.edu/files/2013/01/ChildElder_Abuse_FAQ_2.15.pdf.

Abuse Disclosure Notification in Consent Documents

Disclosing the obligation to report certain types of neglect and abuse in the informed consent process is required for research projects involving mandated reporters. However, even though the requirement to report only applies to mandated reporters, [Section 11166.05](#) broadens the scope of possible reporting beyond the mandated areas by allowing (not requiring) mandated reporters to make reports regarding children suffering from “serious emotional damage or... at a substantial risk of suffering serious emotional

damage, evidenced by states of being or behavior, including, but not limited to, severe anxiety, depression, withdrawal, or untoward aggressive behavior toward self or others”. This should be addressed in the informed consent process.

16.8 Student Subject Pools

A Subject Pool is a research resource used by some departments and schools in academic settings to enroll a large number of “available” subjects as potential volunteers. These volunteers are used in studies for that school or department. Subject Pools serve several roles: to provide researchers a pool from which to recruit primarily student participants for their studies and to familiarize students with the research process as subjects and researchers.

Participants in subject pools may be compensated for their time through course credit, extra credit or other means. These uses make subject pools commonplace in Social and Behavioral Studies.

Note: students must be provided an alternative to participation in the subject pool. The alternative assignment must not coerce subjects to participate in the subject pool. To prevent undue influence, the assignment should require approximately the same commitment of time and effort to complete as would participation in the subject pool.

At the University of Southern California, subject pools are found in the Department of Psychology in the College of Letters, Arts, and Sciences and the Marshall School of Business.

Extra Credit

The IRB can approve projects that give extra credit to student subjects for participating in a research project only when alternative means of obtaining equivalent extra credit with an equivalent effort is available for students who decide not participate in the research. The IRB carefully reviews the alternatives to participation to ensure that students are not being coerced.

The informed consent form should detail the consequences of withdrawing from a project prior to completing the research activities (extra credit should be given despite withdrawal). In general, the IRB favors giving extra credit even if a subject withdraws,

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unless the student withdraws immediately or there is clear evidence of bad faith on the part of the student.

Marshall School of Business Subject Pools

The Marshall School of Business has an unpaid student subject pool conducted by the Department of Management and Organization and a paid subject pool open to the general public conducted by the Department of Marketing. Links to the Marshall School subject pools and to additional information from Marshall are listed below.

- Policy for Behavioral Studies at Marshall School of Business
<http://www.uscresearch.org/poolinfo.php>
- Department of Management and Organization Consent Procedures
<http://www.uscresearch.org/consentprocedures.html>
- Department of Management and Organization Subject Pool Access
<https://marshall-mor.sona-systems.com/Default.aspx?ReturnUrl=/>
- Department of Marketing Consent Procedures
<http://www.uscresearch.org/mktconsentprocedures.html>
- Department of Marketing Paid Subject Pool Access
<https://marshall-research.sona-systems.com/Default.aspx?ReturnUrl=/>

Department of Psychology Subject Pool

The Department of Psychology subject pool is only open to USC students. To access the Psychology Subject Pool Webpage click on link below.

- Department of Psychology Subject Pool Webpage
<https://usc.sona-systems.com/Default.aspx?ReturnUrl=/>

Recent Federal Guidance on Subject Pool and Penalties for “No Shows”

Penalties for no-shows may not be assessed in subject pools

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The Office for Human Research Protections (OHRP) posted on its website a letter stating that imposing penalty credits on students who fail to show up for scheduled appointments with investigators without canceling by a specified deadline violates the requirement of Department of Health and Human Services (DHHS) regulation 45 CFR part 46.116(a)(8). The letter can be viewed by clicking [here](#). At USC, the OHRP position is upheld for all research and no such penalty credits may be imposed on subject pool participants.

Correspondence with OHRP has indicated that in subject pool policies, penalties may be assessed when students:

- Sign up for a study for which they are not eligible
- Sign up for the same study for multiple different times
- Sign up for a study in which they have already participate

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**Special
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