Guidelines for Course-Related Student Research Projects Involving Human Participants

Course-related activities that involve human participants, which are designed specifically for educational or teaching purposes and not intended for use outside of the classroom, typically do not require IRB approval. Because IRB approval is not required for classroom assignments, however, oversight of these projects ultimately rests with the faculty instructor. The faculty member should ensure that students understand what constitutes ethical conduct as well as how to preserve the safety of themselves and their participants.

Student classroom projects are typically:

- Part of a course requirement and are often completed in one semester.
- Designed to teach research methods.
- Created by faculty members to engage students in interactions with individuals, gather data about individuals, groups, organizations or other collectives and/or illustrate concepts covered in the course.
- For the most part, not intended to create new knowledge or to lead to scholarly publication.
- Low/non-risk, safe for students and participants and highly cognizant of the reputation of the University.

Examples of acceptable projects include: surveys of single parents, focus groups of immigrant service users, observations of elder care givers. Examples of unacceptable projects include: interviews of trauma victims in the ER, paid surveys with active drug users, shadowing of local gang activities.

Faculty should discuss each research proposal involving human participants with their students and require students to submit the Approval for Course-Related Assignments Involving Human Participants form. The student submitting this form must explain how human participants will be involved in the project and should discuss any foreseeable risks and issues of safety or cultural sensitivity that might arise as a result of the project. Students should not begin their projects until they have received the signed approval form from their instructor. Faculty who are unsure of the acceptability of the proposal should consult their vice dean with responsibility for academic programs, the Office for the Protection of Research Subjects (oprs@usc.edu), or the University Park IRB (upirb@usc.edu).

General guidelines for students and faculty:

- Faculty members assigning projects in research methods classes should ensure that students understand what constitutes ethical conduct as well as how to preserve the safety of themselves and their participants.
- Faculty should direct students to practice an IRB application using the Sandbox Training application. The Sandbox site allows students to familiarize themselves with iStar, the online application used for IRB submissions, and work on mock IRB submissions (https://istar.usc.edu).
- Students involved in course-related assignments are expected to follow university policies and abide by the Code of Ethics when designing and conducting projects with human volunteers.
- Students working on course-related projects are encouraged to complete the Collaborative IRB Training Initiative (CITI), the online human subjects education program (www.usc.edu/admin/oprs/citi.html).
• Students should complete the *Approval for Course-Related Assignments Involving Human Participants* form detailing their proposed research project and the faculty member should sign it once the proposal has been approved. A copy should be kept by both the student and the faculty member.
• Students should not deviate from their research design without the written consent of the instructor who approved the project.
• In the event that data obtained from a classroom project later results in new knowledge or useful/publishable information, these should be submitted by the author to the IRB as a secondary data analysis of existing data.
Approval for Course-Related Assignments Involving Human Participants*

Student Name __________________________________________________         Student ID Number ________________

Course Name ________________________________________________________         Course Number ______________

Title of the Project ____________________________________________________________________________________

Description of the project (use additional pages if necessary) – include information on how human participants will be involved in the project. Discuss any foreseeable risks or issues of safety or cultural sensitivity. Consider how this project will reflect on USC.

By signing below, I certify that I agree to abide by the university’s code of ethics (http://about.usc.edu/files/2011/07/USC_Code_of_Ethics_2004.pdf). I understand the responsibilities of conducting a classroom project involving human participants, as explained to me by my faculty member, and I agree not to deviate from the above description of the project without the written consent of the professor.

Student Signature ____________________________________          Date _____________

I approve the project as stated above. I have informed the student of the ethical considerations and responsibilities of conducting a classroom project involving human participants, and how to preserve the safety of themselves and their participants.

Professor Name ______________________________________         Professor Signature ____________________________

*Both the faculty member and student should retain a copy of this form for their records.
**IRB Policies and Procedures – Activities that Require IRB Review**

The following information is from the **University of Southern California Human Subjects Protection Program (HSPP) Policies and Procedures**, which can be found here:

(http://www.usc.edu/admin/oprs/private/docs/oprs/pnp/PnPsFinal.pdf)

**Activities that Require IRB Review**

Dissertations, theses, independent study projects and honors projects involving human subjects require Institutional Review Board (IRB) review and approval prior to the commencement of the research project. Human subjects research is defined as any activity that meets the HHS definitions of both “research” and “human subjects.”

**Research** is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**Human subject** is a living individual about whom an investigator (whether professional or student) conducting research obtains:

- data through intervention or interaction with the individual, or
- identifiable private information.

**International Research Conducted by Students**

Faculty are expected to remain in contact with students conducting research at any foreign sites to ensure safety of the student and participants. Students are expected to be aware of the cultural differences they will encounter. For all international research USC requires protocol review and approval by an outside IRB Ethical Review Committee (EC) or equivalent organization in the country where the research will occur in addition to USC IRB review, if applicable. If there is no local IRB, and the local entity is considered to be “engaged” in the research, the principal investigator must obtain a site permission letter (refer to chapter 12.4) from the host entity to perform research. **In addition, students travelling abroad for a project should notify Student Affairs (studentaffairs@usc.edu) prior to the trip.**

Federal regulations acknowledge that local customs, norms, and laws where the research will take place may differ from the US regulations governing research, and they provide for accepting different standards in foreign assurances of compliance.

At USC, UPIRB policies for research studies conducted within the United States apply to international research wherever possible. **In addition, international research protocols may include:**

- 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.

• 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.