



The University is committed to ensuring that students who conduct classroom projects involving human subjects do so in a safe and ethical manner. The goal of these new procedures is to assist instructors in determining when classroom research is purely for instructional purposes and when it is human subjects research that needs to be reviewed by the University's institutional review board, called the Protection of Human Subjects Committee (PHSC).

Oversight for classroom projects involving human subjects but designed exclusively for pedagogical purposes falls under the full purview of the course instructor, who has primary responsibility for assuring that the rights and welfare of human subjects are not violated. This responsibility includes communicating to students the ethical principles for the protection of human subjects. At a minimum, the faculty member teaching the course should be able to certify that the following requirements have been conveyed to the students in the class:

- That the students will not use vulnerable populations in their studies (other than children in very specific situations)
- That the projects will involve no more than minimal risk to participants (e.g., physical harm or potential harm psychologically, socially, economically, legally, or to one's reputation)
- That the project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed
- That the anonymity of participants (e.g., no names, social security numbers, or any other codes that can be linked to a list of names) will be protected
- That participation is voluntary and without coercion
- That appropriate informed consent will be obtained from each participant
- That participants must consent to any use of audio taping or videotaping
- That no deception will be employed
- That the review of existing data, documents, records or specimens will occur only if they are publicly available and if the data are recorded in such a manner that subjects cannot be identified
- That data collected cannot be used for publication or public presentation (e.g., web blogs, newsletters, poster presentations) or other research purposes without PHSC approval.

Research proposals that do not conform to the above stipulations require PHSC review.

Course instructors are also expected to review student research protocols and monitor the integrity of the project to insure that human subjects are protected. The course instructor is responsible for thoroughly reviewing each classroom research protocol to determine if PHSC review is required.

The instructor must keep a record for at least one calendar year of research protocols which include the research project title (i.e., topic being investigated), the student researchers' names, type of data collection, survey/interview schedules, and the date of the instructor's review and approval.

Supervising faculty of both undergraduate and graduate students must be CITI certified (http://www.shsu.edu/~rgs_www/certification.html) to conduct research with human participants. Questions about training should be directed to ORSP staff at sharla_miles@shsu.edu.

Questions about any aspects of these guidelines or whether projects fall under the definition of pedagogical purposes versus human subjects research should be addressed to the Office of Research and Sponsored Programs.

Human Subjects Research for Pedagogical Purposes FAQs

To what classroom projects does this policy apply?

This policy applies to human subjects research conducted purely for pedagogical purposes that does not meet the definition of human subjects research that would require approval from the PHSC. The policy is intended to primarily apply to those courses where students are being taught research methodology and are required to develop and conduct a research study involving human subjects. The assignment must be clearly stated in the course syllabus, the research project is to be performed by students enrolled in a graduate or undergraduate course at SHSU as requirement for completion of the course.

What is the definition of human subjects research that would require PHSC review?

Per the federal regulations 45 CFR 46, under which the University operates, research is defined as a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge. A human subject is defined as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Any research meeting this definition is subject to PHSC review.

What are some examples of class projects that need PHSC review?

Many graduate level research courses, and a few undergraduate, require students to conduct research that meets the definition of human subjects research. These class projects must have PHSC review. Theses, dissertations, and honors research projects involving human subjects that are considered research always require review by the PHSC. Investigations designed to

develop or contribute to generalizable knowledge are those that seek to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program.

What is minimal risk human subject's research?

The risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life.

What is meant by "sensitive information?"

Any interview, survey, or questionnaire that proposes to investigate opinions, behaviors, and/or experiences regarding, but not limited to any of the following sensitive topics requires review by the PHSC.

1. Sexual orientation, incest, rape, sexual molestation, deviant sexual behaviors or attitudes regarding sexual conduct, practices of contraception, abortion and/or pregnancy;
2. Substance use and/or abuse including, but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics and any prescription medication legally or illegally obtained;
3. Questions regarding mental health (e.g., suicide, depression, obsessive compulsive behaviors including, but not limited to, gambling, smoking, eating, etc.);
4. Traumatic experiences of an individual, including war or combat experiences of veterans

What level of consent must be obtained for projects under this policy?

The level of consent for classroom projects should be appropriate to the research being conducted. If the research involves only observation, consent may not be needed. Some classroom projects are conducted completely in the classroom (i.e., using other students in the classroom as subjects) and these would likely not need consent. The instructor must review and approve the procedures for obtaining informed consent and assure that they meet the requirements of informed consent (refer to consent form/cover letter templates in InfoEd online application software).

Why shouldn't deception be used in classroom projects?

Deception of research subjects may result in psychological harm. When deception is involved in human subjects research, the PHSC needs to determine that the deception is justified, that protections are in place to minimize the harm, and that a subject debriefing occurs.

What is meant by "vulnerable subjects"?

Vulnerable subjects may include pregnant women, fetuses, children (with the exception of observational studies), prisoners, persons at high risk of incarceration or deportation, undereducated or illiterate, or those who do not have the mental capabilities to understand or give an informed consent.

What happens when a complaint is made?

In cases of complaints by research subjects where the PHSC has no jurisdiction, the department, school or college needs to be prepared to be involved in dealing with the complaint and should be able to show that the faculty member operated under the department’s policy.

What if my question is not answered here?

If you have any further questions or need clarification, please call the Office of Research and Sponsored Programs.

Flow Chart for Determining Whether a Class Project Requires PHSC Review

