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1. GENERAL

- 1.01 The Institutional Review Board reviews and approves *research* involving human subjects to ensure that it is conducted in an ethical manner in compliance with <u>45 CFR 46</u>. Research as defined by 45 CFR 46 is defined as "a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge." Course projects that do not meet this definition are NOT subject to IRB review. The results of course-based projects are not to be disseminated (e.g., published, presented) beyond the classroom. Course projects that do not conform to the stipulations in Section 3 of this SOP will require submission of the appropriate PHSC application.
- 1.02 The purpose of the following standard operating procedures is to assist faculty in determining when course projects are for instructional purposes and when they constitute research involving human subjects (as defined by the federal regulations, 45 CFR 46) that needs to be reviewed by the University's Institutional Review Board (IRB), which is also referred to as the Protection of Human Subjects Committee (PHSC).

2. PURPOSE

The purpose of this SOP is to delineate the procedures that faculty will follow for ensuring the successful completion of their students' course projects.

3. DEFINITIONS

Go to the <u>Glossary</u> for definitions.

4. FACULTY RESPONSIBILITIES

4.01 Oversight for course projects involving human subjects but designed exclusively for pedagogical purposes (e.g., to instruct students in the use of methods to be used in the conduct of research) falls under the purview of that course's faculty member who has the primary responsibility for assuring that the rights and welfare of human subjects are not violated. This responsibility includes, but is not limited to, 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:

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- a. That the students will not use vulnerable populations in their studies
- b. 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)
- c. That the project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed
- d. That the anonymity of participants (e.g., no names, social security numbers, or other codes or identifiers that can be linked to a list of names) will be protected
- e. That participation is voluntary and without coercion
- f. That appropriate permission will be obtained from each participant [NOTE: students must use the <u>Subject Information Sheet template</u>]
- g. Projects that involve the use of audiotaping or videotaping should secure a signed release from the individual being recorded
- h. That no deception will be employed
- i. 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
- j. That data cannot be used for publication or public presentation (e.g., journal articles, conference papers, Web blogs, newsletters, poster presentations, etc.) or other research purposes without PHSC approval
- 4.02 Course projects that involve any of the above prohibited activities may be considered a violation of the guidelines for Ethical Conduct in Academic Research and Scholarship and may result in the referral of the instructor to the Provost and Vice President for Academic Affairs under Academic Policy Statement 920808.

5. GUIDANCE FOR FACULTY SPONSORS

5.01 Course instructors are also expected to review students' project protocols and monitor the integrity of the project to insure that human subjects are protected.

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The course instructor is responsible for thoroughly reviewing each classroom project protocol to determine if PHSC review is required.

5.02 The instructor must keep a record for at least one calendar year of project protocols, which will include the course project's title (i.e., topic being investigated), the names of students who are conducting the project (i.e., class roster), type of data collection, survey/interview schedules, and the date of the instructor's review and approval.

6. TRAINING AND EDUCATION IN THE PROTECTION OF HUMAN SUBJECTS

Supervising faculty of both undergraduate and graduate students must be certified through the <u>Collaborative Institutional Training Initiative (CITI)</u> for conduct of research involving human subjects. Questions about the training should be directed to the Office of Research and Sponsored Programs staff at <u>irb@shsu.edu</u>.

APPROVED: Dana G. Hoyt, President

DATE: 06/17/15

CERTIFICATION STATEMENT

This academic policy statement (APS) has been approved by the reviewer(s) listed below and represents SHSU's Division of Academic Affairs' policy from the date of this document until superseded.

Original:	April 25, 2014	Review Cycle:	April 1, ENY*
Reviewer(s):	Council of Academic Deans	Review Date:	April 1, 2018
	Faculty Senate		
	Academic Affairs Council		
Approved:	< signed >	Date:	06/18/15
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