

UNDERGRADUATE AND GRADUATE STUDENT COURSE-RELATED RESEARCH PROJECTS

Note: This policy does not apply to master's theses or doctoral dissertations. Those protocols must follow standard IRB review policies and procedures.

Federal regulations require that research protocols involving human subjects be reviewed by an Institutional Review Board for the Protection of Human Subjects in Research (IRB). In some courses, students collect data involving human subjects by using professional research methods, even though the student's work is not expected to contribute to generalizable knowledge.

Faculty and students are to adhere to the following criteria for determining when IRB approval is necessary for projects that are part of an academic course:

Student projects that are solely classroom directed exercises (purpose of the student investigation is solely for the fulfillment of a course requirement) **do not require IRB review if they meet ALL of the following criteria:**

1. Involve no more than minimal risk; AND
2. The data is recorded anonymously by the students (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names, or the recorded data will not identify the subject through their behavior); AND
3. The data will not be used beyond the classroom environment (**i.e. will not be published or orally presented at a major conference** AND
4. The research review category would normally fall under the exempt or expedited review categories (defined by CFR 45 Part 46 available at the following website:

[45 CFR Part 46 HHS Regulations for Human Research](#)

If the instructor is not certain that all of the criteria above have been met, the UT Tyler IRB Chair should be contacted.

Further, any "study" that involves any of the following must be approved by IRB before sample recruitment and data collection:

1. When data involves a sensitive subject matter, for example (list not all inclusive)
 - a. Domestic abuse
 - b. AIDS/HIV
 - c. Mental health issues

- d. Psychological issues
 - e. Substance abuse
 - f. Human trafficking
2. When the sample includes a vulnerable population group, for example (list not all inclusive)
- a. Prisoners
 - b. Children under the age of 18
 - c. Students in any academic setting and any age
 - d. Persons with impaired decisional capacity
 - e. Persons at risk for suicide
 - f. Pregnant women
3. Any research involving more than minimal risk to human subjects

COURSE FACULTY RESPONSIBILITIES

The primary responsibility for assuring that the rights and welfare of human subjects are protected is delegated to the faculty member/instructor. These rights are explained in Attachment A. In addition, the course faculty member is accountable and responsible for:

- completing the UT Tyler IRB training (CITI); student completion of training is at the discretion of the course faculty.
- effectively communicating to students ethical principles of research
- reviewing and approving student research protocols prior to initiation of the research project
- monitoring students' research activities and reports of findings
- assuring that the students' work does not violate human subjects' protection
- assuring that for any interventional research, that
 - it is minimal risk
 - that participants sign a written informed consent that reflects the UT Tyler procedures for written informed consent
- reviewing and approving the instruments, methods and procedures of the research protocol in their final form prior to their use by student researchers
- maintaining a record for at least one calendar year of research protocols which includes the research project title, the student researchers' names and the date of the instructors' review and approval

DEFINITIONS

1. "Student Research" means any observation or intervention by a student as part of a course which is designed to develop or contribute to student learning or to general knowledge, and for which publication of findings outside class will not take place.

Examples of such research are:

- a. observation of public behavior except where it is recorded in such a way that the subject can be identified directly or by identifiers linked to the subject and the subject's responses, if they became known, could place the subject at risk of legal liability or financial loss, or deals with sensitive aspects of behavior or use of alcohol;
 - b. research involving the collection or study of existing data, documents, records or specimens, if they are publicly available or if they are recorded in such a manner that subjects cannot be identified; or
 - c. observation in established or commonly accepted educational settings.
2. "Human Subject" means an individual about whom an investigator conducting research obtains data through some type of observation or interaction with the person
 3. "Student Researcher" means any student enrolled in a course at UT Tyler who conducts research on human subjects as an assignment or project in the course (excluding master's or doctoral theses research which are not designated as classroom projects).
 4. "Minimal risk" is the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals, or in the routine medical, dental or psychological examination of healthy individuals. Minimal risk does not involve data that, if made public, could place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing.
 5. Categories for exempt and expedited research to which this policy applies
 - a. research conducted in established or commonly accepted educational settings involving normal educational practices;
 - b. research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if the information is recorded in such a manner that the subjects cannot be identified directly or through identifiers linked to the subject;
 - c. research on individual or group behavior or characteristics or individuals such as studies of perception, cognition, game theory, or test

development, where the investigator does not manipulate subjects' behavior and the research will not stress the subjects;

- d. research involving survey or interview procedures except where responses are recorded in such a way that the subjects can be identified directly or through identifiers linked to the subject AND the subject's responses, if they became known, could place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing;
- e. moderate exercise by health volunteers;
- f. recording of data from subjects 18 years or older using noninvasive procedures routinely employed in clinical practices.

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ATTACHMENT A

1. Ethical Principles for the Protection of Human Subjects of Research
 - 1.1. Every person has the right to determine what shall be done to him or her, what activities he or she shall engage in and what risks he or she will take. Consequently, research on human subjects cannot be carried out without the subjects' competent, voluntary and informed consent.
 - 1.2. No person should be placed at risk as a subject of research unless the risks are reasonable in relation to the anticipated benefits of the research.
 - 1.3. The risks and burdens to subjects should not be unjustly distributed. The recruitment and selection of subjects should be reasonably related to the research and should not impose inequitable risks and burdens on any segment of society.
 - 1.4. Special consideration and protection should be given in research to persons who may lack full capacity to secure their own rights and interests, due to age, mental capacity, involuntary custody, cultural barriers or other special circumstances.