

## The University of Texas at Tyler

### Undergraduate and Graduate Student Course-Related Research Projects

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). These regulations also allow certain types of studies to be exempted from IRB review. The University of Texas at Tyler (UT Tyler) abides by an approved "Federal Wide Assurance" assuring the Office for Human Research Protections (OHRP) the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the university are adequately protected.

In the case of a student course-related research project assignment, it may be difficult at times to distinguish between that which would require IRB review and that which is designed simply to provide an experience in research methodology. In some courses, students collect data by using professional research methods, even though the student's work is not expected to contribute to generalizable knowledge. Some of the methods involve human subjects and, in some instances, subjects may be placed at risk.

In an effort to clarify the matter, the UT Tyler- IRB has drafted the following guidelines for determining when institutional review and 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:

- (a) involve the learning of research techniques; AND
- (b) involve no more than minimal risk; AND
- (c) 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
- (d) the data will not be used beyond the classroom environment (**i.e. will not be published, orally presented, presented at a conference, colloquium, departmental colloquium, poster presentation or used in further research by the student, other class members or the instructor**); AND
- (e) the research review category would normally fall under the exempt or expedited review categories (defined by [CFR 45 Part 46](#) ).

**If protocols/projects meet ALL of the above criteria, these projects shall be deemed to be "classroom exercises" and are not subject to review by the IRB.**

In these cases, **the primary responsibility for assuring that the rights and welfare of human subjects are protected is delegated to the faculty member/instructor in accordance with Attachment A.** The faculty member/instructor shall take responsibility for communicating to students ethical principals of research, review/approve student research protocols prior to initiation of the research project, monitor students' research activities and reports of findings, and assure that the students' own work does not violate human subjects' protection.

If the instructor is not certain that all of the criteria above have been met, they should contact the IRB Chair. If the instructor/student has reason to believe they may wish to present the results of this research in an activity such as a poster presentation or colloquium, the protocol must go before the Board for approval.

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

**The University of Texas at Tyler-Institutional Review Board  
Undergraduate Student Course-Related Research Projects\***

**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.
2. **Definitions**
  - 2.1. "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.
  - 2.2. "Human Subject" means an individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the person, or (2) personally identifiable information.
  - 2.3. "Student PI" means any student enrolled in a course at The University of Texas at 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).
  - 2.4. "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.

### **3. Responsibility of Instructors**

- 3.1. Instructors of courses in which students do research involving human subjects must complete the UTTyler IRB required Training Post prior to review/approval of any student project.
- 3.2. Instructors of courses in which students do research involving human subjects are responsible for informing students of the ethical principles for the protection of the human subjects of research and applicable policies and procedures.
- 3.3. Instructors of courses in which students do research involving human subjects are responsible for prior review of that research in accordance with these policies and procedures.

### **4. Instructor Review of Student Research**

- 4.1. If student research involves passive observation of public behavior, poses no more than minimal risk, and subjects will remain anonymous or their identity will be kept confidential, instructors shall review and approve the research. Informed consent of subjects is not required. 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.
- 4.2. If student research involves intervention but poses no more than minimal risk, the course instructor will be responsible for the review and approval of the research. Informed consent of subjects is required. If the research involves more than minimal risk, it must be reviewed by the IRB as described in Section 5.

- a). The instructor is responsible to assess whether risk is more than minimal as defined in 2.4. If there is any question or doubt about the degree of risk posed by the research and if there is any possibility of more than minimal risk, the protocol must be reviewed under Section 5 below.
- b). The instructor must review and approve the procedures for obtaining informed consent and assure that they meet the requirements of The University of Texas at Tyler, Institutional Review Board prior to their use by student PIs.
- c). The instructor must review and approve the instruments, methods and procedures of the research protocol in their final form prior to their use by student PIs.
- d). The instructor must keep a record for at least one calendar year of research protocols which includes the research project title, the student PIs' names and the date of the instructors' review and approval.
- e). Examples of research which may be approved by the procedures of this section are:
  - i) research conducted in established or commonly accepted educational settings involving normal educational practices;
  - ii) 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;
  - iii) 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;
  - iv) 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;
  - v) moderate exercise by health volunteers;
  - vi) recording of data from subjects 18 years or older using noninvasive procedures routinely employed in clinical practices.

## 5. IRB Review of Student Research

- 5.1. If student research involves more than minimal risk, the research protocol must be submitted to and approved by the IRB prior to any data collection activity.
- 5.2. If the research protocol is generic (i.e., all student PIs will use the same instruments, methods and consent procedures), the course instructor will submit a regular IRB application form. Once approved by the IRB, the generic protocol may continue to be used by student PIs without further review by the IRB unless:
  - a) the protocol is changed;
  - b) there is a complaint from a subject;
  - c) there is an adverse reaction by a subject; or
  - d) there is a change in the research environment or new information that would indicate greater risk to human subjects than that assumed when the protocol was initially reviewed and approved.
- 5.3. By law IRB approval is only valid for up to one calendar year. Renewed approval must be sought for projects extending beyond one year.