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TEXAS TECH UNIVERSITY

NEED HELP?

Human Research Protection Program

The name of the office coordinating with the Texas Tech University Institutional Review Board (IRB) has changed to the Human Research Protection Program (HRPP). The IRB's mission to protect the rights and welfare of human subjects participating in research at Texas Tech will not change. The new name will better reflect services provided by the office that do not involve the IRB. This website continues to offer step-by-step instructions for submitting human subjects research proposals, forms for proposal packets, and policies and procedures. You also will find training information, information on federal regulations as well as other resources.

Getting Started

Begin here. Find suggestions on how to get started and what resources you will need.

Does the project need IRB review?

Use the interactive module to help determine if IRB review is needed

Steps to Proposal Submissions

Step-by-step instructions on submitting a complete human subjects research proposal.

Frequently Asked Questions

Have a question? Check here first to find the answer you're looking for.

Human Subjects Research Training

Find information and links to human subjects research training courses.

Calendar and Review Time Frame

Meeting days for Full Board and proposal review time frame.

Resource Toolbox

The resource toolbox contains regulations, reports, documents and website links important to human subjects research.

Forms & Examples

Forms and examples needed for human subjects research



HRPP/IRB ANNOUNCEMENTS

- Webinar Invite
"When PIs Come a 'Knockin': Everything Investigators Want to Know but are Afraid to Ask"
Thurs. Nov. 8, 1 p.m.
Admin Room 333
- Thanksgiving Holiday - Nov. 22 and 23
- Nov. IRB Meeting
3 p.m. Nov. 27
Full Board Proposals Due Nov. 13



TEXAS TECH UNIVERSITY™

Operating Policy and Procedure

OP 74.09: Protection of Human Subjects in Research

DATE: March 19, 2009

PURPOSE: The purpose of this Operating Policy/Procedure (OP) is to allow for the protection of human subjects involved in research conducted by Texas Tech University faculty, staff, and students, in a manner consistent with federal regulations as stated in 45 CFR 46, Protection of Human Subjects (revised October 1, 2002), or any subsequent federal regulation relating to the subject matter of this OP.

In conjunction with these federal regulations, Texas Tech University has established the Protection of Human Subjects Committee to serve as the institutional review board (IRB) required by 45 CFR 46.

REVIEW: This OP will be reviewed in February of odd-numbered years by the chair of the Protection of Human Subjects Committee and the senior associate vice president for research with recommended revisions presented to the vice president for research and the provost/senior vice president for academic affairs by March 31.

POLICY/PROCEDURE

The Protection of Human Subjects Committee operates according to its own set of policies and procedures that are available from the Office of Research Services (ORS) and published on the ORS Web site. It is, and has been, the policy of Texas Tech University to implement a review process for ALL RESEARCH that will involve human subjects.

1. Human Subjects Research and IRB Authority

The IRB regulates all activity that constitutes *research with human subjects*, as defined below (see 45 CFR 46.102, Definitions) that (a) is conducted by Texas Tech personnel in the course of their employment by the university or (b) uses Texas Tech facilities or resources. Generally, this means that Tech personnel conducting research elsewhere (including the Texas Tech University Health Sciences Center) need approval by the Texas Tech IRB, even if the work is approved by another IRB. Likewise, work that is conducted on the Tech campus needs approval by the Tech IRB, even if it has approval by another institution. Individuals who are in doubt about whether an activity constitutes research with human subjects or who have questions about the applicability of this policy to a research project should confer with the chair or a member of the IRB.

Under no circumstances may an investigator undertake research involving human subjects without approval by the full IRB, approval by expedited review, or approval of a claim for exemption. Retrospective approvals and exemptions cannot be granted.

2. Definitions

* 45 CFR 46.102

The following definitions from federal regulations apply:

- a. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- b. **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
- c. **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject. **Private information** includes: (1) information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place; and (2) information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

3. Non-research Activities

Non-research activities are not subject to review by the IRB and do not have to be certified as exempt from IRB review. Examples of activities that fall outside the jurisdiction of the IRB because they do not have the purpose of contributing to generalized knowledge or are not systematic investigations include, but are not limited to:

- a. Teacher and student evaluations
- b. Program evaluations for internal purposes
- c. Texas Tech employee performance evaluations
- d. Marketing research designed to market the institution as a product
- e. Classroom projects that are conducted for didactic purposes and do not extend beyond the classroom
- f. Journalism
- g. Art

Examples of activities that fall outside the jurisdiction of the IRB because they do not involve interaction or intervention with human subjects and the data do not constitute identifiable private information include, but are not limited to:

- Studies using aggregated archival data

- Studies using people to obtain information that does not involve human subjects (e.g., “how many widgets did you produce last quarter?” or “how many sick days were taken last year by people who work in your school district?”)

It is possible that some activities such as those above may evolve into research, at which time they begin to fall under IRB jurisdiction and a proposal for IRB approval or a claim for exemption should be submitted. For example, a program evaluation intended solely to aid in improving the performance of a government agency might incidentally yield data that would be of interest to a wider audience through publication. When the intent in analyzing or presenting the data becomes one that involves a contribution to generalized knowledge, an exemption or IRB approval becomes necessary.

It is important to bear in mind that activities that fall outside the purview of the IRB may still involve some of the same ethical issues that confront researchers (e.g., confidentiality). Such issues ought to be considered from the perspective of ethics for teachers, practitioners, clinicians, or other professions or groups whose ethical guidelines or legal authority are relevant to the activity.

Non-research activities should not be confused with research that may be exempt from review. If an activity meets the definition of research with human subjects, it is exempt only if (a) it meets one or more criteria for exemption, and (b) a proper claim for exemption is filed and approved. (See detail in the committee’s policies and procedures).

4. Committee Make-up and Appointment

a. Federal Requirements

The Protection of Human Subjects Committee, in compliance with federal regulation 45 CFR 46.107, shall have **at least** five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by Texas Tech University. The committee should be sufficiently qualified through the experience and expertise of its members. The committee shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The committee, therefore, shall include persons knowledgeable in these areas. If the committee regularly reviews research that involves a vulnerable category of subjects, it shall include one or more individuals who are primarily concerned with the welfare of these subjects. The committee's make-up must also take the following factors into consideration:

- (1) The committee may not consist entirely of men or entirely of women, or entirely of members of one profession;
- (2) The committee shall include at least one member whose primary concerns are in non-scientific areas;
- (3) The committee shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution;
- (4) The committee may not have a member participating in its initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the committee;

- (5) The committee, in its discretion, may invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the committee. These individuals may not vote with the committee.

b. Texas Tech University's Specifications

Membership of Texas Tech University's Protection of Human Subjects Committee will include:

- (1) Associate Vice President for Research, ex officio
- (2) Director of Environmental Health and Safety, ex officio
- (3) One representative from the Office of the Provost/Senior Vice President for Academic Affairs, ex officio
- (4) One representative from the Office of the Associate Vice President for Information Technology, ex officio
- (5) Two members of the Lubbock community
- (6) One member to represent the interest of prisoners
- (7) Ten faculty members from Texas Tech University
- (8) Two faculty members from the Texas Tech University School of Medicine

The provost/senior vice president for academic affairs will appoint members of the committee, other than those specified by virtue of position. Each will be appointed for a three-year term, except when lesser terms may be required to maintain balance, membership, and continuity of committee operations. A like number of alternate members will be appointed, normally for three-year terms. Alternates may be solicited to attend meetings as voting members in place of a member who represents the same area of expertise or interest.

5. **Proposals for Research with Human Subjects**

Instructions on how to prepare proposals are available in the Office of Research Services and on its Web site: <http://www.ors.ttu.edu/Newors/newhome/Home/tryMain.html>.

The Protection of Human Subjects Committee (IRB) meets at 3:00 p.m. on the last Tuesday of each month. To be assured of consideration, a proposal **must** be submitted to ORS no later than 5:00 p.m. Tuesday, two weeks prior to the full board meeting. Claims for exemption or proposals for expedited review may be submitted at any time. Normally, ten days should be allowed for processing, longer if the proposal involves children or other vulnerable populations.

Only full-time or tenured Texas Tech University faculty members or full-time staff employees with the terminal degree in their discipline (Ph.D., Ed.D., J.D., or M.D.) may submit proposals. Proposals for research by students, other personnel, or individuals from outside Texas Tech must have a Texas Tech faculty sponsor.

In virtually all instances, investigators work with the IRB to reach agreement on the best ways to meet human subjects requirements while conducting research. In cases where the investigator and committee reach an impasse, a decision by the IRB to disapprove a project is final. Federal regulations specifically prohibit the university from approving a project that the IRB has disapproved.
