TEXAS TECH UNIVERSITY

Operating Policy and Procedure

OP 74.09: Protection of Human Subjects in Research

DATE: May 22, 2023

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, and other federal regulations.

Texas Tech University has established the Institutional Review Board for the Protection of Human Subjects (IRB) to serve as the institutional review board required by 45 CFR 46.

REVIEW: This OP will be reviewed in February of odd-numbered years by the Chair of the IRB, the Director of the Human Research Protection Program (HRPP), and the Associate Vice President for Research Integrity with substantive revisions presented to the Vice President for Research & Innovation and the Provost and Senior Vice President.

POLICY/PROCEDURE

The IRB operates according to its own set of policies and procedures, available from the HRPP office and website, http://www.hrpp.ttu.edu. At TTU, all research involving human subjects is to be reviewed by the IRB.

1. Human Subjects Research and IRB Authority

The IRB regulates all activity that involves *research* with *human subjects* that (a) is conducted by TTU personnel in the course of their employment by the university or (b) uses TTU facilities or resources. TTU investigators need approval by the TTU IRB to conduct human subject research, even if the research has IRB approval from another institution. (The approval may be in the form of a reliance agreement.) 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 HRPP Director or the IRB Chair.

Before an investigator begins research involving human subjects, IRB approval is necessary. TTU requires investigators to complete human subjects research training prior to IRB approval and requires all study personnel who engage with participants to complete human subjects research training prior to conducting any human research-related activities. Training must be renewed every three years.

2. Definitions

The following definitions from federal regulations (45 CFR 46.102) 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 (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(1) **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(2) **Interaction** includes communication or interpersonal contact between investigator and subject.

(3) **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).

(a) **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(b) **Identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

3. Non-research Activities

Non-research activities are not subject to review by the IRB (45 CFR 46.102). These include:

a. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

b. Public health surveillance activities (including the collection and testing of information or biospecimens) conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk

factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters).

c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

d. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Examples of activities that fall outside the jurisdiction of the IRB because they do not meet the definition of research include, but are not limited to:

- Teacher and student evaluations
- Program evaluations for internal purposes
- Texas Tech employee performance evaluations
- Marketing research designed to market the institution as a product
- Classroom projects that are conducted for didactic purposes and do not extend beyond the classroom
- Journalism
- 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 de-identified 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?")

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 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, IRB review 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.

4. IRB Membership and Appointment

a. Federal Requirements

According to federal regulations (45 CFR 46.107), the IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB 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 IRB, therefore, shall include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

The membership of the IRB must also take the following factors into consideration:

(1) The IRB shall include at least one member whose primary concerns are in non-scientific areas.

(2) The IRB 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.

(3) The IRB 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 IRB.

(4) The IRB, 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 IRB. These individuals may not vote with the IRB.

b. The TTU IRB may include:

(1) Associate Vice President for Research Integrity, ex officio

(2) Representative of Information Technology, ex officio

(3) Representative of the Office of Research Services, ex officio

(4) Representative of Environmental Health & Safety, ex officio

(5) Representative of Responsible Conduct of Research, ex officio

(6) Representative of HIPAA Privacy and Security, ex officio

(7) At least one member of the community not affiliated with TTU

(8) One member to represent the interest of prisoners

(9) Faculty members from TTU

(10) One or more faculty members from the TTU Health Sciences Center

The Vice President for Research & Innovation will appoint members of the IRB, 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 IRB operations. Alternate members will be appointed, normally for three-year terms. Alternates may 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, and information about required human subjects research training for investigators and research personnel, are available in the HRPP office and website http://www.hrpp.ttu.edu.

The IRB meets at 3:00 p.m. on the last Tuesday of each month. To be assured of consideration, a full board proposal must be submitted to the HRPP at least 15 working days before the full board meeting. Claims for exemption or proposals for expedited review may be submitted at any time.

The principal investigator must be a full-time TTU faculty member or a full-time employee with a terminal degree in his or her discipline (Ph.D., Ed.D., J.D., or M.D.). Faculty members or employees conducting research for the purpose of earning a degree must have their thesis or dissertation committee chair serve as the principal investigator.

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 IRB reach an impasse, a decision by the IRB not to approve a project is final. Federal regulations specifically prohibit the university from approving a project that the IRB has disapproved.