15.99.01.H1 Use of Human Subjects in Research

Approved: October 2014
Reviewed: March 12, 2019
Revised: March 13, 2024
Next Scheduled Review: March 13, 2029

Rule Statement

Texas A&M University-Texarkana (A&M-Texarkana) will comply with applicable laws and regulations relating to human subjects' research including 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56. A&M-Texarkana assures that all its research involving human subjects will comply with the terms of its Federalwide Assurance (FWA) for Protection of Human Subjects. This commitment to comply with the Common Rule (46 C.F.R, Part 46, Subpart A) will apply to all non-exempt human subject research that the university is engaged in, regardless of the funding source (if any).

This rule is required by System Regulation *15.99.01, Use of Human Subjects in Research,* and is developed to ensure compliance with federal and state laws and regulations, and university procedures applicable to the protection of human research subjects, including the ethical principles and guidelines set forth in The Belmont Report, April 18, 1979, for the protection of human subjects of research.

Procedures and Responsibilities

1. ADMINISTRATIVE REQUIREMENTS

1.1 The Office of Research and Sponsored Projects (ORSP) has oversight responsibility and authority for the university's Institutional Review Board (IRB) and appoints the chair and members of the IRB with the President's approval.

1.2 A five or more member IRB will be appointed to staggered three-year terms. Composition of the IRB must be consistent with the requirements outlined in 45 C.F.R. §46.107.

1.3 A&M-Texarkana will obtain a Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services' Office of Human Research Protections (OHRP).

1.4 All research activities performed under the auspices of A&M-Texarkana, including cooperative research conducted with one or more public or private entities, in which human subjects are involved, must be reviewed, and approved by an IRB prior to initiation of the research to ensure that it is conducted in accordance with applicable laws and regulations, university rules and procedures, and ethical guidelines, including A&M-Texarkana's FWA and 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56.

1.5 In the conduct of cooperative research projects involving more than one institution, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable laws and regulations. Joint review arrangements, where

the university seeks to rely on the review of another qualified IRB, or similar arrangements must be documented in writing and are subject to approval by the ORSP.

1.6 The IRB will maintain procedures reflecting current practices of the IRB in conducting reviews and approvals. The procedures will be consistent with applicable laws and regulations, including those specified in 45 C.F.R., Part 46. The procedures will include processes for:

1.6.1 Conducting initial and continuing review (not less than once per year) of research and reporting IRB findings and actions to the Investigator and the university.

1.6.2 Determining which projects require review more often than annually and which projects need verification from sources other than the Investigators that no material changes have occurred since previous IRB review.

1.6.3 Ensuring prompt reporting to the IRB of proposed changes in a research activity and that such changes in approved research are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject; and

1.6.4 Ensuring prompt reporting to the IRB, appropriate university officials, the head of any U.S. federal department or agency conducting or supporting the research (or designee), OHRP, and any other external entities, as required, of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB and any suspension or termination of IRB approval.

2. INSTITUTIONAL REVIEW BOARD (IRB) REVIEW OF RESEARCH

2.1. The IRB shall register with the OHRP and comply with the Common Rule and any other applicable federal or state, laws, regulations and policies. All research involving human subjects, regardless of funding source and whether funded or unfunded, must be reviewed by the IRB before initiation of the research project. This includes survey research; research conducted by students, faculty, or staff; and both internally and externally funded research. Joint research and scholarly activities will be conducted in accordance with System Regulation *15.99.01, Use of Human Subjects in Research.*

2.2. The IRB will review research and other scholarly activity proposals regarding the protection of human subjects in research. The IRB has the authority to approve, tentatively approve pending receipt of additional information, require modifications (to secure approval), or disapprove the proposed research or other scholarly activity in accordance with applicable federal regulations, including 45 C.F.R. §46.109.

2.3. Investigators shall be notified via university email of the IRB's decision. Notification will include resubmittal instructions if required. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the Investigator an opportunity to respond in person or in writing.

2.4. Research or scholarly activity protocols involving the use of human subjects must provide evidence of the following:

2.4.1. Risks to subjects are minimized by using procedures consistent with sound research design, which do not unnecessarily expose subjects to risk;

2.4.2. Risks to subjects are reasonable in relation to anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result;

2.4.3. Selection of subjects is equitable in terms of the purposes of the research and the setting in which it will be conducted;

2.4.4. Informed consent is documented and in accordance with state and federal regulations;

2.4.5. Informed consent is documented or waived in accordance with 45 CFR 46.117;

2.4.6. The research proposal makes adequate provision for continued monitoring to ensure safety of the subjects;

2.4.7. Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate; and

2.4.8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

2.5. Participation of human subjects in any study must be voluntary and the information provided to gain subject consent must be adequate and appropriate. ORSP may require additional safeguards be taken to protect the rights and welfare of vulnerable populations.

2.6. All documentation associated with IRB review is maintained by ORSP. ORSP provides staff support to the IRB in all phases of its work, including tracking and monitoring submissions, and maintaining records related to all research involving human participants. The ORSP is responsible for determining that projects involving human participants for thesis and dissertation research have received approval by the IRB before data collection begins.

2.7. The IRB shall conduct continuing reviews of research covered by this rule at intervals appropriate to the degree of risk, but not less than once per year and shall have authority to observe or have a third party observe the consent process and the research.

2.8. The IRB has the authority to determine whether an activity falls within the definition of research involving human subjects as specified in the Common Rule and may set the criteria, consistent with applicable state and federal laws and regulations, for exemption in its policies and procedures.

3. TRAINING

3.1. The IRB Chair or designee(s), in conjunction with the ORSP staff, are responsible for communicating and monitoring training faculty, student, staff, and new appointees to the IRB regarding additional procedures and requirements for the protection of human subjects.

3.2. The ORSP is responsible for monitoring and maintaining records of faculty, staff, and students regarding training requirements for the protection of human subjects. Training records will be maintained in accordance with the System Records Retention Schedule.

4. PROTECTED HEALTH INFORMATION

4.1. The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the regulations promulgated thereunder contain provisions to protect patients from inappropriate disclosures of their protected health information (PHI), as defined under

HIPAA. HIPAA establishes the conditions under which covered entities are allowed to disclose PHI to researchers to access and use such PHI for research purposes. Research projects involving the disclosure of PHI from a covered entity are subject to review and approval by the university's IRB. The study cannot be started prior to receiving both approvals.

5. NON-COMPLIANCE

5.1. The Office of ORSPs is responsible for IRB oversight and may suspend any previously approved research for non-compliance with IRB procedures or unexpected serious harm to subjects. Any suspension or termination of approval will be reported promptly to the Investigator, appropriate university officials and appropriate federal agencies.

5.2. Reports of non-compliance shall be made to the ORSP, the IRB Chair, ORSP staff or the University Compliance Officer.

Related Statutes, Policies, or Requirements

System Regulation *15.99.01, Use of Human Subjects in Research*
45 C.F.R. Part 46, *Protection of Human Subjects*
21 C.F.R. Part 50 and Part 56
The Belmont Report, April 18, 1979
Federal Policy for the Protection of Human Subjects ('Common Rule')
Additional U.S. Food and Drug Administration Regulations
42 U.S.C. 289
Internal A&M-Texarkana Human Research Protection Program SOP

Contact Office

Office of Research and Sponsored Projects
(903) 334-6629

System Approvals*

Approved for Legal Sufficiency:

Ray Bonilla
General Counsel

3/12/24
Date

Approved:

John Sharp
Chancellor

3/13/24
Date

***System approvals are contingent upon incorporation of any and all System-required changes in the rule's final posting.**