15.99.01.R1 Human Subjects Protection

Revised October 9, 2024
Next Scheduled Review: October 9, 2029

Rule Summary

East Texas A&M University-Commerce (the University) recognizes the need for investigation in which human beings may serve as research subjects, and this rule provides guidance in complying with federal laws and regulations and The Texas A&M University System (System) regulations relating to research involving human subjects including upholding the ethical principles and guidelines set forth in the Belmont Report, April 18, 1979, for the protection of human subjects of research.

The University and its employees 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, system policies and regulations, and university rules, procedures, and guidelines. The University assures that all of its research involving human participants will comply with the terms of its Federalwide Assurance (FWA) for Protection of Human Subjects, as well as the ethical principles and guidelines set forth in the Belmont Report.. This rule is required by System Regulation *15.99.01, Use of Human Subjects in Research.*

Procedures and Responsibilities

1 GENERAL

1.1 All university activities related to human subjects research, regardless of source of funding, will be guided by the ethical principals and guidelines set forth in the Belmont Report, and must be reviewed and approved by the Institutional Review Board (IRB) before the research begins and any data is collected.

1.2 The University holds an FWA from the Office for Human Research Protections (OHRP). The FWA applies to all federally-funded research involving human subjects conducted by the University.

1.3 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. Institutional authorization agreements, 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 IO or designee. All institutional authorization agreements will be reviewed with the corresponding IRB protocol from the relied-upon institution by the IRB chair or vice chair.

2 IRB REVIEW OF RESEARCH

2.1 The Institutional Officer (IO) must appoint five or more members to the IRB. Members will have staggered three-year terms. Qualifications for membership are set forth in 45 CFR 46.107.

2.1.1 The IRB Chair is appointed by the IO. The IRB Chair is granted a minimum of one-course reassigned time from his/her assigned teaching responsibilities during each long semester for the duration of the appointment and may be granted a stipend for service during summer months.

2.2 The IRB will register with OHRP and comply with 46 C.F.R, Part 46, Subpart A and any other applicable federal or state, laws, regulations, and policies.

2.3 The IRB has the authority to review, approve, disapprove, or require changes in research or related activities involving human subjects in accordance with applicable federal regulations, including 45 C.F.R. §46.109. The IRB also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to human subjects.

2.4 Research covered by this rule that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by the IO. However, the IO may not reverse IRB decisions involving disapproval, deferral, suspension, or termination of a research study.

2.5 The IRB will establish specific criteria for approval of research protocols in accordance with relevant federal, state, system, and university guidelines.

2.6 Research protocols involving the use of human subjects must provide evidence of the following:

2.6.1 Risks are minimized through procedures consistent with sound research design (reasonable risks beyond those incurred in daily life may be outweighed by benefits to the subjects).

2.6.2 Selection of subjects is equitable and the setting appropriate.

2.6.3 Informed consent is in accordance with state and federal regulations.

2.6.4 Consent is documented. Waivers of documentation must be granted in accordance with 45 CFR 46.117.

2.7 Principal Investigators (PIs) must be notified via university email of the IRB's decision. No research activity may be started prior to the receipt by the PI of final approval from the IRB. Notification will include resubmittal instructions if required as well as any required modification to the research activity required to secure approval of the IRB. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision and provide the PI an opportunity to respond in person or in writing. Any suspension or termination of IRB approval will be reported promptly to the PI, appropriate university officials, including the IO, external research sponsors, and appropriate federal agencies.

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

2.9 All documentation associated with IRB reviews is maintained by the Research Compliance staff in the Research Integrity and Compliance (RIC) office. RIC 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.

2.10 Continuing review of research not determined as exempt is conducted at intervals appropriate to the degree of risk or at a minimum annually. Prior to any changes being made, the PI, during the course of conducting the research, revises the protocol (e.g., makes changes to the informed consent form, survey instruments used or number and nature of participants), they must submit immediately an addendum to the approved protocol for review by the IRB. The process for continuation/review will be outlined in each approved protocol.

3 TRAINING

3.1 RIC is responsible for developing and maintaining a training, outreach, and education plan regarding the protection of human subjects in research. The plan must be approved by the IRB prior to implementation.

3.2 All individuals conducting research (including faculty, staff, postdocs, research assistants, students, etc.) that involve human subjects are required to successfully complete training assigned by RIC staff prior to commencing any activities involving human subject research, and on an ongoing basis as determined by the RIC.

3.3 The IRB Chair and/or others the chair may designate, in conjunction with the RIC staff, are responsible for training faculty, students, staff, and new appointees to the IRB regarding additional procedures and requirements for the protection of human subjects.

3.4 The RIC 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 university and System records retention rules, guidelines, and procedures.

4 PROTECTED HEALTH INFORMATION

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. When human subjects research involves the disclosure of PHI from a covered entity, the IRB will review and approve such research taking into account HIPAA.

5 RECORDS RETENTION

Records related to research on human subjects, including any protected health information, will be retained in the RIC in accordance with federal and state laws. RIC is responsible for maintaining records related to the functions and activities of the IRB including, but not limited to, copies of all protocols reviewed, continuing review reports, documentation of informed consent procedures, reports of any adverse events in research studies, meeting minutes, and records of all correspondence to/from principal investigators of official actions, in accordance with all state and federal laws and regulations, system policies and regulations, and university Procedure 61.99.01.R0.01, *Retention of State Records.*

6 REPORTING AND HANDLING REPORTS OR ALLEGATIONS OF NON-COMPLIANCE

6.1 Reports or allegations of noncompliance by researchers, or individuals other than researchers, such as research staff, IRB staff, IRB members, with federal and state laws and regulations, IRB requirements, system policies and regulations, or this rule may be submitted to the IRB chair, RIC, or the IO, as well as via the EthicsPoint Hotline/Website. The processing of reports or allegations of noncompliance will be conducted according to IRB procedures and in accordance with system policies and regulations and university rules and procedures.

6.2 Oversight of the IRB must be vested in the IO, who may suspend any previously approved research for noncompliance with an IRB protocol, concerns expected to lead to noncompliance, or unexpected harm to subjects.

6.3 Any allegation of noncompliance with federal rules on a project with a federal agency-sponsored grant must also be reported to the A&M System chief research compliance officer.

Related Statutes, Policies, or Requirements

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21 CFR Part 50 *Protection of Human Subjects*

21 CFR Part 56 *Institutional Review Boards*

45 CFR 46 *Protections of Human Subjects*

Belmont Report

Federal Policy for the Protection of Human Subjects ('Common Rule')

System Regulation *15.99.01, Use of Human Subjects in Research*

System Regulation *61.99.01, Retention of State Records*

University Procedure *61.99.01.R0.01, Retention of State Records*

Definitions

Federalwide Assurance (FWA) is the written assurance approved by the Office for Human Research Protections that the university will comply with the requirements for human subjects of research set forth in 45 C.F.R., Part 46.

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Institutional Officer (IO) is the individual authorized to act for the university and to assume on behalf of the obligations imposed by federal law and regulations. The Vice President for Research and Economic Development is IO for purposes of this rule and is the individual who executes the FWA and is responsible for determining the management of the IRB. The IO ensures ongoing compliance with applicable state and federal law and may collaborate with appropriate institutional officials to place sanctions on faculty failing to comply with these laws, or failing to comply with System regulations, university rules, procedures and guidelines.

Institutional Review Board (IRB) is the administrative body appointed by and reports to the IO in accordance with 45 C.F.R. §46.107.

Non-compliance for purposes of this rule means the failure to comply with state and federal regulations, system policies or regulations, university rules or procedures, IRB procedures or the requirements or determinations of the IRB in the conduct of human subjects research.

Principal Investigator (PI) means the individual responsible for the conduct of a human subjects research study as described in this rule. Only full-time faculty and staff at the level of director or above may be listed as PIs.

Revision History

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