

15.99.01.R1 Human Subjects Protection

Approved June 30, 2014
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Next Scheduled Review: July 15, 2022



Rule Summary

Texas A&M University-Commerce (A&M-Commerce) 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.

A&M-Commerce 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-Commerce assures that all of its research involving human participants will comply with the terms of its Federalwide Assurance (FWA) for Protection of Human Subjects. This commitment to the protection of human subjects applies to all research involving human subjects for which A&M-Commerce acknowledges and accepts its responsibilities for ensuring that the privacy, safety, health, and welfare of human subjects, regardless of the source of funding or whether the research is funded or unfunded. This rule supplements System Regulation 15.99.01, *Use of Human Subjects in Research*.

Procedures and Responsibilities

1 GENERAL

- 1.1 All research conducted under the auspices of A&M-Commerce that involves human subjects must be reviewed and approved by the Institutional Review Board before the research begins and any data is collected. This includes without limitation, survey research; research conducted by students, faculty, or staff; regardless of funding.

2 INSTITUTIONAL REVIEW BOARD (IRB) REVIEW OF RESEARCH

- 2.1 The Institutional Officer (IO) shall appoint five or more members to the IRB. Members shall 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 a 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 has 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 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 serious harm to human subjects.
- 2.3 Research protocols involving the use of human subjects must provide evidence of the following:
 - 2.3.1 Risks are minimized through procedures consistent with sound research design (reasonable risk beyond those incurred in daily life may be out-weighted by benefits to the subjects)
 - 2.3.2 Selection of subjects is equitable and the setting appropriate
 - 2.3.3 Informed consent is in accordance with state and federal regulations
 - 2.3.4 Consent is documented. Waivers of documentation shall on be granted in accordance with 45 CFR 46.117.
 - 2.3.5 Continued monitoring takes place to ensure the safety of the subjects
 - 2.3.6 Privacy and confidentiality are maintained consistent with A&M-Commerce's obligation under the Texas Public Information Act
- 2.4 Principal Investigators (PIs) shall be notified via university email of the IRB's decision. Notification will include resubmittal instructions if required.
- 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. The IO may require additional safeguards be taken to protect the rights and welfare of vulnerable populations.
- 2.6 All documentation associated with IRB reviews is maintained by the Research Compliance staff in the Office of Sponsored Programs (OSP). OSP 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.
- 2.7 Continuing review of research is conducted at intervals appropriate to the degree of risk or at a minimum annually. If 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), he/she 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 All individuals conducting research (including faculty, staff, postdocs, research assistants, students, etc.) that involve human subjects are required to successfully complete training assigned by OSP staff.

3.2 The Chair and/or others the Chair may designate, in conjunction with the OSP 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.

3.3 The OSP 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 System Records Retention Schedule.

4 PROTECTED HEALTH INFORMATION

Records related to research on human subjects, including any protected health information, will be retained in the OSP in accordance with federal and state laws.

5 NON-COMPLIANCE

5.1 Oversight of the IRB shall be vested in the IO, who may suspend any previously approved research for non-compliance with IRB protocol or unexpected serious harm to subjects.

5.2 Reports of non-compliance shall be made to the IO via direct reporting, OSP staff, or [EthicsPoint](#) hotline/website.

Related Statutes, Policies, or Requirements

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](#)

Suspended University Procedure *15.99.01.R0.01 Human Subject Protection*

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 A&M-Commerce and to assume on behalf of A&M-Commerce the obligations imposed by federal law and regulations. The Vice President for Research and Economic Development is A&M-Commerce's 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.

Contact Office

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