

15.99.01.R1 Human Subjects Protection

Approved June 30, 2014
Next Scheduled Review: June 30, 2019



Rule Statement

Texas A&M University-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 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*.

Reason for Rule

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 A&M 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.

Procedures and Responsibilities

1 GENERAL

- 1.1 Following federal guidelines (45 CFR Part 46), the IRB review and approval process is conducted in accordance with A&M-Commerce's Federalwide Assurance (FWA) and all federal, state, Texas A&M University System, and University rules, policies, regulations, and laws that govern the use of human participants in research, including the ethical principles, considerations, and concerns of the Belmont Report.

1.2 All research and scholarly activities conducted under the auspices of A&M-Commerce that involves human subjects must be reviewed and approved by the Institutional Review Board (IRB) before the research begins and any data is collected. 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 Regulations 15.99.01 § 2.3.

2 INSTITUTIONAL REVIEW BOARD (IRB) REVIEW OF RESEARCH

2.1 A five or more member IRB shall be appointed by the President of the University, in consultation with the Vice Provost for Research, to staggered three-year terms. Qualifications for membership are set forth in 45 CFR 46.107.

2.2 The IRB Chair is granted a minimum of a one-course reassigned time from his/her assigned teaching responsibilities each semester and each summer session for the term of the appointment.

2.3 The IRB will review research and other scholarly activity proposals in regard to the protection of human subjects in research. The IRB has the authority to approve, tentatively approve pending receipt of additional information, or disapprove the proposed research or other scholarly activity.

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

2.4.1 Risks are minimized through procedures consistent with sound research design (reasonable risk beyond those incurred in daily life may be out-weighed by benefits to the subjects)

2.4.2 Selection of subjects is equitable and the setting appropriate

2.4.3 Informed consent is in accordance with state and federal regulations

2.4.4 Consent is documented. Waivers of documentation shall on be granted in accordance with 45 CFR 46.117.

2.4.5 Continued monitoring takes place to ensure the safety of the subjects

2.4.6 Privacy and confidentiality are maintained consistent with A&M-Commerce's obligation under Texas Public Information Act

2.5 Primary Investigators shall be notified via university email of the IRB's decision. Notification will include resubmittal instructions if required.

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

- 2.7 All documentation associated with IRB reviews is maintained by the Research Compliance Office in the Office of Research and Sponsored Programs (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.
- 2.8 Continuing review of research and other scholarly activities is conducted at intervals appropriate to the degree of risk, but not less than once per academic year. The IRB can approve a protocol for 12 months and a continuation/renewal for an additional 12 months. All reviews for a continuation/renewal will be conducted by expedited review if no changes have been made to the research protocol and no adverse or unexpected reaction or side effects have occurred or are expected to occur. If the research or scholarly activities are not completed within this timeframe, then a new protocol must be submitted for review. If the investigator, during the course of conducting the research or scholarly activities, 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 or other scholarly activity (including faculty, staff, postdocs, research assistants, students, etc.) that involve human subjects are required to complete training successfully for the *Social & Behavioral Research – Basic/Refresher* and *Responsible Conduct of Research* for the specific area of research/scholarly activity. Training is assigned through CITI by ORSP staff.
- 3.2 The Chair and/or others the Chair's designee, in conjunction with the ORSP 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 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 System Records Retention Schedule.

4 PROTECTED HEALTH INFORMATION

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) 42 U.S.C. §1320d, *et seq.*, contains provisions on the privacy of individually identifiable health information and establishes the conditions under which covered entities might release such information for research purposes. Research projects involving the acquisition of protected health information (PHI), as defined by the Act, from a covered entity are subject to review by the System's HIPAA Compliance Officer or designee, in addition to IRB review, before the IRB's approval is finalized. The study cannot be started prior to receiving both approvals.

5 HUMAN SUBJECT ASSURANCE

A&M-Commerce is committed to a policy of safeguarding the rights and welfare of human subjects and hereby gives assurance that it will comply with the U.S. Department of Health & Human Service Regulations regarding the use of human participants in research.

6 NON-COMPLIANCE

6.1 Oversight of the IRB shall be vested in the Vice Provost for Research, who as Chief Research Compliance Officer may suspend any previously approved research for non-compliance with IRB protocol or unexpected serious harm to subjects.

6.2 Reports of non-compliance shall be made to the Chief Research Compliance Officer via direct reporting, ORSP 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*

Contact Office

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