

UNIVERSITY RULE

15.99.01.M1 **Human Subjects in Research**

Approved October 5, 1999

Revised March 28, 2012

Revised July 30, 2014

Revised November 22, 2019

Next Scheduled Review: November 22, 2024

Rule Statement

Texas A&M University is committed to protecting the rights and welfare of human research participants and ensuring compliance with all applicable ethical and legal requirements, including but not limited to 45 C.F.R. 46 and 21 CFR 50 and 56.

Reason for Rule

This rule establishes the framework for the university's Human Research Protection Program and provides guidance in complying with applicable laws and regulations and institutional rules and procedures 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.

Definitions

Human Subject generally means an individual who becomes a participant in research. However, more specific definitions are applied depending on the type of research and its funding source such as the Department of Health and Human Services (DHHS) regulation 45 CFR 46.102 which defines a human subject as 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; and the Food and Drug Administration (FDA) regulation 21 CFR 50.3(g) and 21 CFR 56.102(e) which define a human subject as an individual who is or becomes a subject in

research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

Research is defined by DHHS as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (see 45 C.F.R. §46.102(l)); and by the FDA (see 21 C.F.R. §50.3(c)) as any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- (1) Must meet the requirements for prior submission to the US Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- (2) Must meet the requirements for prior submission to the US Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- (3) Any activity the results of which are intended to be later submitted to, or held for inspection by, the US Food and Drug Administration as part of an application for a research or marketing permit.

Official Rule/ Responsibilities/ Process

1. GENERAL

1.1 Texas A&M University is committed to the ethical principles, considerations, and concerns expressed in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled [*Ethical Principles and Guidelines for the Protection of Human Subjects of Research \(The Belmont Report\)*](#).

1.2 This rule applies to all employees, students and agents of Texas A&M University who are engaged in human subjects research as part of their duties or studies at Texas A&M University regardless of the location of the research and regardless of the source of funding or whether the research is funded or unfunded. It also applies when the research involves use of university resources.

An individual who is not an employee is considered an agent of Texas A&M University when the individual has been specifically authorized to conduct human subjects research on behalf of Texas A&M University.

1.3 Texas A&M University holds a Federalwide Assurance of Compliance with DHHS regulations (FWA) for the protection of human subjects. The FWA applies to all federally-funded research with human subjects (as defined in 45 CFR 46.102(3))

and (f)) being conducted by investigators acting as agents of Texas A&M University regardless of the site of the activity.

- 1.4 The university complies with requirements stipulated by other federal agencies when they serve as sponsors or have oversight of research conducted at Texas A&M University, and assures compliance with applicable FDA regulations including, without limitation, 21 CFR parts 50, 56, applicable state laws, and university policies for the protection of human subjects in research.
- 1.5 The university is responsible for securing written agreements of commitment to relevant federal regulations from other institutions participating in collaborative research with Texas A&M University as applicable.

2. ROLES AND RESPONSIBILITIES

2.1 HUMAN RESEARCH PROTECTION PROGRAM

Texas A&M University has established a Human Research Protection Program (HRPP) to comply with the ethical and legal requirements for the conduct and oversight of human subject research. It oversees all research involving human subjects at Texas A&M University.

2.1.1. The HRPP is responsible for the following:

- 2.1.1.1 Establishing and following policies and procedures designed to ensure that human research will be conducted in compliance with ethical and legal requirements and that the rights and welfare of research participants are protected. The HRPP Standard Operating Procedures are found on the following website: <https://rcb.tamu.edu/humansubjects/forms>.
- 2.1.1.2 Supporting the administration of the Institutional Review Board (IRB) including all record keeping functions.
- 2.1.1.3 Working with other units and offices to ensure research compliance.
- 2.1.1.4 Providing educational and training programs for investigators involved in human subjects research.
- 2.1.1.5 Ensuring each investigator has fulfilled any educational requirements prior to the IRB approving their human subjects research.
- 2.1.1.6 Implementing a process to receive and act on concerns, complaints

and allegations regarding human subjects research.

- 2.1.1.7 Implementing a program to monitor compliance and improve compliance in identified problem areas.
- 2.1.1.8 Establishing and following written policies and procedures to ensure that the university can effectively share oversight of research with another organization by confirming or denying requests for external IRB reliance.
- 2.1.1.9 Ensuring that the appropriate authorization agreements (reliance agreements) are in place to document respective authorities, roles, responsibilities, and communication between the IRB of Record and relying institutions.
- 2.1.1.10 Notifying investigators (and relying organizations, when applicable) of IRB decisions, and making relevant IRB procedures and records available to the university's investigators and relying organizations.
- 2.1.1.11 Ensuring that the composition of the IRB is appropriate to review the research including that the IRB is appropriately constituted, members are appropriately qualified, members will not participate in the review of research in which they have a conflict of interest; and that the IRB separates business functions from ethical review.

2.2 INSTITUTIONAL OFFICIAL

The Vice President for Research serves as the university's Institutional Official and has oversight authority for the HRPP and responsibility for implementation of and compliance with federal regulations, state laws and university policies and procedures concerning human subjects research at Texas A&M University. The Vice President for Research appoints chairs and members of the Institutional Review Board(s) in accordance with federal regulations and has delegated daily operation of the HRPP to the HRPP Director.

2.3 INSTITUTIONAL REVIEW BOARD

- 2.3.1 All non-exempt human subject research performed under the auspices of or by Texas A&M University faculty, staff and students must be reviewed and approved by an Institutional Review Board (IRB) prior to initiation. This requirement applies regardless of location, source of funding, and regardless of whether the research is funded or not.

- 2.3.2 The primary responsibility of the IRB is the protection of human subjects from undue risk and from deprivation of personal rights and dignity consistent with the principles of the Belmont Report.
- 2.3.3 The IRB has the sole authority to grant IRB approval for human subjects research. If it does not grant IRB approval or suspends or terminates IRB approval, the decision may not be overturned at a higher level. Implementation of IRB-approved studies may be prevented or terminated by a decision of the Vice President for Research or by any other appropriate level of authority of the university.

2.4 PRINCIPAL INVESTIGATOR

- 2.4.1 The principal investigator has primary responsibility for the conduct of the research in accordance with federal requirements and university policies and procedures, ensuring that the rights and welfare of the individuals are protected, and for acquiring the appropriate knowledge regarding human subject protections, ethics, federal regulations, training, and monitoring to conduct his/her proposed research.
- 2.4.2 The principal investigator must assure that he or she, as well as study personnel, are adequately trained, competent and knowledgeable regarding human subject protections, ethical considerations, federal regulations and protocol requirements applicable to the research and duties assigned. Trained and competent may be defined by licensure when the human subjects research involves clinical or invasive procedures or is determined by the IRB to represent more than minimal risk.
- 2.4.3 The principal investigator for a study must meet the eligibility criteria defined in University SAP 15.01.01.M5.01 regardless of whether the research is sponsored or not. Otherwise, a faculty sponsor who meets the criteria set forth in University SAP 15.01.01.M5.01 must be identified on the application and included on the project. Any exceptions to this requirement must be approved by the Vice President for Research following the exception process outlined in University SAP 15.01.01.M5.01.
- 2.4.4 Faculty members who assign or supervise research conducted by students are responsible for overseeing the research to ensure that students adequately safeguard the rights and welfare of subjects and conduct the research as approved.

2.5 DEPARTMENT/UNIT HEADS

Department/unit heads are responsible for:

- 2.5.1 Promoting compliance with Federal and State regulations, sponsor, and university policies and procedures regarding the safety and welfare of human participants involved in research studies initiated within his/her department or unit.
- 2.5.2 Reviewing and approving IRB applications prior to submission, as documented by his/her signature on the IRB application, to assure the soundness of the research design, scientific and scholarly merit in relation to the departmental/unit capacities and adequate staff and resources to conduct the study.

3. REPORTING

Complaints or concerns related to human subjects research conducted under the authority of Texas A&M University can be reported to the HRPP at irb@tamu.edu or 979 458-4067. Reports may also be submitted online via EthicsPoint.

Related Statutes, Policies, or Requirements

42 U.S.C. §1230d, *et seq.*
45 C.F.R., Part 46
21 C.F.R., Parts 50, 56, 312 and 812
Belmont Report

[System Regulation 15.99.01, *Use of Human Subjects in Research*](#)

[SAP 21.01.99.M0.03, *Payment of Survey and Research Participants.*](#)

[SAP 15.01.01.M5.01 *Principal Investigator Eligibility on Sponsored Agreements*](#)

Contact Office

Division of Research
Human Subjects Protection Program
(979) 458-1467