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
Revised January 7, 2025
Next Scheduled Review: January 7, 2030

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.

In the context of Clinical Trials/Clinical Investigations consistent with 45 C.F.R. Part 46, 21 C.F.R Part 312 and 21 C.F.R. Part 812, the following definitions apply.

Clinical Trial/Clinical Investigation means a research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Investigator means the individual who actually conducts the clinical investigation (i.e. under whose immediate direction the drug or test article is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the Investigator is the responsible leader of the team. Sub-Investigator includes any other individual member of the team.

Sponsor means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, government entity, academic institution, private organization or other organization. The Sponsor does not actually conduct the investigation unless the Sponsor is a Sponsor Investigator.

Sponsor Investigator means an individual who both initiates and conducts, alone or with others, a clinical investigation, and under whose immediate direction the investigational drug or device is administered, dispensed or used. The obligations of a Sponsor Investigator include those of an Investigator and those of a Sponsor.

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), as well as The Declaration of Helsinki.

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 research involves the 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 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. CLINICAL TRIALS AND CLINICAL INVESTIGATIONS

2.1 All university research, whether funded or unfunded, meeting the definition of a Clinical Trial/Clinical Investigation (biomedical or behavioral) or any study with the intent to affect the structure and function of the body utilizing clinical procedures is subject to review by the Clinical Research Support Team/Office prior to the initiation of the study and any contract discussions for related agreements (e.g. nondisclosure agreements, clinical trial agreements, collaboration or service agreements, etc.).

2.2 The conduct of a Clinical Investigation under an FDA-accepted Investigational New Drug (IND) or Investigational Device Exemption (IDE) application invokes a complex set of FDA regulations, requirements, and obligations; to include the submission of initial and supplemental IND or IDE applications; continuing oversight (i.e., monitoring) of the manufacture of the investigational drug or device; routine monitoring of the conduct of the clinical trial at all involved study sites; and the requisite reporting. The FDA holds the "Sponsor" of the IND or IDE application responsible for ensuring that all these regulations, requirements and obligations are being met. (see, 21 CFR Part 312, Subpart D; 21 CFR Part 812, Subpart C).

2.3 The university is potentially liable for the actions of its faculty members; thus, necessitating that the university be engaged in the communications between the FDA and university-based sponsors of IND or IDE applications. In addition, the university must assume certain oversight of the manufacturing of investigational drugs and devices being used or evaluated under university-based IND or IDE applications and must also ensure appropriate monitoring of the progress and appropriate conduct of respective Clinical Investigations.

2.4 All research involving university-based IND or IDE applications is subject to review by the Clinical Research Support Team prior to initiation of the study and any contract discussions for related agreements (e.g. nondisclosure agreements, collaboration agreements, etc.), and prior to submission to the FDA, and the Institutional Review Board (IRB), as applicable. As part of the review process, the Investigator is expected to provide supporting documentation including (i) a monitoring plan utilizing clinical trial monitoring services; (ii) a feasibility assessment completed on a form prescribed by the Clinical Research Support Team and providing for the services of a clinical research organization (or equivalent).

3. 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 is conducted in compliance with ethical and legal requirements and that the rights and welfare of research participants are protected. The HRPP Standard Operating Procedures can be found on the following website: https://vpr.tamu.edu/human-research-protection-program/toolkit/.

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.

3.2 INSTITUTIONAL OFFICIAL

3.2.1 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 IRB(s) in accordance with federal regulations and has

delegated daily operation of the HRPP to the HRPP Director.

3.2.2 As Institutional Official, the Vice President for Research may place limitations or conditions on the privilege of individuals to serve as Sponsors or Sponsor-Investigators, due to failure to comply with applicable federal regulations or institutional requirements.

3.3 INSTITUTIONAL REVIEW BOARD

3.3.1 The IRB(s) will register with DHHS's Office for Human Research Protection (OHRP) and comply with 46 C.F.R, Part 46, Subpart A and any other applicable federal or state laws, regulations, and policies.

3.3.2 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 IRB prior to initiation. This requirement applies regardless of location, source of funding, or whether the research is funded or not.

3.3.3 The primary responsibility of the IRB is the protection of human subjects from undue risk and from deprivation of personal rights and dignity.

3.3.4 The IRB has the sole authority to grant IRB approval for human subjects research. If the IRB does not grant approval, or if the IRB suspends or terminates 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.

3.4 PRINCIPAL INVESTIGATOR

3.4.1 The principal investigator has primary responsibility for the conduct of the research in accordance with applicable federal requirements and university policies and procedures, ensuring that the rights and welfare of the individuals are protected.

3.4.2 3.4.2 The principal investigator is responsible for ensuring 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 or certification when the human subjects research involves clinical or invasive procedures including venipuncture or is determined by the IRB to represent more than minimal risk.

3.4.3 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.

3.4.4 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.

3.4.5 Regardless of the IRB of Record (internal or external) an Investigator conducting a Clinical Trial/Clinical Investigation with or without and IND or IDE or acting as the Principal Investigator on a university held IND or IDE shall comply with the following:

- Register their proposed study with the Clinical Research Support Team/Office prior to initiation of the study or any agreement/contract;
- Complete training consistent with federal regulations, and as designated by the HRPP and/or sponsor;
- Submit required documents to HRPP outlining their plan to meet all Clinical Trial/Clinical Investigation requirements that apply to the study including sponsor or FDA reporting requirements;
- Utilize clinical trial monitoring services as required by the sponsor or the HRPP; and
- Submit copies of all documents relevant to the FDA consultation process, pre-submission and the IND/IDE application to the HRPP.

These requirements are in addition to the obligations that apply through the IRB, and any other applicable federal, state, local or institutional requirements.

3.5 DEPARTMENT/UNIT HEADS

Department/unit heads are responsible for:

3.5.1 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 their department or unit.

3.5.2 Reviewing and approving applications submitted to the IRB as documented by their signature (or designee) on the IRB application, to assure the department/unit has the resources for the protection of human research participants, including but not limited to adequate time, facilities, and qualified investigators and research staff.

4. REPORTING

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

Related Statutes, Policies, or Requirements

45 C.F.R., Part 46

21 C.F.R., Parts 50, 56, 312 and 812

The Belmont Report

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

SAP 15.99.01.M1.01, *Institutional Conflict of Interest in Human Research*

SAP 15.01.01.M5.01, *Principal Investigator Eligibility on Sponsored Agreements*

Contact Office

Division of Research
Human Research Protection Program
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