15.99.01. E1 Use of Human Subjects in Research

Approved April 23, 2015
Reviewed April 5, 2019
Revised May 2, 2024
Next Scheduled Review: May 2, 2029

Supplements System Regulation 15.99.01

Rule Summary

In accordance with System Regulation *15.99.01*, *Use of Human Subjects in Research*, Texas A&M Engineering Experiment Station (TEES) will comply with all applicable laws and regulations relating to human subjects in research, including 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56 and the terms of its Federal Wide Assurance (FWA) for Protection of Human Subjects.

This rule is required by System Regulation *15.99.01*, *Use of Human Subjects in Research*, and is developed to ensure compliance with federal and state laws and regulations, and agency procedures applicable to the protection of human research subjects.

Procedures and Responsibilities

1. GENERAL

1.1 TEES will obtain a Federal Wide Assurance (FWA) with the U.S. Department of Health and Human Services' Office of Human Research Protections (OHRP). In accordance with 45 C.F.R. §46.103(b), the TEES Deputy Director or designee is the TEES official authorized to act for TEES and to assume on behalf of TEES the obligations imposed under TEES's FWA.

Per TEES's FWA, compliance with the Common Rule (46 C.F.R, Part 46, Subpart A) will apply to all federally funded, non-exempt human subjects research that TEES is engaged.

All TEES activities related to human subjects' research, regardless of funding source, will be guided by the ethical principles and guidelines set forth in the Belmont Report, published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

1.2 TEES does not have an internal Institutional Review Board (IRB) and designates the Texas A&M University (Texas A&M) IRB for review of all research to which the TEES FWA applies as documented in an agreement between TEES and Texas A&M that describes the responsibilities of the parties.

1.3 The Texas A&M IRB will register with OHRP and comply with the Common Rule and any other applicable federal or state, laws, regulations, and policies.

1.4 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. Joint review arrangements, where the agency 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 TEES Deputy Director or designee.

1.5 TEES Research Compliance is the responsible office for compliance associated with TEES awards and will closely coordinate with the Texas A&M Office of Research Compliance and Biosafety, Texas A&M Sponsored Research Services (SRS), the principal investigator (PI), and other appropriate parties in connection with Texas A&M IRB's review and approval.

2. PROCEDURES FOR REVIEW AND APPROVAL

2.1 All research activities involving human subjects that are overseen and conducted under the auspices of TEES, regardless of the location of the research activities, including cooperative research involving more than one institution, must be reviewed and approved by the Texas A&M IRB prior to initiation of the research to ensure that it is conducted in accordance with applicable laws and regulations, agency and university rules and procedures, and ethical guidelines, including TEES's FWA and 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56.

Policies and procedures for criteria, review, and approval by the Texas A&M IRB for research involving human subjects will be conducted in accordance with Texas A&M Rule *15.99.01.M1*, *Human Subjects in Research*. For more information regarding the approval process, please refer to the Texas A&M Office of Research Compliance and Biosafety website.

2.2 SRS is responsible for sponsored research administration for TEES and will notify TEES Research Compliance of TEES research involving the use of human subjects in research.

2.3 Responsibility for ensuring that all research involving human subjects is submitted to the Texas A&M IRB for review and approval lies with both the PI and division/department head, in coordination with SRS and TEES Research Compliance.

3. NONCOMPLIANCE

Reports and allegations of noncompliance with applicable laws, policies, regulations, rules, and procedures may be submitted to the Director for Research Compliance at TEES, the Human Research Protection Program (HRPP) at the Texas A&M Office of Research Compliance and Biosafety, or via The Texas A&M University System Risk, Fraud, and Misconduct Hotline. 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.

4. RECORDKEEPING

Records will be kept in accordance with System Regulation *15.99.01* and TEES procedure *61.99.01.E0.01*, *Records Management*.

Related Statutes, Policies, or Requirements

45 C.F.R., Part 46
21 C.F.R., Parts 50, 56, 312, and 812
Belmont Report, April 18, 1979
System Regulation 15.99.01, Use of Human Subjects in Research
System Regulation 61.99.01, Retention of State Records
TAMU Rule 15.99.01.M1, Human Subjects in Research
TAMU IRB Standard Operating Procedures
TEES SAP 61.99.01.E0.01, Records Management

Contact Office

Office of Research Compliance
researchcompliance@tees.tamus.edu