



Rule

15.99.01.L1 Use of Human Subjects in Research

First Approved: January 31, 2014
Revised: October 19, 2018
Next Scheduled Review: October 19, 2023

Rule Statement and Reason for Rule

This Rule establish IRB procedures, including procedures relating to the review of human subject research protocols and reporting guidelines, as required by [System Regulation 15.99.01, Use of Human Subjects in Research](#).

Procedures and Responsibilities

1. GENERAL

- 1.1 Texas A&M International University (TAMIU) has a responsibility to safeguard the rights and welfare of human subjects in research and other research activities. In compliance with federal regulations and [System Regulation 15.99.01, Use of Human Subjects in Research](#), TAMIU requires all research involving human subjects to be approved by the TAMIU Institutional Review Board (IRB). TAMIU further agrees to apply additional regulations, such as the U.S. Food and Drug Administration Human Subject Regulations and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when applicable, to research involving human participants under review.
- 1.2 Researchers seeking approval for projects may obtain the appropriate forms from the IRB Chair or the [IRB webpage](#).
- 1.3 Once per year, in January, the IRB Chair shall submit a report to the Provost and VP for Academic Affairs (Provost) listing all protocols reviewed during the past year by the IRB, including a summary of any adverse events and the IRB's response to those events

2. **SCOPE OF THE IRB**

It is the policy of TAMIU's IRB to have jurisdiction over all human subject research, subject to TAMIU's Federalwide Assurance.

- 2.1 Review and Approval of Human Subjects Research - No intervention or interaction with human subjects in research, including advertising, recruitment, and/or screening, may begin until the IRB has reviewed and approved the research.
- 2.2 Failure to Submit a Project for IRB Review - If research involving human subjects is conducted without prior IRB review and approval, the matter will be referred to the IRB and the Associate Vice President for Research and Sponsored Projects.

3. **MEMBERSHIP OF THE IRB**

- 3.1 In addition to the Federal regulations on IRB membership, the TAMIU IRB will be subject to the following provisions
 - a. The TAMIU IRB shall consist, whenever possible, of at least one faculty member from each College or School within TAMIU. The majority of IRB members shall be from the tenure/tenure-track faculty members.
 - b. Federal regulations divide research into Social Sciences, Biomedical, and Educational. The TAMIU IRB shall have on its committee at a minimum two individuals with expertise in each of these three areas. One of the biomedical experts will be a medical doctor or equivalent.
 - c. The TAMIU IRB shall have on its committee at least one individual with experience in research involving children.
 - d. The TAMIU IRB shall have on its committee at least one individual who has experience with the local community, preferably a priest/minister/rabbi.
 - e. The TAMIU IRB shall have two non-scientific members.
- 3.2 Each member of the committee will be appointed for a term of three years by the Provost. A single member can serve multiple consecutive terms by mutual agreement between the Provost, or their designee, and the individual. The IRB Chair shall be appointed by the Provost from among the tenured/tenure-track faculty at TAMIU. The IRB Chair shall be appointed for a term of three years. The IRB Chair may serve multiple consecutive terms by mutual agreement between the Provost, or their designee, and the faculty member.

4. **MEETINGS OF THE IRB**

The IRB will convene meetings as needed to conduct Full Review and at a minimum twice a year. Research will be reviewed at convened meetings at which the majority of the IRB members are present. Quorum for the meeting is defined as a simple majority, including at least one member whose primary concerns are in non-scientific areas. The IRB may establish its own operating procedures within these prescribed guidelines.

5. **IRB REVIEW OF HUMAN SUBJECTS RESEARCH**

Human subject research activities under TAMIU jurisdiction will be reviewed to determine whether the research is Exempt, Expedited, or Full Review. TAMIU faculty conducting human subject research at a location other than TAMIU must still receive approval from TAMIU's IRB.

5.1 **Exempt Review**

Eligibility for Exempt Review - The IRB may determine a research activity to be exempt only when the involvement of human subjects will be in one or more of the exemption categories, as defined by 45 CFR 46.

5.2 **Expedited Review**

- a. Eligibility for Expedited Review - TAMIU may use an Expedited Review procedure to review either or both of the following:
 - (i) Research that involves no more than minimal risk and which appears on the list of Expedited Review categories as defined by Office of Human Research Protections.
 - (ii) Minor changes in previously approved research during the period of one year or less for which approval is authorized.
- b. Review may be carried out by two faculty members of the IRB. At least one of the reviewers should be in the subject area of the research being conducted. The reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove research.
- c. Expedited Review may not be used when:
 - (i) Identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.
 - (ii) The research is classified.

5.3 **Full Review**

All protocols that do not qualify for either Exempt Review or Expedited Review shall be subject to Full Review by the IRB.

6. **IRB RECORDS AND DOCUMENTS**

The IRB Chair will obtain and maintain documentation of IRB activities as defined by federal regulations. This documentation will include, but is not limited to, copies of all research proposals reviewed, continuing review reports, reports of injuries to subjects, copies of all correspondence between the IRB and the Principal Investigators, minutes of IRB meetings, and the IRB Policy Manual which has the written procedures for the IRB as required by 45 CFR 46.103(b)(4) and (b)(5).

Related Statutes, Policies, Regulations, or SAP's

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

Contact Office

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