TEXAS A&M UNIVERSITY
SAN ANTONIO

Institutional Review Board

GUIDELINE # 17: INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL GUIDELINES FOR THESIS AND DISSERTATIONS

I. PURPOSE AND SCOPE

In compliance with federal regulations and ethical research standards, all student research involving human subjects at Texas A&M University – San Antonio (A&M-SA) must be reviewed and approved by the university's Institutional Review Board (IRB) prior to data collection. This requirement applies to undergraduate honors thesis, master's thesis, doctoral dissertations, and any capstone or culminating research project intended for public dissemination. The university is committed to protecting the rights and welfare of human subjects as mandated under Title 45 CFR Part 46 of the U.S. Department of Health and Human Services (HHS) policy.

Students and their faculty advisors share the responsibility for ensuring that all research involving human participants adheres to federal and institutional standards.

II. FEDERAL AND TEXAS A&M UNIVERSITY-SYSTEM (TAMUS) REGULATORY FRAMEWORK

The ethical conduct of research involving human subjects is governed by the Common Rule (45 CFR 46). Key elements include:

- Informed Consent: Participants must voluntarily consent to participate after being fully informed of the study's nature, risks, and benefits.
- Minimization of Risk: Research protocols must be designed to minimize potential harm.
- Equitable Subject Selection: Researchers must ensure that participant selection is fair and justified.
- Privacy and Confidentiality: Adequate safeguards must be in place to protect participant data.
- IRB Oversight: All human subjects research must undergo IRB review and approval before commencement.
- The IRB determines whether a project qualifies as "human subjects research" and whether it meets criteria for **Exempt**, **Expedited**, or **Full Board** review.

III. STUDENT RESPONSIBILITIES

Students must complete the following steps to obtain IRB approval before initiating research activities:

1. Human Subjects Research Training: All students and faculty advisors must complete IRB-approved training (e.g., CITI Program certification) in the protection of human research subjects. A training certificate must be submitted with the IRB application.
2. Proposal Alignment: The student's IRB application must align with the approved research

proposal submitted to the thesis or dissertation committee. Any substantial changes require submission of an IRB amendment after discussion with their advisor.

3. IRB Application Submission: Students must submit a complete IRB application via the university's electronic IRB system (CAYUSE). The application should include:
   - A detailed protocol
   - Recruitment materials
   - Informed consent documents
   - Survey instruments or interview guides (if applicable)

IV. TIMELINE FOR REVIEW

Students should plan for a minimum of:

- A minimum of 15 business days for Exempt or Expedited reviews,
- Up to one month or more, for Full Board reviews
- Longer delays may occur during academic breaks or due to incomplete applications.

V. INCLUSION IN FINAL THESIS/DISSERTATION

A copy of the IRB approval letter (or exemption determination) must be included in the appendix of the final thesis or dissertation. If applicable, include a statement in the methodology section indicating IRB approval and ethical compliance.

VI. FACULTY ADVISOR RESPONSIBILITIES

Faculty advisors serve as the Principal Investigator (PI) on all student-led IRB protocols. Responsibilities include:

- Reviewing and approving the students' IRB submission for accuracy and completeness.
- It is the PI responsibility to adequately train students to perform procedures listed on the protocol including consenting.
- Ensuring ethical oversight of the research project throughout its duration.
- Notifying the IRB of any adverse events, non-compliance, or including the closure of the approved protocol.
- It is the PI's responsibility to ensure amendments are submitted and approved by IRB prior to implementing any changes.
- Advisors are responsible for storage of research documents as per record retention schedule.

VII. SPECIAL CONSIDERATIONS

1. International Research: Projects conducted outside the United States must comply with both U.S. federal regulations and host country guidelines. Additional documentation may be required.
2. Secondary Data Analysis: Studies using de-identified or publicly available data may qualify

for IRB exemption. However, prior IRB determination is required before proceeding.

3. Vulnerable Populations: Research involving children, prisoners, pregnant women, or individuals with impaired decision-making capacity may require Full Board review and enhanced protections.
4. Students from Other Institutions: Studies approved by other IRBs that will be conducted on A&M-SA campus require IRB review and determination before it can proceed.
5. Students and advisors are responsible for compliance with SOP 9 (Post Approval Monitoring).

VIII. NON-COMPLIANCE

Engaging in human subjects' research without IRB approval constitutes a serious ethical and regulatory violation. Refer to SOP 10 (Managing Noncompliance). Consequences for non-compliance may include but are not limited to:

- Suspension of research activities
- Invalidation of thesis or dissertation
- Academic disciplinary action
- Ineligibility for publication or conference presentation

IX. RESOURCES AND CONTACTS

For assistance, students should contact the Office of Research Compliance or visit the university's IRB webpage for:

- Submission platform
- Templates and guidance documents
- Office hours and consultation appointments

NOTE: IRB review is not a formality. Approval must be obtained prior to any interaction with human subjects, including pilot studies or recruitment.

X. REVISIONS

Guideline: #17	**Version: V.1**
Title: INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL GUIDELINES FOR THESIS AND DISSERTATIONS	
Date Approved: 9/19/2025	