

TEXAS A&M UNIVERSITY-SAN ANTONIO
INSTITUTIONAL REVIEW BOARD (IRB) STANDARD OPERATING PROCEDURE (SOP)

SOP #: 7	Version: 2.0	Effective Date: 11/17/2023
Title: Exempt Review		
Approved by: Dr. Vijay Golla, Vice Provost for Research and Health Sciences		Date: 11/17/2023

1. Purpose

- 1.1 This SOP covers the process for reviewing submitted IRB Protocol Applications.
- 1.2 To determine Exempt review and category for the submitted IRB Protocol Application.

2. Scope

- 2.1 Federal, System and University policy are all formed and enforced for the ultimate purpose of human subjects' protection. The IRB review process is subject to 45 CFR Part 46 Subpart A.

3. Responsibilities

3.1. Principal Investigators (PIs) are responsible for:

- 3.1.1. Submitting the IRB Protocol Application and all required supporting documents to the IRB Office.
- 3.1.2. Submitting the signed Assurance Page (as applicable) for all study personnel.
- 3.1.3. Submitting CITI completion reports for all study personnel.

3.2. IRB Chair or designee is responsible for:

- 3.2.1. Review and final determination of Exempt protocol applications.
- 3.2.2. Signing the Memorandum of Exempt Determination.

3.3. Research Compliance Administrator (RCA) is responsible for:

- 3.3.1. Receiving the IRB Protocol Application, signed Assurance Page, CITI completion reports and required supporting documents from the PI.
- 3.3.2. Submitting all documents received from PI to the IRB Reviewer for review and determination.
- 3.3.3. Sending the Memorandum of Exempt Determination to the IRB Chair or designee for final review and determination.
- 3.3.4. Sending the Memorandum of Exempt Determination to the PI.
- 3.3.5. Updating the IRB Log Spreadsheet.
- 3.3.6. Filing all documents and correspondences in the protocol folder.

3.4. IRB Members are responsible for:

- 3.4.1. Reviewing and determining (as applicable) assigned IRB Protocol Applications.

4. Procedure

4.1. Designating a Reviewer

- 4.1.1. RCA will send the IRB Protocol Application, and all required supporting documents from the PI to the IRB Reviewer.
- 4.1.2. The IRB Reviewer has ten business days from receipt of all documents from RCA to review and provide determination.
- 4.1.3. Upon receipt of determination from the IRB Reviewer, the RCA will draft the Memorandum of Exempt Determination.
- 4.1.4. The RCA will send the Memorandum of Determination to the IRB Chair or designee for signature and final review and determination.
- 4.1.5. The RCA will send the Memorandum of Exempt Determination to the PI.
- 4.1.6. The RCA will save all documents in the protocol folder.
- 4.1.7. The RCA will update the IRB Log spreadsheet.

5. Reference Documents and Forms

Available online <https://www.tamusa.edu/academics/research-and-graduate-studies/research-compliance/institutional-review-board/irb-forms.html>

- 5.1. IRB Protocol Application Form
- 5.2. [Human Subject Regulations Decision Charts](#)
- 5.3. IRB Log Spreadsheet (office use only)

6. Revision History

- 6.1 March 2019, October 2023