

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

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