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

SOP #: 4	**Version:** 2.0	**Effective Date:** 9/25/2023
Title: Continuing Review		
Approved by: Dr. Vijay Golla, PhD Vice Provost for Research and Health Sciences		**Date:** 9/25/2023

1. **Purpose**

1.1 This SOP covers the administrative process for reviewing and approving submitted IRB continuing reviews for appropriate Expedited or Full Board Protocols.

1.2 To describe the administrative steps in processing an IRB continuing review.

1.3 To review the submitted IRB continuing review Form.

1.4 To determine if the submitted IRB continuing review form remains in the same category of review.

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.

2.2 A&M-San Antonio IRB can override the decision of protocols not requiring continuing review as long as the IRB documents the decision and the rationale for the decision.

3. **Responsibilities**

3.1. Principal Investigators (PIs) are responsible for:

3.1.1. Submitting the Continuing review and all relevant documents for the approved IRB protocol to the IRB Office by the due date referenced on the protocol determination letter.

3.2.IRB Chair or IRB Vice-Chair are responsible for:

3.2.1. Assigning, reviewing, and approving (as applicable) appropriate protocols requiring continuing review.

3.2.2. Signing the IRB continuing review approval letter.

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

3.3.1. Sending the Principal Investigators (PIs) 30-, 60- and 90-day notification(s) of renewal and/or expiration (closure).

3.3.2. Sending the IRB Members documents for review and approval.

3.3.3. Sending all correspondence to the PI to and from the reviewer.

3.3.4. Drafting approval letters.

3.3.5. Updating the IRB Log Spreadsheet.

3.4. IRB Members are responsible for:

3.4.1. Reviewing and approving (as applicable) assigned continuing reviews for approved protocols.

4. Procedure

4.1. Identified protocols for continuing review.

4.1.1. Continuing review notifications will be sent to the PI for protocols identified by the IRB Office.

4.1.2. In the 1st week of each month, the RCA will identify the protocols that will expire within 30-, 60- and 90-days, using the expiration date listed in the determination memorandum.

4.1.3. The RCA will send 30-60- and 90-days email notifications to identified PIs attaching the PI's originally approved protocol with the IRB Continuing Review form, IRB Closure form and IRB CITI Training Instructions.

4.1.3.1. If the PI submits the IRB Closure form, refer to standard operating procedure titled Protocol Closure.

4.2. Designating a Reviewer

4.2.1. Once the RCA receives the IRB Continuing Review form, Consent form and other relevant documents (if applicable) from the PI, the RCA will identify the review category in which the protocol was originally approved.

4.2.1.1. The RCA will send the submitted forms and previously approved protocol to the IRB Chair or IRB Vice-Chair as primary reviewer.

4.2.1.1.1. If the IRB Chair or IRB Vice-Chair has a conflict of interest, the RCA will forward the protocol for review to the chair without a conflict of interest.

4.2.1.1.2. If the IRB Chair and IRB Vice-Chair both have a conflict of interest, the RCA will forward the protocol to an IRB member.

4.2.1.2. The IRB Chair or IRB Vice-Chair has <u>three business days</u> from the day the continuing review form and supporting documents are sent to review and respond to the RCA with their determination.

4.2.1.2.1. Upon receipt of determination from the IRB Chair or IRB Vice-Chair, the RCA will draft the approval letter and send it to the PI.

4.2.1.2.2. In the event that the IRB Chair or the IRB Vice-Chair determine additional reviewers are required, the RCA will designate an IRB member.

4.2.1.3. Once the Reviewer submits his/her determination, the RCA will draft the approval letter and send it to the PI.

4.3. Approval Notification

4.3.1. The RCA will generate the approval letter and stamp the approved version of the Consent form.

4.3.2. The draft approval will be sent to the IRB Chair or IRB Vice-Chair for review and signature.

4.3.3. Once the IRB Chair or IRB Vice-Chair has signed the approval letter, the RCA will send the approval letter and approved consent form to the PI.

4.4. Protocol Filing

4.4.1. The RCA will file the approved IRB Continuing Review form in the appropriate IRB folder.

4.4.2. The RCA will update the IRB Log Spreadsheet.

5. **Reference Documents and Forms**

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

7.2 IRB Log Spreadsheet (office use only)

6. **Revision History**

6.1. August 2023, September 2023