SOP #: 6	**Version:** 2.0	**Effective Date:** 11/17/2023
Title: IRB Protocol Study Closure Report		
Approved by: Dr. Vijay Golla, PhD Vice Provost for Research and Health Sciences		**Date:** 11/17/2023

1. **Purpose**

1.1 This SOP covers the process for reviewing and approving submitted IRB Study Closure Reports for determined Exempt and approved Expedited and Full Board protocols.

1.2 To describe the steps for submitting and processing an IRB Protocol Study Closure Report.

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 Study Closure Report and all relevant documents to the IRB Office upon completion of the research.

3.2. IRB Vice Chair or designee are responsible for:

3.2.1. Assigning, reviewing, and approving (as applicable) appropriate protocols requiring an IRB Study Closure Report.

3.2.2. Signing the IRB Study Closure Report.

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 study expiration/closure.

3.3.2. Sending the IRB Vice Chair or designee the IRB Study Closure Report documents for review and approval.

3.3.3. Sending all correspondence to the PI to and from the Vice Chair or designee.

3.3.4. Drafting the Memorandum of Approval and sending it to the PI.

3.3.5. Updating the IRB Log Spreadsheet.

4. **Procedure**

4.1. Identified protocols for IRB Study Closure Reports

4.1.1. Expiration/closure 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 protocols that expire within 30-, 60- and 90-days, using the expiration date listed in the Memorandum of Approval or Determination.

4.1.3. The RCA will send 30-60- and 90-days email notifications with the originally approved protocol and IRB Study Closure Report to identified PIs.

4.2. Designating a Reviewer

4.2.1. The RCA will send the IRB Study Closure Report with the approved protocol to the IRB Vice Chair or designee.

4.2.1.1.1. If the IRB Vice Chair has a conflict of interest, the RCA will send the submitted forms for review to the designee without a conflict of interest or to an IRB member.

4.2.1.1.2. The IRB Vice Chair or designee have three business days from the day the submitted forms are sent to review and respond to the RCA with their determination.

4.2.1.1.3. Upon receipt of determination from the IRB Vice Chair or designee, the RCA will draft the Memorandum of Approval and send it to the PI.

4.3. IRB Study Closure Approval and Notification

4.3.1. The RCA will generate the Memorandum of Approval, stamp the approved IRB Study Closure report.

4.3.2. The RCA will send the Memorandum of Approval to the IRB Vice Chair or designee for final approval.

4.3.3. The RCA will send the Memorandum of Approval to the PI.

4.3.4. The RCA will file all documents and correspondence in the protocol folder.

4.3.5. The RCA will update the IRB Log spreadsheet.

5. **Reference Documents and Forms**

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

5.2. IRB Log Spreadsheet (office use only)

6. **Revision History**

6.1. August 2023, October 2023