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

SOP #: 5	**Version:** 1.0	**Effective Date:** 11/17/2023
Title: IRB Protocol Amendment Review		
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 protocol amendments.
1.2. To describe the steps for submitting and processing an IRB amendment for determined Exempt and approved Expedited and Full Board protocols.

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. **Amendment Categories**

3.1. Administrative Amendments
- Personnel changes to add or remove student investigator(s).
- Protocol title to match a grant.

3.2. Minor Amendments to Exempt, Expedited and Full Board protocols

3.2.1. Minor amendments to Exempt protocols:
- Addition or removal of study personnel other than the principal investigator such as Co-PI, manager, and coordinator.
- Changes to recruitment materials and method, such as a change to the phone number or the addition of a newspaper ad when using language similar to an already approved flyer.
- Changes to surveys, interviews, or focus group instruments that do not fall outside the scope of the original approved instruments such as wordsmithing and the addition of clarifying or similar questions to those previously approved, or deletion of questions.

3.2.2. Minor amendments to Expedited and Full Board protocols:
- Clarification of issues.
- Addition of risks to the informed consent and other study documents at the IRB's request.
- Increase in the amount of blood drawn.
- Increase in medication dose.
- Requested changes by the Radiation Safety Office.
- Extended accrual period.
- Addition of non-invasive test (e.g., urine pregnancy test).
- Addition of audio recording.
- Addition of video recording.

3.3. Major Amendments to Exempt, Expedited and Full Board protocols

3.3.1. Major amendments to Exempt protocols:
- Change to Principal Investigator.
- Change in funding source.

- Change to study purpose or procedures such as adding a survey on a different topic than previously approved or collection of data falling outside the parameters of the data collection previously approved.
- Changes to study population targeted for recruitment such as adding a new population or substantively revising the inclusion/exclusion criteria for the current population.
- Changes to the identifiability of the research data you will receive or record. For example, your Exempt protocol states that you will not collect names with the surveys, but you now want to, or you now want to record identifiable data from an existing dataset.
- Changes to the risks involved in the study.

3.3.2 Major amendments to Expedited and Full Board protocols:

- Change of Principal Investigator.
- Increase in the amount of blood drawn.
- Safety issues.
- Extension of the study duration.
- Multiple changes in the study design.
- New software in devices.
    - The original performance and effectiveness or the safety or the intended use of the SaMD (Software as Medical Device). These changes may include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.
- Additional arm added to the study.
    - Arm: A group or subgroup of participants in a clinical trial that receives a specific intervention/treatment, or no intervention, according to the trial's protocol.
        - Arm type: A general description of the clinical trial arm. It identifies the role of the intervention that participants receive. Types of arms include experimental arm, active comparator arm, placebo comparator arm, sham comparator arm, and no intervention arm.
- Additional population added to the study (including vulnerable populations).
- Increase of medication dose.
- Increase in infusion rate.
- Increase in radiation exposure.

4. **Responsibilities**

4.1. Principal Investigators (PIs) are responsible for:

4.1.1. Submitting the amendment to the IRB Office describing any changes to the approved IRB protocol prior to implementation.

4.1.2. Submitting an updated signed Assurance Page (as applicable) with all personnel added.

4.1.3. Submitting CITI completion reports for all personnel added.

4.2. IRB Vice Chair or designee is responsible for:

4.2.1. Receiving the amendment submission and signed Assurance Page from the Research Compliance Administrator (RCA).

4.2.2. Reviewing and approving Exempt and Expedited protocol amendments as described in 3.2 and 3.3.

4.2.3. Reviewing, assigning and or approving Full Board protocol amendments.

4.2.4. Signing the IRB Memorandum of Approval.

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

4.3.1. Receiving the amendment, signed Assurance Page, and required supporting documents from the PI.

4.3.2. Reviewing and approving administrative amendments as described in 3.1.

4.3.3. Submitting all documents received to the IRB Vice Chair or designee for review and approval.

4.3.4. Sending reviewer comments to the PI.

4.3.5. Drafting of the Memorandum of Approval and submitting it to the IRB Vice Chair or designee for final approval.

4.3.6. Sending the Memorandum of Approval to the PI.

4.3.7. Updating the IRB Log Spreadsheet.

4.3.8. Filing all documents and correspondences in the protocol folder.

4.4. IRB Members are responsible for:

4.4.1. Reviewing and approving Full Board protocol amendments.

5. Procedure

5.1. IRB Protocol Amendment Review

5.1.1. The Administrative review will be conducted by the RCA within three business days of receipt of the amendment from the PI. The RCA will ensure all applicable supporting documents and training have been received from the PI.

5.1.2. The Ethical review will be conducted by the Vice Chair or designee within three business days of receipt of the amendment.

5.1.3. After the IRB Vice Chair or designee has reviewed the documents, the Vice Chair or designee will consult the Human Subjects Regulations Decision Chart to determine if the amendment changes the review category (Exempt, Expedited, or Full Board) based upon risk.

5.2. Amendment Review for Exempt protocols

5.2.1. If the IRB Vice Chair or designee re-determines the protocol as Exempt or Expedited, the RCA will draft the Memorandum of Approval and send it to the PI.

5.2.2. If the Vice Chair or designee determines the review category is no longer Exempt or Expedited, the protocol will follow the Full Board amendment review described in 5.3.

5.3. Amendment Review for Full Board protocols

5.3.1. If the IRB Vice Chair, or designee determines the amendment increases the risk of research, the RCA will send the amendment submission, approved IRB Protocol Application, Human Subject Regulations Decision Charts, IRB Protocol Review Checklist 45 CFR 46.111, and 45 CFR

46.116 Informed Consent Checklist to IRB members for review at least seven business days before the convened meeting.

5.4. Protocol Approval and Notification

5.4.1. After the Reviewer has submitted their approval, the RCA will compile all required documents.

5.4.2. The RCA will stamp the approved version of the Consent form (if applicable).

5.4.3. The RCA will draft the Memorandum of Approval.

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

5.4.5. The RCA will send the Memorandum of Approval to the PI after final approval.

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

5.4.7. The RCA will update the IRB Protocol Log spreadsheet.

6. Reference Documents and Forms

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

6.1. Signed Assurance Page

6.2. Human Subject Regulations Decision Charts

6.3. IRB Protocol Review Checklist

6.4. Informed Consent Form Checklist

6.5. IRB Log Spreadsheet (office use only)

7. Revision History

7.1 October 2023