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

SOP #: 3	**Version:** 1.0	**Effective Date:** 8/24/2023
Title: Expedited & Full Board Review		
Approved by: Dr. Vijay Golla, PhD Vice Provost for Research and Health Sciences		**Date:** 8/24/2023

1. Purpose

1.1. This SOP outlines the criteria and process to review a submitted IRB Protocol Application Form (henceforth referred to as application) determined by the IRB Chair or designee as expedited or full board.

2. Scope

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.

2.1. Expedited Review: Applications may be reviewed via an expedited review process if they meet the following criteria:
- 2.1.1. Research poses no more than minimal risk to subjects, as assessed by the reviewer; AND
- 2.1.2. Research for which all the procedures fall within the list of categories of research published by the Secretary of (United States Department of Health & Human Services (HHS) and the Food and Drug Administration (FDA)

2.2. Full Board Review: All proposed human subject research that does not meet the criteria for exemption or expedited review must be reviewed by a majority of the IRB members at a convened meeting.

3. Responsibilities

3.1 IRB Office Responsibilities:
- 3.1.1 Receiving protocol from Principal Investigator (PI).
- 3.1.2 Performing Administrative Pre-Review.
- 3.1.3 Serving as a liaison between PI and IRB.
- 3.1.4 Routing protocols to appropriate number of reviewers.
  - 3.1.4.1 Expedited Review: Two reviewers (Primary and Secondary) receive protocol to perform an in-depth review of pertinent documentation and materials submitted by the PI and IRB Office.
  - 3.1.4.2 Full Board Review: All IRB Members receive protocol at least seven days prior to the next convened IRB meeting to perform an in-depth review of pertinent documentation and materials submitted by the PI and IRB Office.
- 3.1.5 Routing to the IRB Chair or designee for final review and approval.
- 3.1.6 Generating approval documentation.
- 3.1.7 Maintaining records of pertinent documentation and materials related to all protocols.

3.2 IRB Chair Responsibilities:

3.2.1 Making or designating an initial determination of all incoming protocols.
3.2.2 Reviewing and granting final approval of expedited and full board applications.
3.2.3 Consulting the Human Subject Regulations Decision Charts to determine the appropriate review process for the protocol (i.e., Not Human Subjects Research, Exempt, Expedited, or Full Board).
3.2.4 Signing the IRB Memorandum of Determination or Approval.

3.3 IRB Member Responsibilities:
3.3.1 Reviewing proposed research projects that involve human subjects; ensuring that the individuals involved in the project are treated ethically; ensuring that all subjects are provided with substantial information about the study and that they consent to be a subject in the study; and ensuring that all information is handled appropriately.
3.3.2 Expedited Review: The IRB Chair or designee assigns two reviewers to perform an in-depth review of pertinent documentation and materials submitted by the PI and IRB Office.
3.3.3 Full Board Review: The RCA will distribute the protocol and all pertinent materials to the IRB at least seven days prior to the next convened IRB meeting. At the meeting, a majority of board members reviewing the proposal must agree on the board's determination.

4 Procedure

4.1 The PI will submit the protocol to the RCA, along with the following documents:
4.1.1 Training documentation: A Completion Report is required for all investigators with a minimum overall score of 80% for each training course.
4.1.2 Required CITI training courses for PIs and Co-PIs:
- Advanced RCR for PIs and Co-PIs (CITI Course ID: 378204)
- Social & Behavioral Research (CITI Course ID: 120579)
- Other training (as applicable)

4.1.3 Consent documentation (as applicable): consent form and assent form.
4.1.4 Recruitment materials (as applicable): flyers, letters, scripts, e-mail, etc.
4.1.5 Procedural materials: survey, interview, focus group questions, and/or questionnaire.
4.1.6 Agreements, contracts and permissions (as applicable): Referenced in the protocol.
4.1.7 Additional documentation (as applicable): Any other documents referenced in the protocol.
4.1.8 Signature Assurance page (as applicable): signed by each listed investigator who did not sign on the protocol (i.e. additional investigator).

4.2 Administrative Pre-Review
4.2.1 RCA will conduct an initial Administrative pre-review within three business days following the receipt of the initial protocol and all related documents for completeness. If incomplete, the RCA will work with the PI to correct this.
4.2.2 PI will submit a revised version of the protocol addressing all administrative pre-review concerns.
4.3 Expedited Review Determination Process:
4.3.1 Based on the Administrative pre-review the RCA suggests an initial risk assessment based upon the eligibility criteria and description of activities in one or more categories. Expedited review categories are found here.
4.3.2 RCA assigns two reviewers (Primary and Secondary) to perform an in-depth review of pertinent documentation and materials submitted by the PI and IRB Office using the Human Subject Regulations Decisions Charts as a guide.

4.3.3 The reviewers (Primary and Secondary) will complete the review process within 10 business days.
4.3.4 If reviewers determine a protocol does not qualify as an expedited review, the reviewers notify the IRB Chair or designee who will then reevaluate the protocol for the type of review.
4.3.5 If the reviewers determine the expedited review is appropriate and if modifications to the application are required, the reviewers will provide written comments to the IRB Office.
4.3.6 Reviewer's written comments will be sent to the PI for modifications to be completed. Once PI has submitted the modified protocol, the RCA will then forward it to the reviewers.
4.3.7 If the protocol is disapproved, the RCA will send written notification to the PI explaining the disapproval. The PI will have an option to meet with the IRB Chair or designee to discuss the IRB's concerns.
4.3.8 The IRB Chair or designee may request additional review by other member(s) of the IRB with applicable expertise. The additional assigned reviewer provides comments in writing.
4.3.9 After the reviewers deem the application acceptable, the RCA will send the final revised protocol and all pertinent documents to the IRB Chair or designee for final review.
4.3.10 Expedited Review Approval Process
4.3.10.1 After approval by the IRB Chair or designee, the RCA will draft an Expedited Memorandum of Approval and send it to the IRB Chair or designee for review and signature.
4.3.10.2 Once the Expedited Memorandum of Approval is complete, the RCA will send it to the PI with the final stamped protocol and consent form or information sheet, if applicable.
4.3.10.3 Any relative entities, funding agency, or other collaborative institution will be notified of the approval or disapproval (if applicable).

4.4 Full Board Review Determination Process:
4.4.1 If the RCA makes an initial risk assessment that the activity is research with human subjects but does not fall under any of the exemption or expedited categories and determines the research is greater than minimal risk, it is submitted to the IRB Chair or designee for consideration to add to the full board agenda for IRB full board review.
4.4.2 Distribution of IRB Protocol Form
4.4.2.1 Once the Full Board determination has been made by the IRB Chair or designee, the RCA will distribute the protocol and pertinent documents to IRB members for review at least seven business days before the scheduled meeting.
4.4.2.2 The IRB will review the protocol using the Human Subject Regulations Decisions Charts as guide.
4.4.3 Convened Meeting Review of the IRB Protocol Form
4.4.3.1 The IRB Chair or designee will provide a summary of the protocol to the IRB members and lead the discussion regarding any concerns they may have as it pertains to the proposed study.
4.4.3.2 The RCA will take notes of the deliberations and after review by the IRB Chair or designee will send the notes to the PI for modifications, if applicable.
4.4.4 Full Board Review Approval Process:
4.4.4.1 A majority of board members reviewing the protocol must agree on the board's determination by vote.
4.4.4.2 If the protocol is deferred for modifications, the IRB Chair or designee may assign a Primary Reviewer to review the revised protocol or may elect to table the protocol for consideration at a future convened IRB meeting.

4.4.4.3 If the protocol is approved, the RCA will draft a Full Board Memorandum of Approval and send it to the IRB Chair or designee for review and signature.

4.4.4.4 Once the Full Board Memorandum of Approval is approved by the IRB Chair, the RCA will send it to the PI with the final stamped protocol and consent form or information sheet, if applicable.

4.4.4.5 If protocol is denied approval, the RCA will send written notification to the PI explaining the denied approval. The PI will have an opportunity to meet with the IRB Chair or designee to discuss the IRB's concerns.

4.4.4.6 Any relative entities, funding agency, or other collaborative institution will be notified of the approval or disapproval (if applicable).

5 Informed Consent considerations for Expedited and Full Board Review

5.1 Considerations regarding reviewing the informed consent form and the informed consent process for both Expedited and Full Board protocols, include:

5.1.1 Consideration of the required and additional elements of informed consent. IRB Informed Consent training is available for Reviewers and PIs.

5.1.2 Translation of the informed consent form for non-English speaking participants, when applicable.

5.1.3 For HHS-conducted or -supported research, consideration of a waiver or alteration of the consent procedure.

5.1.4 For both HHS-conducted or -supported research and FDA- regulated research, consideration of a waiver of documentation of consent.

5.2 Considering whether the study includes participants that are likely to be vulnerable to coercion or undue influence, and, if so, whether additional safeguards have been included to protect the rights and welfare of these subjects.

5.3 Reviewing studies requesting an exception from informed consent requirements for emergency research.

5.4 For HHS-conducted or -supported research, determining the applicability of additional protections for pregnant women, human fetuses, neonates, and prisoners.

5.5 Reviewing research involving children as subjects in accordance with applicable regulations.

6 SMART IRB Process

6.1 Institutions may choose to rely on another IRB to review, approve, and oversee a research study through SMART IRB as pre-determined by study sponsor, grant or prior arrangement. The Reviewing IRB takes on IRB oversight responsibilities associated with that study throughout its duration.

6.2 Investigators and institutions retain their respective responsibilities for the protection of human subjects, compliance with applicable laws, regulations, ethical standards, and the terms of the institution's Federal wide Assurance.

6.3 SMART IRB Reliance agreements will be processed on a case-by-case basis.

6.4 The Director of Research Compliance (DRC) serves as the POC for A&M- SA IRB.

6.5 The PIs must request the Reliance by submitting a summary of the study or approved protocol to the IRB Office.

6.6 After discussion with IRB Chair the DRC, the designated SMART IRB officer. DRC will initiate the SMART IRB process.

6.7 When the request is received from the external institution the DRC follows up with the external institution for any outstanding compliance issues associated with the study. If all issues are resolved or there are no outstanding compliance issues the DRC will accept Reliance.

6.8 If there are outstanding compliance issues the DRC will present the details to the IRB.
6.9 The external institution will remain the approving IRB for the study.
6.10 The IRB Office will create an internal protocol number/record of the study and maintain all supporting documentation.
6.11 SMART IRB Reliance agreements will be listed and presented on the IRB Agenda for the convened meetings.
6.12 DRC will present a summary of the Reliance agreements and answer questions pertaining to the Reliance process.
6.13 IRB may invite the PI or designee to the convened meeting for further clarification or questions if necessary.

7 Full Board and Expedited Continuing Review Requirements

7.1 Continuing review is required for research that is regulated by the Food & Drug Administration (FDA).
7.2 Per federal regulations outlined in 45 CFR 46.109(e) here, an approved, federally-sponsored human subjects study must be reviewed, at least annually, by the IRB. For this continuing review, the IRB reviews the:
- 7.2.1 Protocol application
- 7.2.2 Informed consent and other documentation or materials; and
- 7.2.3 Any adverse events (AEs) or other reportable events that occurred during the current approval period.

7.3 The IRB may recommend modifications or updates to a study upon continuing review.
7.4 The continuing review process is not used to update an IRB protocol application at the time of renewal. The study team would submit these changes for IRB review via the amendment process.
7.5 Under the revised Common Rule, here, the following no longer requires continuing review:
- 7.5.1 Most of the new protocols (i.e., those approved after January 21, 2019) that qualify for expedited review.
- 7.5.2 Protocols approved prior to January 21, 2019 that have completed subject intervention/interaction, where the activity is limited to either the final analysis of identifiable data/biospecimens or involves accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

7.6 Protocols approved prior to January 21, 2019 that have completed subject intervention/interaction, where the activity is limited to either the final analysis of identifiable data/biospecimens or involves accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. Exceptions are as follows:
- 7.6.1 If the protocol sponsor requires Continuing Review PIs should submit the Continuing Review to the IRB.
- 7.6.2 The project involves additional regulatory oversight, such as conflict of interest (COI) management.
- 7.6.3 The research will be conducted internationally or at non-A&M- SA sites.
- 7.6.4 An amendment or incident report reveals new findings that require additional oversight.
- 7.6.5 The investigator has had previous serious non-compliance or a pattern of non-serious non-compliance.

7.7 The A&M-SA IRB issued approval is three years for Expedited research and requires an annual status report if:
- 7.7.1 Research eligible for Expedited review.
- 7.7.2 Research reviewed by the IRB in accordance with the limited IRB review.

7.7.3 Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study.
7.7.3.1 Data analysis, including analysis of identifiable private information or identifiable biospecimens.
7.7.3.2 Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care;
7.7.4 The A&M-SA IRB may elect on a protocol-specific basis, to apply the 2018 Revised Common Rule to the studies that were approved prior to January 21, 2019.
7.8 The A&M-SA IRB issued approval is three years for Full Board research and requires an annual status report, along with stipulations as determined by the IRB.

8 Amendments

8.1 The PI must submit an amendment if changes to the approved protocol application are intended. No changes to the protocol can be implemented until the amendment is approved.

9 Post-Approval Monitoring

9.1 All approved protocols are subject to post-approval monitoring.
9.2 The PI must submit to the IRB all post-approval reports that meet the submission criteria.

10 Full Board and Expedited Closure Reports

10.1 A closure report is required to be submitted on all approved protocols when:
10.1.1 All collection of data involving interventions and interactions has been completed for all participants. No further contact with participants is necessary; and
10.1.2 All collection of individually identifiable private information has been completed for all study participants. No further collection of data/information from or about the individuals will be obtained; and
10.1.3 All publications, presentations, additions to web sites derived from individually identifiable private information have been completed; and
10.2 PI Closure of protocols include:
10.2.1 Investigators can close a protocol for IRB reviewed research by submitting a study Closure Form to irb@tamusa.edu. This must be submitted 30 days prior to the expiration of the protocol.
10.2.2 Protocols that are transferred to another IRB are closed when the new IRB assumes jurisdiction.
10.2.3 Expedited protocols are retained for a minimum of five (5) years after study completion and Closure Report is submitted to the IRB Office. If other regulations and policies apply to a particular protocol, the protocol is retained in accordance of the applicable record retention requirements (e.g., a minimum of six (6) years for research covered by HIPAA - 45 CFR 164.530).
10.3 Administrative Closure of protocols include:
10.3.1 Approved protocols that pass their designated expiration or “end date” if the investigator fails to renew the protocol following established renewal procedures relevant to the given protocol. The Investigator fails to submit the materials for continuing review within 30 days, then the lapsed study will be classified as administratively closed.
10.3.2 Duplication or submission error.

11 References Documents and Forms

11.1 UCLA. Office of the Human Research Protection Program. Guidance and Procedure: IRB Review Level-Expedited Review. Retrieved November 24, 2020 from: https:// ora.research.ucla.edu/OHRPP/Documents/Policy/4/Expedited.pdf

11.2 The University of Utah. Institutional Review Board. Standard Operating Procedures. SOP 402: Expedited Review. Retrieved November 25, 2020 from: https://irb.utah.edu/resources/documents/pdf/IRB%20SOP%20402%20version%20A2119.pdf

11.3 McLennan Community College, Institutional Review Board. Forms and Guidelines of policies and procedures for research involving human subjects. Retrieved June 3, 2020, from: https://www.mclennan.edu/employees/policy-manual/docs/B-VIII-IRB.pdf

11.4 U.S. Department of Health & Human Services (2021, December 21). Revised Common Rule. HHS.gov. Retrieved February 27, 2023, from https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html#transition-provision

11.5 Smart IRB (n.d.). For IRBs and Institutions. Smart IRB For. Retrieved February 27, 2023, from https://smartirb.org/irbs-and-institutions/

11.6 Available online https://www.tamusa.edu/graduate-studies-research/institutional-review-board/index.html

11.6.1 IRB Protocol Application Form

11.6.2 Human Subject Regulations Decision Charts

12 Revision History

12.1 May 2022, March 2023, July 2023