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

| SOP #: 3 | Version: 1.0 | Effective Date: August 14, 2020 |
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| **Title: Full Board Review** | | |
| **Approved by: Dr. Vijay Golla** | | |

## 1. Purpose

The review of IRB Protocol Application(s) as previously determined by the IRB Chair as requiring Full Board Review.

## 2. Scope

Regulations at 45 CFR 46.108(b) (the Federal Policy (Common Rule) for the Protection of Human Subjects) require that the IRB conduct initial and continuing reviews of all non-exempt research at convened meetings at which a majority of the members are present, unless the research falls in to one or more of the categories appropriate for expedited review. This procedure applies to all convened meetings of any A&M-SA IRB.

## 3. Responsibilities

3.1. *IRB Chair is responsible for:*

3.1.1. Receiving the *IRB Protocol Application Form* from the Research Compliance Coordinator.

3.1.2. 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).

3.1.3. Carrying out procedures.

3.1.4. Reviewing and presenting protocols to the Full Board for discussion.

3.1.5. Call to vote for determinations.

3.1.6. Signing the *IRB Memorandum of Approval*

3.2. *IRB Members are responsible for:*

3.2.1. It is the role of the A&M-SA IRB to review proposed research projects that involve human subjects; ensure that all individuals involved in the project are treated ethically; ensure that all study subjects are provided with substantial information about the study and that they consent to be a subject in the study; and that all private information is handled appropriately with confidentiality.

3.2.2. Reviewing and participating in full board discussions.

3.2.3. Voting on protocols presented to the Full Board unless previous Conflict of Interest (COI) declared.

## 4. Procedure

4.1. Call the meeting to order.

4.2. Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the response.

4.2.1 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting or if present by teleconference, be placed on hold or disconnect for discussion and voting.

4.3. Summarize the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and note previously determined and documented.

4.4. Make a motion for one of the following actions:

4.4.1 Approve: Made when all criteria for approval are met.

4.4.1.1 Include in the motions for initial and continuing review a specific period approval (continuing review interval) when applicable and the level of risk (minimal risk or greater than minimal risk). The period of Approval cannot exceed one year for:

4.4.1.2 FDA Regulated Research

4.4.1.3 Research Subject to the Pre-2018 Common Rule

4.4.1.4 Research where Continuing review is not required in accordance with the 2018 Common Rule but the reviewer has determined otherwise

4.5. Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable.

4.5.1 When making this motion, summarize the IRB's reasons for the decision and describe recommendations that may make the research approvable.

4.6. Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and there are extensive deficiencies or the IRB has no recommendations that might make the protocol approvable.

4.6.1 When making this motion, summarize the IRB's reasons for the decision and recommendations, if any.

4.7. Suspension: Based on new information the previously approved research no longer meets the criteria for approval, but some research activities may meet the criteria for

approval or the IRB has recommendations that may make the research meet the criteria for approval.

4.7.1 Include in the motion: Which research activities must stop or be modified.

4.7.2 If the research in its entirely no longer meets the regulatory criteria for approval, include in the motion: Stop all research procedures (except as noted below) and stop enrollment.

4.7.3 If stopping enrollment will adversely affect the best interest of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed.

4.7.4 Lead the IRB members through a discussion to consider what additional actions are needed, if any.

4.8. Termination: Based upon new information the previously approved research no longer meets the criteria for approval and the IRB has no recommendation to make the research approvable.

4.9. Open the floor for additional discussion.

4.10 Ensure the IRB staff is taking minutes has recorded the IRB's actions, required modifications, reasons, recommendations, determinations and findings.

4.11Call for a vote.

4.11.1 Only IRB members may vote.

4.11.2 If a member and an alternate are both present, only one may vote.

4.11.3 Consultants may not vote.

4.11.4 For motion to be approved, it needs the approval of more than half of members present at the meeting.

4.11.5 Record the vote by electronic polling when available or by voice or show of hands.

4.12Re-invite IRB members with a Conflicting Interest back into the meeting.

4.13Provide any written information provided by a member or consultant to the IRB staff. Adjourn the meeting when there is no further business or when notified by the IRB staff that quorum has been lost and cannot be restored.

**5. Administrative Hold and Suspension and Termination of Research**

*5.1 Administrative Hold*

5.1.1 Principal Investigators may initiate an administrative hold either at the request of the leadership of a multi-center study or on their own initiative.

5.1.2 The investigator must report the administrative hold to the IRB, along with the rationale for the hold and the corrective action plan, as applicable. If the hold is related to a deficiency or circumstance that otherwise requires reporting by regulatory agencies, this information must also be included with the administrative hold notification.

5.1.3 In order to reactivate the research, including subject recruitment and enrollment, the Principal Investigator must submit an amendment to the IRB. The amendment must explain and outline the resolution of the study-wide or site-specific issue that resulted in the administrative hold.

*5.2 University Directed Hold*

5.2.1 Initiated by IO after direction of System Officials.

5.2.2 PI must complete a research update form:

- Stating that the research has been suspended.
- List types of interactions with participants.
- Notify The Office of Research and Graduate Studies if there are any changes.

## 6. Reference Documents and Forms

6.1 Available online https://www.tamusa.edu/graduate-studies-research/institutionareview-board/index.html

6.2 IRB Protocol Application Form

6.3 Human Subject Regulations Decision Charts Available here

**Revision History**

Revised Version 06.17.20 JF

**References**

Texas A&M University. Institutional Review Board. Standard Operating Procedures. SOP: IRB Meeting Conduct-Committee Review. Retrieved August 4, 2020 from: https://rcb.tamu.edu/humansubjects/forms/standard-operating-procedures-sops

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