TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Investigations, Suspension/Termination by the Institution**	
	Section IV: Post-Approval Monitoring and Non-Compliance	
	Number	Date
	IRB IV-007	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process for conducting investigations of noncompliance when the investigation is not conducted by the Post-Approval Monitoring (PAM) program.

1.2. This SOP outlines the process by which an individual or entity other than the convened IRB to initiate a suspension or termination of IRB Approval.

1.3. The individual or entity initiating a suspension or termination of IRB Approval may withdraw approval for some or all research procedures.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. This SOP applies to faculty, staff, students, residents, and affiliated investigators or other affiliated individuals who are involved in human subjects research being conducted under the auspices of Texas A&M University—Kingsville (TAMUK), regardless of the location of the research.

3.2. The IRB Chair may institute a Suspension of IRB Approval when, in the opinion of the IRB Chair (or designee), subjects may be at risk of adverse effects on their rights and welfare prior to consideration of this issue by the convened IRB. The risk of adverse effects may be due to Non-Compliance with institutional or other regulatory requirements or an Unanticipated Problem Involving Risks to Participants or Others.

3.3. The Institutional Official or designee may institute a Suspension of IRB Approval or Termination of IRB Approval.

3.4. Whenever possible, the individual following these procedures communicates with investigators orally and in writing.

3.5. Administrative Hold:

3.5.1. An “administrative hold” is a voluntary pause of participant enrollments and ongoing research activities, initiated by the research investigator or sponsor. This type of hold may be initiated due to various reasons, including changes in research staffing or funding, concerns about participant welfare even in the absence of any adverse event, or intent to modify the study protocol, etc.

3.5.2. An administrative hold cannot be used to extend IRB approval beyond the expiration date of a protocol without approval of a continuing review.

3.5.3. The term “administrative hold” does not apply to interruptions of research related to concerns regarding the safety, rights, or welfare of human research subjects, research investigators, research staff, or others.

3.5.4. An “administrative hold” cannot be used to avoid reporting deficiencies or circumstances otherwise covered by institutional policies or other regulatory requirements governing research.

3.5.5. An Administrative Hold directed by the IRB is a suspension and must be classified and reported as such.

4. RESPONSIBILITIES

4.1. Investigations:

4.1.1. The IRB Chair or designee:

4.1.1.1. Appoints the members of the investigative committee based on the expertise and background needed to answer the question.

4.1.1.2. Appoints a chair of the investigative committee.

4.1.1.3. Charges the investigative committee with the question to be answered.

4.1.2. The Investigative committee:

4.1.2.1. Carries out these procedures within 60 days or as otherwise stipulated.

4.1.2.2. Make decisions based on a preponderance of the evidence.

4.1.2.3. Use majority vote to finalize committee decisions.

4.2. Suspensions/Termination by the Institution:

4.2.1. The individual instituting a Suspension or Termination of IRB Approval or Termination follows these procedures.

5. PROCEDURE

5.1. Suspensions/Termination by the Institution:

5.1.1. Notify the investigator in writing of the Suspension or Termination of IRB Approval including justification for the decision.

5.2. Ask the investigator for a list of Human Subjects currently involved in the research.

5.3. Ask the investigator whether any actions are required to protect those subjects' rights and welfare or to eliminate an apparent immediate hazard.

5.3.1. Consider whether any of the following additional actions are required to protect those or other subjects' rights and welfare or to eliminate an apparent immediate hazard:

5.3.1.1. Transferring subjects to another investigator.

5.3.1.2. Making arrangements for clinical care outside the research.

5.3.1.3. Allowing continuation of some research activities under the supervision of an independent monitor.

5.3.1.4. Requiring or permitting follow-up of subjects for safety reasons.

5.3.1.5. Requiring adverse events or outcomes to be reported to the IRB and the sponsor.

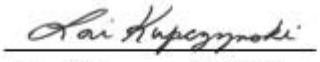
5.3.1.6. Notification to current and former human subjects.

5.4. Forward the matter to the research compliance staff assigned to the IRB for inclusion on the agenda of the next convened IRB meeting, under Suspension or Termination of IRB Approval.

6. REFERENCES

6.1. 21 CFR §56.108(b)(3), 21 CFR §56.113

6.2. 45 CFR §46.103(b), 45 CFR §46.108(a), 45 CFR §46.113

Approved by: 

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