TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Post-Review**	
	Section IV: Post-Approval Monitoring and Non-Compliance	
	Number	Date
	IRB IV-002	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process for communicating the IRB's determinations and actions.

1.2. The process begins when the IRB has completed a review.

1.3. The process concludes when communications related to the IRB determinations and actions have been sent and additional tasks have been completed.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. The IRB reports its findings and actions to the Principal Investigator (PI). Communication of review results to PIs is to be completed within five (5) business days of the IRB meeting.

3.2. When the IRB disapproves research, it provides the PI with a statement outlining the reasons for the decision and offers the PI an opportunity to respond either in person or in writing.

3.3. Appeal of IRB Decisions

3.3.1. If an investigator disagrees with the IRB's decision, the investigator may submit a written appeal to the IRB Chair or research compliance staff assigned to the IRB within 30 days of decision notification.

3.3.1.1. The appeal should include documentation or evidence supporting the grounds for their disagreement.

3.3.1.2. For appeals involving research conducted by designated review, the appeal is reviewed by the designated reviewer, and IRB Chair.

3.3.1.3. For appeals involving research reviewed by the convened board, the appeal is reviewed by the convened board.

3.3.1.3.1. The PI may request to address the board directly at the scheduled IRB meeting to provide clarification or additional information to the IRB.

3.3.1.4. The PI is given written notification of the decision following the review of the appeal.

3.4. The IRB reports its findings and actions to the institution, as required. The IRB may also report its findings and actions to external entities, such as to research sponsors, in accordance with mandatory reporting requirements.

3.5. Reporting of Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Closure of IRB Approval, and Unanticipated Problem Involving Risks to Subjects or

Others to external agencies must take place within 30 days from the recognition of a reportable event.

4. RESPONSIBILITIES

4.1. The research compliance staff assigned to the IRB carries out post-review administrative procedures. The IRB Chair facilitates any appeal process.

4.2. The research compliance staff assigned to the IRB will communicate the results of the IRBs decisions, including approval determinations. The correspondence is considered to have been signed under the authority of the IRB chair or designee.

5. PROCEDURE

5.1. Calculate the approval period for initial or continuing review of research. Refer to TAMUK SOP: Approved Review and End Dates (IRB SOP III-005).

5.1.1. Verify the calculated dates entered into Cayuse electronic system and approval letters.

5.1.2. Generate the outcome letter using the appropriate template and modify the letter as needed.

5.1.3. Send the outcome letter when complete.

5.1.4. Retain documentation of the outcome following TAMUS records retention policies.

6. REFERENCES

6.1. 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66.

6.2. 45 CFR §46.103(b)(4)(i), 45 CFR §46.207, 45 CFR §46.306(2)(C), 45 CFR §46.306(2)(D), 45 CFR §46.407.

6.3. DoD Directive 3216.02

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