TEXAS A&M UNIVERSITY KINGSVILLE	SOP: Monitoring for Study Closure	
	Section III: IRB Protocols	
	Number	Date
	IRB III-010	9/13/2025

1. PURPOSE

1.1. This SOP describes the process by which a study closure is submitted to and reviewed by the IRB.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. A final project report is submitted by the Investigator

3.2. When an investigator concludes a study such that it no longer constitutes human research requiring oversight by the IRB, a final project report is submitted to notify the IRB of the completion/termination of the project, providing information to the IRB regarding the final status of the project and ensuring appropriate study file closure by the IRB.

4. RESPONSIBILITIES

4.1. The Principal Investigator or designee is responsible for submitting the final project report. The research compliance staff assigned to the IRB is responsible for processing the final project report, and the IRB is responsible for issuing a determination on the closure of the study.

5. PROCEDURE

5.1. A final report/study closure form should be submitted within 30 days after study completion.

5.2. The criteria for when a study is eligible for closure by the IRB are as follows:

5.2.1. All research participants have completed all study-related interventions and procedures, including any follow-up;

5.2.2. The research team has obtained all private identifiable data and/or specimens from all participants (who have not dropped out of the study or been dismissed for any reason) or from data/specimen sources when the study involves secondary analysis of data/specimens;

5.2.3. The research team has completed the analysis of all private identifiable data and specimens, as described in the IRB application.

5.3. A study should be closed as long as identifiable private data or identifiable specimens are not being obtained, used, or analyzed.

5.3.1. When the analysis of identifiable data/specimens is complete and the only remaining activities are the write-up of results and storage of the data/specimens, the study should be closed even if the research team retains identifiers or a key linking identifiers to coded data/specimens.

5.4. The IRB chair will review the final project reports and, if needed, request further information from the investigator to clarify any questions that may arise.

5.5. Once the IRB Chair has determined that sufficient information is provided, the investigator will receive acknowledgement of the final project report and closure of the study.

5.6. Expiration and lapse in approval:

5.6.1. If a study expired and an application for continuing review or a final project report has not been submitted, this is considered a lapse in approval and is addressed per TAMUK SOP: Expiration of IRB Approval (IRB SOP III-006).

6. REFERENCES

6.1. None

Approved by: Lori Kupczynski

Lori Kupczynski, EdD
Special Assistant to the Vice President,
Office of Research and Innovation

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