TEXAS A&M UNIVERSITY KINGSVILLE	SOP: Expiration of IRB Approval	
	Section III: IRB Protocols	
	Number	Date
	IRB III-006	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process for determining whether current subjects may continue in expired research. Expired research is any expedited or convened protocol that has not gone through the renewal process as described in TAMUK SOP: Approval Review and End Dates (IRB SOP III-005).

1.2. This process should only be used in rare cases. Per TAMUK SOP: Approval Review and End Dates (IRB SOP III-005), PIs are notified 31 calendar days prior to expiration of need for renewal. This process only applies to research involving longitudinal studies, or treatment studies as described in 5.3.2 below.

1.3. The process begins when an investigator submits a request to an IRB Chair or designee for current subjects to continue in expired research. In cases where the PI requests a renewal prior to the protocol's expiration date but the convened review cannot be completed prior to that expiration date, the procedure outlined in this SOP will be followed. Once the expiration date is reached, the protocol will be considered expired.

1.4. The process concludes when the research compliance staff assigned to the IRB has formally communicated and documented the final decision in writing to the PI.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. If research approval expires before continuing IRB approval is obtained, these procedures are to be followed.

3.2. If research is granted "Modifications Required to Secure Approval" status and expires before responsive materials are reviewed and approved, these procedures are to be followed.

4. RESPONSIBILITIES

4.1. The Investigator, IRB Chair, and IRB members sufficient to meet quorum are responsible for carrying out these procedures.

5. PROCEDURE

5.1. The investigator provides the research compliance staff assigned to the IRB a request explaining why subjects need to continue in the expired research and what procedures are being requested to continue.

5.2. New subjects are not to be enrolled under any circumstances.

5.3. Information is forwarded to the IRB Chair or designee to determine which subjects can continue in the research based on the following principles:

5.3.1. In general, research procedures should be discontinued when this can be done safely.

5.3.2. In general, the only research procedures that should continue are those where the research treatments are not available outside of the research context. If the required procedures can be provided as standard of care treatment, these should be provided as such.

5.3.3. In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.

5.3.4. In some cases, an ethical issue may arise where the above general principles cannot be followed.

5.3.5. No data are to be collected during the period of time that the protocol is expired. If any data are or have been collected, that data are to be given to the IRB and destroyed.

5.4. The research compliance staff assigned to the IRB will send correspondence to the Principal Investigator about the continuation of subjects in expired research.

5.4.1. This will include that the continuing review progress report must be submitted as soon as possible.

5.5. A copy of the determination is placed in the study records within the Cayuse electronic system.

5.6. Any protocol going through this procedure where data has been collected after expiration of IRB approval will be reported to TAMUS as a non-compliance incident.

6. REFERENCES

6.1. 21 CFR §56.108(a) and 56.109(f).

6.2. 45 CFR §46.109(e).

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