TEXAS A&M UNIVERSITY KINGSVILLE	SOP: Management of Multi-Site Studies	
	Section III: IRB Protocols	
	Number	Effective Date
	IRB III-011	9/13/2025

1. PURPOSE

1.1. This document outlines the management of multi-site research study information and communications, specifically when TAMUK serves as the coordinating institution for a research study. It also details the role of the TAMUK Institutional Review Board (IRB) in overseeing multi-site research, including when serving as a Single IRB (sIRB) for external sites.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. When TAMUK is the coordinating institution for a multi-site research study, the TAMUK IRB is responsible for conducting the review, approval, and ongoing monitoring of all study-related documents and communications. This includes, but is not limited to, reportable events, protocol modifications, consent documents, and continuing review reports, in compliance with the sIRB process for studies involving human subjects.

3.2. The lead TAMUK Principal Investigator (PI) serves as the central point of contact and is responsible for disseminating all relevant multi-site research study information to all participating sites. This includes ensuring that external sites engaged in the research comply with the sIRB's approval process and that they adhere to TAMUK's IRB requirements.

3.3. When TAMUK is the coordinating institution, the TAMUK IRB will serve as the sIRB for participating sites. In instances where TAMUK does not serve as the sIRB, TAMUK will identify the sIRB.

4. RESPONSIBILITIES

4.1. The lead TAMUK investigator or designee and the Institution's IRB carry out these procedures.

5. PROCEDURE

5.1. Lead Principal Investigator Responsibilities

5.1.1. The lead TAMUK Principal Investigator is responsible for submitting an electronic IRB application in the Cayuse electronic system and providing the following information to the IRB, following the instructions in the software application:

5.1.1.1. A list of all participating sites/locations involved in the research study.

5.1.1.2. Contact information (names, emails, physical addresses) for all sites/locations participating in the research.

5.1.1.3. A plan for reviewing each external site's IRB approval correspondence and approved consent documents. This includes confirmation of the type of review and any approval conditions for each site.

5.1.1.4. A method to ensure no participating site begins the research (including recruitment activities) until IRB approval is granted.

5.1.1.5. A plan to ensure that all sites have the most current version of the study protocol.

5.1.1.6. A process for sharing protocol amendments with all participating sites.

5.1.1.7. A process to ensure that all sites receive relevant study communications, including adverse events, unanticipated problems, and interim results.

5.1.1.8. A plan for the collection and management of data from all participating sites.

5.1.1.9. A centralized system for the collection and reporting of reportable events from all sites, to the sIRB.

5.1.1.10. If an external site is relying on the TAMUK IRB, the lead PI is responsible for coordinating with the TAMUK IRB Chair (or designee) to initiate a TAMUK IRB Authorization Agreement. The completion and execution of the agreement then fall under TAMUK IRB responsibilities.

5.1.2. IRB Submissions (e.g., modifications, continuing review reports, reportable events, etc.):

5.1.2.1. If the TAMUK IRB application is the mechanism for the initial and continuing review of any external relying organization. The lead TAMUK PI is responsible for gathering and submitting relevant reports from all participating sites.

5.1.2.2. If an external site's IRB application is the mechanism for review, the external site's PI must submit the necessary documentation to TAMUK IRB, as the coordinating institution and sIRB.

5.2. TAMUK IRB Responsibilities

5.2.1. When TAMUK is the coordinating institution and acting as the sIRB, the TAMUK IRB will:

5.2.1.1. Conduct the initial review of the research study and all documentation related to the protection of human subjects.

5.2.1.2. For federally regulated or funded studies, confirm that each participating site holds a Federalwide Assurance (FWA) with the Office of Human Research Protections (OHRP).

5.2.1.3. Confirm that Registration of the study on ClinicalTrials.gov has been completed, when applicable.

5.2.1.4. Complete and execute an Authorization Agreement (continued from 5.1.1.10)

5.2.1.4.1. The Authorization Agreement will define the roles and responsibilities of TAMUK IRB and the relying site, clarifying that TAMUK is acting as the sIRB.

5.2.1.4.2. The external site will update its FWA to reflect its reliance on the TAMUK IRB, in accordance with OHRP guidance.

5.2.1.4.3. Both the external site and the TAMUK IRB will maintain the fully executed original documentation of the agreement, if required.

5.2.1.4.4. The external site must submit the IRB Authorization Agreement to the TAMUK IRB prior to any review of the study protocol by an IRB.

5.2.1.4.5. The external site is also required to submit a Local Context Worksheet to the TAMUK IRB after approval. This worksheet will provide context-specific information to ensure that the study's procedures comply with local regulations, policies, and conditions at the external site.

5.2.1.5. Review and approve all subsequent modifications to the research protocol, continuing review reports, and any reportable events from all participating sites, as required by the sIRB process.

5.2.1.6. Ensure that the research complies with all applicable regulations and standards for human subjects research, including maintaining oversight of all participating sites' adherence to approved protocols.

5.2.1.7. Ensure that each relying site submits the IRB Authorization Agreement and the Local Context Worksheet to TAMUK IRB after obtaining study approval, to ensure compliance with both local and institutional regulations.

6. REFERENCES

6.1. 45 CFR §46.103

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