	SOP: Reliance on External IRB	
	Section III: IRB Protocols	
	Number	Effective Date
	IRB III-012	9/13/2025

1. PURPOSE

1.1. This SOP describes how TAMUK may use an external IRB for human research.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. The Institution may rely on an external IRB to serve as the IRB of Record for certain TAMUK research protocols.

3.1.1. TAMUK may rely upon the IRB of another institution when faculty are doing a study that originates at another institution, for example, faculty working on their dissertation with another university. That institution would, therefore, be the reviewing IRB or IRB of Record.

3.1.1.1. However, if the study originates from TAMUK and the use of an external IRB is requested, the request will not be approved unless an exception is granted by the TAMUK IRB. Exceptions are typically made when a commercial IRB is required.

3.1.2. The TAMUK IRB Chair reserves the right to determine on an individual study basis whether to accept an External IRB review, including determining whether the external IRB meets specific criteria for the review of human subjects research and has a FWA and IRB registration with OHRP.

3.2. Authorization Agreement:

3.2.1. An authorization agreement, initiated by the External IRB is used to document the agreement of both parties and is required to delineate the roles and specific responsibilities of each party.

3.2.2. The authorization agreement is kept in the IRB administrative files per record retention requirements.

4. RESPONSIBILITIES

4.1. The Institution's investigators in conjunction with the IRB Office and IRB Chair are responsible for carrying out these procedures.

5. PROCEDURE

5.1. Document the Reliance on an External IRB of Record

5.1.1. The Principal Investigator is responsible for documenting the intent to rely on an External IRB and confirmation that the named IRB will serve as the IRB of Record for a protocol that would otherwise be designated TAMUK research by completing the following:

5.1.1.1. Notifying the research compliance staff assigned to the IRB about the External IRB and provide the following:

5.1.1.2. Notification to the research compliance staff assigned to the IRB regarding the external IRB and attaching the following documentation:

5.1.1.2.1. Protocol specific materials

5.1.1.2.2. Supporting documentation

5.1.1.2.3. All correspondence

5.1.1.2.4. Completed IAA form

5.1.1.2.5. Approval letter from External IRB

5.1.1.3. Once all documentation is provided, the research compliance staff assigned to the IRB will forward the information to the IRB Chair for review and approval of the reliance agreement. The approval or disapproval will documented within the Cayuse electronic system.

5.2. IRB Chair Responsibilities:

5.2.1. The IRB Chair assesses whether an external IRB is qualified to serve as the IRB of Record for a TAMUK human subject research project by verifying the following:

5.2.1.1. The institution maintains an active Federalwide Assurance (FWA) on file with the Federal Office for Human Research Protection (non-commercial IRBs), by checking the OHRP database.

5.2.1.2. The IRB is registered with OHRP, by checking the OHRP database.

5.2.1.3. The external IRB has an adequate process in place to receive notifications from the PI and/or TAMUK IRB and notify the TAMUK IRB and researcher(s) of its approvals, determinations, reportable events, suspensions, and terminations.

5.2.1.4. The external IRB can fulfill its responsibilities as outlined in the written authorization agreement.

5.2.1.5. If it is determined that the external IRB is not qualified to serve as the IRB of Record, the researcher(s) will need to complete an IRB application with TAMUK.

5.2.2. If it is determined that the external IRB will be relied upon as the IRB of Record for a specific study, TAMUK will sign the external IRB’s written authorization agreement for that study.

5.2.3. The following information should be included in the written agreement or separately documented by TAMUK IRB Office:

5.2.3.1. The IRB's Federalwide Assurance (FWA) number

5.2.3.2. The contact information for the external IRB's Institutional Official (name, address, telephone number, e-mail address)

5.2.3.3. The contact information for the external IRB's Administrator and/or designated point of contact (name, title, telephone number, e-mail address)

5.3. TAMUK Investigator Responsibilities:

5.3.1. Comply with the external IRB's requirements/directives per the Authorization Agreement and local institutional requirements.

5.3.2. Must not enroll individuals in any research protocol prior to the following:

5.3.2.1. Review and approval by the external IRB, and

5.3.2.2. Verification of local review requirements and written confirmation of the external IRB approval from the TAMUK IRB.

5.3.3. TAMUK investigators are responsible for adhering to the protocol as approved by the external IRB and all applicable TAMUK policies and procedures, including appropriate COI disclosures and the reporting of any reportable events to TAMUK.

5.3.4. Document request for reliance on the External IRB through the research compliance staff assigned to the IRB.

5.3.4.1. The investigator agrees not to proceed with any study-related activities until the TAMUK IRB has evaluated and given written confirmation of the reliance on the External IRB.

5.3.4.2. Document any updates, continuing reviews, and modifications to the research approved by the external IRB, including the following reportable new information:

5.3.4.2.1. New risks and unanticipated problems

5.3.4.2.2. Harm experienced by a subject

5.3.4.2.3. Non-compliance, audits by external agencies

5.3.4.2.4. Monitoring reports, protocol deviations

5.3.4.2.5. Breach of confidentiality

5.3.4.2.6. Un-reviewed changes taken to eliminate apparent immediate harm to a subject

5.3.4.2.7. Incarceration of a subject

5.3.4.2.8. Unresolved subject complaint

5.4. External IRB Responsibilities include, but are not limited to:

5.4.1. Conduct review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modifications to previously approved research.

5.4.2. Conduct review of potential unanticipated problems, adverse events, and/or serious or continuing non-compliance.

5.4.3. Provide notification to research staff associated with the IRB and relying institution in writing of its determinations and decisions. Make available relevant IRB minutes, IRB membership rosters, and standard operating procedures to the relying institution upon request.

5.4.4. When appropriate, and as indicated in the written authorization agreement, conduct on-site or remote post-approval monitoring or audits.

5.4.5. Maintain an IRB membership that satisfies the requirements of 45 CFR 46.107 and 21 CFR 56.107 and which provides specialized expertise as needed to adequately assess all aspects of each study.

5.4.6. Promptly notify the TAMUK Institutional Official or designee if there is a suspension or termination of the external IRB's authorization to review a study.

5.4.7. Provide the TAMUK research compliance staff assigned to the IRB, the contact person and contact information for the reviewing IRB.

5.4.8. Maintain appropriate documentation per record retention policies, including an OHRP-approved Federalwide Assurance (non-commercial IRBs) for human subjects research.

5.4.9. Notify the research compliance staff assigned to the IRB of any changes to external IRB's FWA.

6. REFERENCES

6.1. None

Approved by: Lori Kupczynski

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