TEXAS A&M UNIVERSITY KINGSVILLE	SOP: IRB Formation Update and Deactivation	
	Section II: IRB Members and Meetings	
	Number	Effective Date
	IRB II-001	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process to form a new IRB, update the OHRP IRB registration of an existing IRB, and deactivate an IRB.

1.2. The process begins when the IRB Chair or designee determines the need for a new IRB or updated OHRP IRB registration.

1.3. The process concludes when the IRB is registered, the Federal wide Assurance (FWA) is updated (if needed), and all members have completed training or new IRB member orientation (if needed).

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. STATEMENT

3.1. Internal IRB rosters are maintained within the IRB share drive and the Cayuse electronic system.

3.2. IRB registrations on file with OHRP will be made or updated as follows:

3.2.1. Register with OHRP any additional IRB before it is designated under an FWA and reviews HHS-supported research.

3.2.2. Notify OHRP of any changes to the IRB contact person or chairperson within 90 days.

3.2.3. Update OHRP within 30 days if an FDA regulated IRB adds or stops reviewing any type of FDA-regulated product.

4. RESPONSIBILITIES

4.1. Research compliance staff assigned to the IRB carries out these procedures.

4.2. The Institutional Official or designee appoints IRB members and alternate members.

5. PROCEDURE

5.1. Determine from the IRB Chair or designee whether the IRB will conduct all reviews without limitation or will be limited to certain types of reviews. Indicate this on the IRB roster.

5.2. For new IRBs:

5.2.1. Select:

5.2.1.1. At least five individuals to serve as IRB members.

5.2.1.2. One member whose primary concerns are in nonscientific areas, and one member who is not part of the immediate family of a person who is affiliated with the institution.

5.2.1.3. Additional individuals to serve as alternate IRB members, if needed.

5.2.1.4. At least one of the individuals to be the IRB chair.

5.2.1.5. A Vice Chair may be appointed to support the role of the IRB chair.

5.2.2. Follow TAMUK SOP: IRB Membership (IRB SOP II-002) for each IRB member.

5.2.3. Notify the IRB Chair when all individuals have completed training.

5.2.4. Create the new committee in the Cayuse electronic system.

5.2.5. Once training is completed, add committee members to the Cayuse electronic system

5.3. Register the new IRB, or update an existing IRB's OHRP registration by following the instructions available at the OHRP website at https://ohrp.cit.nih.gov/efile/.

5.4. For use of external IRBs see TAMUK SOP: Reliance on External IRB (IRB III-014).

5.5. IRB Deactivation:

5.5.1. Notify each IRB member who will no longer serve as an IRB member. Prepare and send a letter signed by the Institutional Official or designee.

5.5.2. Unregister the IRB with OHRP[1].

5.5.3. Remove the IRB from the Federalwide assurance (FWA).

5.5.4. Update the IRB roster to indicate the IRB is deactivated.

5.5.5. Remove each individual's role as an IRB Reviewer in the Cayuse electronic system.

5.5.6. File:

5.5.6.1. IRB Roster

5.5.6.2. Federalwide assurance (FWA)

5.5.6.3. IRB Member Notification Letter

6. REFERENCES

6.1. 21 CFR §56.107, 21 CFR §56.115(a)(5).

6.2. 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).

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