TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Cayuse Electronic System**	
	Section I: Administrative Management	
	Number	Effective Date
	IRB I-007	9/13/2025

1. **PURPOSE**

1.1. The purpose of this Standard Operating Procedure (SOP) is outline the process for using the Cayuse electronic system, the online platform for managing Institutional Review Board (IRB) submissions and tracking, to ensure compliance with institutional, federal, and ethical guidelines in the review and approval of human subjects research.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. STATEMENT

3.1. This SOP applies to all faculty, staff, and researchers submitting research protocols for IRB review using the Cayuse electronic system at Texas A&M University-Kingsville. It includes guidance for creating, submitting, reviewing, and managing protocols, amendments, determinations of human subjects research, adverse events and all other documents in the Cayuse electronic system.

4. RESPONSIBILITIES

4.1. Principal Investigators (PIs) are responsible for initiating and completing the Cayuse electronic system submission process, ensuring all required documents are uploaded, and responding to IRB feedback.

4.1.1. The Cayuse electronic system will close all in-progress protocols and other submissions after 60 days of inactivity by the researcher(s).

4.2. IRB members review submissions for ethical and regulatory compliance and provide feedback within Cayuse electronic system.

4.3. Research compliance staff assigned to the IRB is responsible for managing the Cayuse electronic system, assisting researchers with submissions, and ensuring timely and accurate submission tracking.

4.4. The IRB Chair oversees the review process and facilitates communication between the IRB and researchers.

5. PROCEDURE

5.1. System Access and Training

5.1.1. All personnel involved in IRB submissions and reviews must complete appropriate training on the Cayuse electronic system, which is provided by the IRB office or designated personnel.

5.1.2. Access to the Cayuse electronic system is granted based on the user's role. For example, researchers submitting protocols are granted one type of access whereas IRB members reviewing submissions have another. For all access types, users must complete training and be registered within the Cayuse electronic system before performing Cayuse functions.

5.2. Submission Process

5.2.1. Creating a New Submission

5.2.1.1. Researchers (PIs and co-investigators) should log in to the Cayuse electronic system using their institutional credentials.

5.2.1.2. Once logged in, they should navigate to the Human Ethics and select “Create New Protocol.”

5.2.1.3. Fill out the required protocol forms, including project details, study design, participant information, informed consent procedures, and any other relevant documents.

5.2.1.4. Attach necessary documents such as the study protocol, consent forms, recruitment materials, and other related documents.

5.2.1.5. Once all sections are complete, submit the protocol to the IRB for initial review. An automatic notification is sent to the research compliance staff assigned to the IRB for tracking purposes.

5.2.2. Modifications and Updates

5.2.2.1. If any modifications to the protocol are required by the IRB, the PI will receive feedback through the Cayuse electronic system. The PI must address all comments and upload any revised documents before resubmitting the protocol.

5.2.2.2. All amendments, renewals, or adverse events must be reported via the Cayuse electronic system, and the system will notify the PI and the IRB once these actions are taken.

5.3. Review Process

5.3.1. Initial Review

5.3.1.1. The research compliance staff assigned to the IRB will complete a pre-review to verify completeness, confirm that the protocol adheres to federal, state, and institutional regulations, such as those from the Department of Health and Human Services (HHS), Food and Drug Administration (FDA), and other relevant agencies, and assess the risk level.

5.3.1.2. The research compliance staff assigned to the IRB will assign the submission to the appropriate IRB member(s) for review based on expertise and availability.

5.3.1.3. Each IRB member will assess the submission for compliance with ethical and regulatory guidelines (e.g., informed consent, risks to participants, data privacy).

5.3.1.4. The PI will receive feedback and may be asked to provide revisions or clarifications via the Cayuse electronic system within five business days after the IRB meeting or within 10 business days of submission for exempt and expedited protocols.

5.3.2. Continuing Review

5.3.2.1. Researchers must submit a continuing review protocol via the Cayuse electronic system before the expiration date of their approved study. Refer to TAMUK SOP: Daily or Routine Tasks (IRB SOP 1-004).

5.3.2.2. The IRB will review the progress of the study and the ongoing risk to participants to ensure the study remains compliant with IRB approval.

5.3.3. Final Approval

5.3.3.1. Once the IRB has reviewed and approved the protocol, a final approval notification will be sent to the PI through the Cayuse electronic system.

5.3.3.2. The approval will include an expiration date for the protocol, after which the study will need to be renewed if necessary.

5.4. Reporting and Documentation

5.4.1. All adverse events and unanticipated problems should be reported via the Cayuse electronic system per the requirements noted in TAMUK SOP: Unanticipated Problems and Adverse Event Reporting (IRB SOP IV-005).

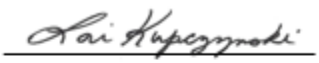
5.4.2. All IRB submissions, approvals, and related documents must be retained within the Cayuse electronic system for a minimum of five (5) years from the date of study completion or final closure noted in TAMUK SOP: Record Retention and Record Management (IRB SOP I-005).

5.5. Communication: Communication regarding submissions, modifications, and IRB decisions will be conducted through the Cayuse electronic system. Researchers should ensure they regularly check their Cayuse account for notifications and updates.

5.6. Troubleshooting and Support—for all technical issues or user support, contact the Research Compliance office at Texas A&M University-Kingsville at tamuk.irb@tamuk.edu or researchcompliance@tamuk.edu

6. REFERENCES

None

Approved by: 

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