TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Record Retention and Record Management**	
	Section I: Administrative Management	
	Number	Effective Date
	IRB I-005	9/13/2025

1. PURPOSE

1.1. This policy describes the requirements for IRB record retention and record management.

1.2. The process begins when records are received or created.

1.3. The process concludes when records have been filed or when records that no longer need to be retained are destroyed.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. The IRB Office must maintain records that contain a complete history of all IRB actions related to the review and approval of any protocol, including initial application, continuing reviews, modifications, reportable new information submissions, compliance-related concerns and inquires, and other administrative actions.

3.2. IRB membership records must be updated per the requirements of FWA and IORG information.

3.3. Study files are to be retained as long as required by law or as stated in the clinical trial agreement but no less than 3 years after completion of the research.

3.4. Protocols in which there was no subject enrollment or no research was conducted are to be retained the same as protocols where research was conducted.

3.5. All records for research conducted or funded by a Common Rule department or agency are to be accessible for inspection and replication by authorized representatives of that agency at reasonable times and in a reasonable manner.

3.6. The following documents are retained indefinitely:

3.6.1. IRB meeting minutes.

3.6.2. Current and previous versions of IRB member rosters.

3.7. All records for research subject to FDA regulations are to be accessible for inspection and replication by authorized representatives of FDA at reasonable times and in a reasonable manner.

4. RESPONSIBILITIES

4.1. The research compliance staff assigned to the IRB is responsible for carrying out these procedures.

5. PROCEDURE

5.1. IRB records are to include:

5.1.1. Electronic study files in the Cayuse electronic system.

5.1.2. Minutes of IRB meetings.

5.1.3. Copies of all relevant correspondence between IRB and the investigators.

5.1.4. Current and previous IRB member rosters.

5.1.5. Current and previous IRB member files.

5.1.6. Current and previous policies and procedures.

5.1.7. Reliance Agreements documenting the specific responsibilities that the IRB of record and the relying IRB will undertake to ensure compliance for federally supported research subject to the 2018-Requirements.

5.2. Protocol files are to include, as applicable:

5.2.1. All submitted materials.

5.2.2. Protocols or research plans.

5.2.3. Investigator brochures.

5.2.4. Scientific evaluations, when provided by an entity other than the IRB.

5.2.5. Recruitment materials.

5.2.6. Consent documents.

5.2.7. HHS-approved sample consent document and protocol, when they exist.

5.2.8. Any relevant Conflict of Interest (COI) documentation, such as management plans related to the protocol.

5.2.9. Progress reports submitted by investigators.

5.2.10. Reports of injuries to subjects caused by the research.

5.2.11. Records of continuing review activities and dates, including the rationale for requiring continuing review of research that otherwise would not require continuing review.

5.2.12. Data and safety monitoring board reports.

5.2.13. Modifications to previously approved research.

5.2.14. Reports of unanticipated problems involving risks to subjects or others.

5.2.15. Documentation of non-compliance.

5.2.16. Relevant correspondence between the IRB and investigator related to the protocol, including protocol approval date and expiration date.

5.2.17. Significant new findings and statements about them provided to subjects or others.

5.2.18. For initial and continuing review of research by the expedited procedure required information includes:

5.2.18.1. The specific permissible category or categories.

5.2.18.2. Description of action taken by the reviewer.

5.2.18.3. Any findings required under the regulations.

5.2.18.4. The rationale for a determination that research, that otherwise meets a category for expedited review, is greater than Minimal Risk.

5.2.19. For exemption determinations, the specific category of exemption.

5.2.20. Unless documented in the IRB minutes, documentation of all regulatory determinations and the protocol-specific findings for those determinations for:

5.2.20.1. Waiver or alteration of the consent process.

5.2.20.2. Research involving pregnant women, fetuses, and neonates.

5.2.20.3. Research involving Prisoners.

5.2.20.4. Research involving children.

5.2.20.5. Research involving adults unable to consent.

5.2.20.6. Significant/non-significant device determinations.

5.2.21. For each protocol's initial review and continuing review, when required, the frequency for the next continuing review, including the rationale for requiring continuing review for protocols approved by expedited review that otherwise would not require continuing review under the 2018 Common Rule.

5.3. Policies and procedures include:

5.3.1. Checklists.

5.3.2. Forms.

5.3.3. SOPs.

5.3.4. Template letters.

5.3.5. Template minutes.

5.4. Destruction:

5.4.1. Destroy IRB protocol files three years after the protocol has been closed, withdrawn, or terminated unless otherwise required by law.

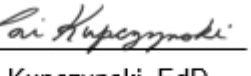
5.5. For multi-center research, the three-year period refers to the organization's involvement in the study, not the duration of the entire study.

5.6. Archival

5.6.1. Utilize and maintain an electronic repository for all archived information (such as shared drive), noting the archival date for each and retaining them in accordance with the requirements of this SOP.

6. REFERENCES

6.1. 21 CFR §56.115

Approved by: 

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