OFFICE OF RESEARCH AND SPONSORED PROGRAMS *Division of Research Compliance*	**Research Compliance** **Standard Operating Procedures**

Title: Record Retention of Research Compliance Committee Documents			
Effective Date:		**Document Number:**	ORSP-SOP-018.01

Approval/Date:

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Vice President & Chief Research Officer

29 OCT 2024
Date

REVISION HISTORY		

PURPOSE
This Standard Operating Procedure establishes a comprehensive framework for the systematic retention of records required by the IRB, IACUC, and IBC, ensuring compliance with regulatory standards and promoting the responsible conduct of research activities.

SCOPE
This SOP applies to all personnel involved in research activities subject to oversight by the IRB, IACUC, and IBC.

DEFINITIONS AND ABBREVIATIONS
IRB: Institutional Review Board
IACUC: Institutional Animal Care and Use Committee
IBC: Institutional Biosafety Committee
PI: Principal Investigator

RESPONSIBILITIES
Principal Investigators (PIs): Responsible for ensuring accurate and timely submission of required documents to the relevant committees and adherence to record retention guidelines.
Compliance Administrators: Responsible for maintaining and organizing records in accordance with this SOP.

Committee Chairs: Oversees compliance with record retention policies and procedures within their respective committees.

PROCEDURE
1. Record Retention Period: All IRB, IACUC, and IBC-required records shall be retained for a minimum of 3 years after study completion, or as per sponsor requirements or institutional policy.
2. Document Categories:

a. Research Proposals: Copies of all research proposals submitted for committee review, including initial submissions and any subsequent modifications.
b. Approved Consent Forms: Copies of all approved consent forms provided to participants.
c. Animal Use Protocols: Copies of all animal use protocols submitted for IACUC review.
d. Approved Biosafety Plans: Copies of all approved biosafety plans detailing the safe handling, storage, and disposal of biohazardous materials.
e. IBC Registration Approvals: Copies of all approvals granted by the IBC for the registration of research involving biohazardous materials.
f. Meeting Minutes: Detailed minutes documenting discussions, decisions, and votes made during committee meetings.
g. Continuing Review Activities: Records of all continuing review activities, including progress reports, adverse events, and protocol amendments.
h. Correspondence: Copies of all correspondence exchanged between the committees and investigators, including approval notifications, clarification requests, and protocol revisions.

3. Storage and Organization:
   a. All records shall be stored in a secure and accessible location, either in physical or electronic format.
   b. Physical documents shall be stored in locked file cabinets in a designated office space accessible only to authorized personnel.
   c. Electronic documents shall be stored in a secure, password-protected database or file system with restricted access permissions.
   d. Documents shall be organized systematically, preferably indexed or cataloged by study name, investigator, or committee protocol number.
4. Expired Approvals:
   a. For projects whose approval has expired, the principal investigator (PI) is responsible for ensuring that no further research activities are conducted until the protocol has been renewed or closed out.
   b. If a study has been expired for longer than 6 months (best practice), the PI will be required to submit a new protocol for review to continue the research.
   c. The expiration date will be clearly documented in all relevant records, and PIs will be notified in advance of the upcoming expiration to allow for timely renewal.
5. Disposal:
   a. At the end of the retention period, all records shall be disposed of in a manner compliant with institutional policies and regulatory requirements.
   b. Physical documents shall be shredded or securely disposed of to prevent unauthorized access.
   c. Electronic documents shall be permanently deleted from all storage locations and backups. PIs and others will be required to certify that these records were

destroyed. Certification of destruction can be accomplished through methods such as:

i. Signed attestation by the PI or designated personnel responsible for record disposal, confirming the destruction of physical documents through shredding or other secure means.
ii. Electronic certification by the responsible personnel, indicating the permanent deletion of electronic documents from all storage locations and backups, along with a timestamp and electronic signature.
iii. Documentation of destruction provided by an authorized third-party service provider, if outsourcing record disposal services, including a certificate of destruction or similar documentation.

6. Audit and Inspection:
    a. Records shall be made available for inspection by authorized personnel, regulatory agencies, or auditors upon request.
    b. Compliance Administrators shall maintain a log of record access and ensure compliance with audit procedures.
7. Training:
    a. All personnel involved in research activities subject to committee oversight shall receive training on record retention policies and procedures.
    b. Training sessions shall be conducted periodically to ensure ongoing compliance and awareness.
8. Revision and Review:
    a. This SOP shall be reviewed and revised as necessary to ensure alignment with current regulatory guidelines and institutional policies.
    b. Any revisions to the SOP shall be communicated to relevant stakeholders and documented appropriately.

REFERENCES

Sam Houston State University Records Retention Policy