1. POLICY

Institutional Review Board (IRB) records will be maintained in a manner such that each protocol file contains a complete history of all IRB actions related to review and approval of the protocol, including continuing reviews, modifications, and reports of unanticipated problems and adverse events. All records pertaining to a submitted research study, regardless of whether it has been approved, will be retained in an appropriate manner as required by federal regulatory requirements, the State of Oklahoma’s Consolidated General Records Disposition Schedule for State Universities and Colleges, and university policy. Category of review (i.e. exempt, expedited, full board) does not alter record retention requirements.

Records must be accessible for inspection and copying by authorized representatives of the sponsor, funding department or agency, regulatory agencies, and institutional auditors at reasonable times and in a reasonable manner.

Required documents must be submitted to the appropriate funding and regulatory entities as required.

Specific Procedures

1.1 Document Retention

The Office of University Research Compliance (URC) will retain all records pertaining to an application received by the IRB in accordance with university policy 3-0190 and other university policies, including URC’s Appropriate Computer Use Policy, Records Retention Policy, and Email Retention Policy. URC and the IRB must also comply with the State of Oklahoma’s Consolidated General Records Disposition Schedule for State Universities and Colleges, which states that the University must “permanently retain files containing applications submitted by faculty, students, and staff to conduct research projects involving human subjects, correspondence related to review of applications, and federal guidelines regarding the uses of human subjects in research projects.”

1.1.1 Study-related documents:

Adequate documentation of the IRB’s activities will be prepared, maintained, and retained in a secure location. Retained documents include:

- Copies of all research applications received by the IRB; revised application materials submitted in response to IRB revision requests; scientific evaluations, if any, that accompany the applications; approved consent documents; continuation reports submitted by Investigators; reports of unanticipated problems and adverse events adversely affecting the rights and welfare of subjects; and reported deviations from the IRB approved protocol.
- Copies of grant applications/research proposals that have been submitted to the IRB for review.
- All correspondence related to review of applications submitted to the IRB as well as approved protocols, including correspondence between the IRB and the Investigator(s).
- Agendas and minutes of all IRB meetings.
- Copies of all submitted monitoring reports, site visit reports, and other continuing review activities.
- Statements of significant new findings provided to subjects.
- Reports of any complaints received from subjects.

1.2 **IRB Administration Documents**

URC will maintain and permanently retain all records regarding IRB administrative activities resulting from review activities as delineated above.

1.2.1 URC will maintain rosters of primary and alternate IRB members, who will be identified by name, earned degrees (if applicable), representative capacity, and indications of experience sufficient to describe each member's chief anticipated contribution to IRB deliberations. In addition, the roster shall indicate the primary member for whom the alternate member may substitute.

The roster of IRB members must be submitted to the Office for Human Research Protections (OHRP). Any changes in IRB membership must be reported to the head of the department or agency supporting or conducting the research, unless the department or agency has accepted the existence of a Federal-wide Assurance (FWA). In the latter case, changes in membership must be reported to OHRP.

1.2.2 URC will maintain current and obsolete copies of the IRB’s Standard Operating Policies and Procedures.

1.2.3 Delegation of specific functions, authorities, and responsibilities by the IRB chair will be documented in writing and filed in the IRB, which is housed in the Office of University Research Compliance.

1.2.4 The IRB manager will ensure that the IRB’s electronic tracking system, traditional records, and files are maintained in a manner that is compliant with pertinent federal regulations, state statutes and guidelines, and university policies and procedures.

With the assistance of URC’s systems administrator and other OSU Information Technology (IT) personnel, the IRB Manager will oversee electronic systems that are used to document administrative actions taken on behalf of the IRB, track submissions and review status, and communicate with Investigators. The IRB Manager will ensure that IRB staff members are trained on the proper use of all electronic systems used to document IRB application review and other compliance activities. The IRB Manager will maintain specific operations and procedures manuals to assist staff and ensure consistency of operations. The IRB Manager, with the assistance of URC’s systems administrator, will oversee the security of electronic system(s) by conducting appropriate reviews of electronic data and audit information.

If user ID/password combinations are used to access electronic systems, passwords will be consistent with the University’s password policy and they will be changed at appropriate intervals in accordance with applicable university policies. Invalidated, stolen, lost or otherwise compromised user IDs or passwords will be replaced.

1.3 **Destruction of Copies**

All material received by the IRB Office that is considered confidential will be collected at the end of IRB meetings and destroyed by a method deemed appropriate by the IRB Manager.
2. SCOPE
This policy and procedure applies to all documents used in the submission, initial review, modification review, and continuing review of research falling within the purview of the IRB.

3. RESPONSIBILITY
The IRB Manager is responsible for maintaining complete files on all proposed research activities reviewed by or submitted to the IRB. The IRB Manager is also responsible for meeting all applicable regulatory compliance requirements.

4. APPLICABLE REGULATIONS AND GUIDELINES
OSU Policy and Procedure 3-0190
State of Oklahoma’s Consolidated General Records Disposition Schedule for State Universities and Colleges
45 CFR 46.103,115

5. REFERENCES TO OTHER APPLICABLE SOPS
This SOP affects all other SOPs.

6. ATTACHMENTS
None

7. PROCESS OVERVIEW
Describe the requirements for document management.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY
A. Creating a Study Folder

<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
<th>Tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Coordinator</td>
<td>Upon receipt of a new application, ensure that relevant study information is entered in the IRB electronic tracking system. Create a file label. Organize the submitted material in the following order once application has been approved: • Approval Letter (when appropriate) • Approved Protocol • Research Plan/Grant Proposal • Submitted Advertising (Recruitment) • Continuations/Modifications • Approved Informed Consent Documents • Adverse Events Documentation • Correspondence</td>
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</tbody>
</table>

IRB Manager
All records regarding a submitted application (regardless of whether it is approved) will be retained in an appropriate manner as required by regulatory requirements and/or institutional policy.
Ensure that all records are accessible for inspection and copying by authorized representatives of the sponsor, funding department or agency, federal (OHRP) and institutional auditors at reasonable times and in a reasonable manner.

### B. Using Electronic Systems

<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
<th>Tool</th>
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<tbody>
<tr>
<td><strong>IRB Manager</strong></td>
<td>Ensure that the IRB’s electronic systems and records are maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, modifications, unanticipated problems and adverse event reports.</td>
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<td>With the assistance of URC’s systems administrator and other OSU Information Technology personnel, oversee electronic systems that are used to document administrative actions taken on behalf of the IRB, track submissions and review status, and communicate with Investigators.</td>
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<td>Ensure that all IRB staff members are trained on the proper use of all electronic systems used to document IRB application review and compliance activities.</td>
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<td>Maintain specific operations and procedures manuals to assist staff and ensure consistency of operations.</td>
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<td>Oversee the security of the electronic system by conducting appropriate reviews of electronic data and audit trails.</td>
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<td>Uphold established security protocols to ensure limited access to secure areas and sensitive information.</td>
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<td></td>
<td>If user ID/password combinations are used to access electronic systems, they will be changed at appropriate intervals; and invalidated, stolen, lost or otherwise compromised user IDs or passwords will be replaced.</td>
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