UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-043
AAHRPP:	Element II.5.A.
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Updated By:	
Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Recordkeeping

1.0 Objective

1.1. To describe policies and procedures for the University of Southern Maine (USM) Institutional Review Board (IRB)/Office of Research Integrity and Outreach (ORIO) record keeping.

2.0 Responsibility

2.1. It is the responsibility of the ORIO staff, Research Compliance Administrator (RCA), IRB, and investigators to execute this SOP.

3.0 General Description

3.1. The ORIO maintains IRB records in accordance with applicable regulatory and institutional requirements.

4.0 Procedure

4.1. Access to Study Records

4.1.1. ORIO staff secure all active IRB records and limit access to the IRB Chair, IRB members, ORIO staff, Institutional Official (IO), and officials of federal and state regulatory agencies, the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and accrediting bodies. In addition;

4.1.1.1. Principal Investigators (PIs) or their authorized study personnel have reasonable access to files related to their research activities; and

4.1.1.2. All other access to IRB records is limited, but records may be disclosed as legally required by state open record statutes when disclosure is authorized by the University of Maine System Office of General Counsel.

4.1.2. Individual Board Members are not authorized to provide information.

4.1.3. Administrative requests for access must be in writing to the Office of Research Integrity and Outreach (ORIO) either by electronic mail or post and contain the following information:

4.1.3.1. The name of the person requesting the information;
4.1.3.2. The information requested;
4.1.3.3. The reason for the request; and
4.1.3.4. Methods for maintaining confidentiality while in retention of the information.

4.1.4. When the ORIO receives a request for IRB records of studies, ORIO staff check to see whether the request is from a PI or his/her authorized personnel.

4.1.4.1. If the person requesting the record is listed as current study personnel on the protocol, ORIO staff may create a PDF with pertinent parts of the IRB record to be or e-mailed to the requestor.
4.1.4.2. If the person requesting the record is not listed as current study personnel, the RCA or designee makes a determination as to whether the request is from an appropriate person that should have access before authorizing the release of any records.
4.1.4.3. Unless the individual provides an acceptable reason for not informing the PI of the request, ORIO staff inform the PI that ORIO has received a request for access to the applicable protocol.

4.2. Storage of Study Records

4.2.1. The PI maintains protocol records for a minimum period of time as follows:

4.2.1.1. The PI maintains signed documents, (e.g., signed consents/assents) and IRB records for at least three (3) years (or six (6) years if PHI is involved) after Study Closure in accordance with HRPP 026 Study Closure, taking measures to prevent accidental or premature destruction of these documents.
4.2.1.2. For research under the authority of FDA or other regulatory agency, the PI retains signed documents and IRB records for the period specified in the applicable regulations if the requirements are longer than three (3) years (or six (6) years if PHI is involved) after Study Closure.
4.2.1.3. For multi-site studies, the PI consults the study sponsor regarding retention requirements but must maintain records for a minimum of three (3) years (or six (6) years if PHI is involved) after Study Closure.
4.2.1.4. For study protocols granted a not research with human subjects determination or exemption from IRB review determination, the PI retains records for at least three (3) years (or six (6) years if PHI is involved) from the most recent submission date.
4.2.1.5. Investigators store records consistent with the plan approved by the IRB in a secured manner to prevent breaches of confidentiality.

4.2.1.6. Investigators store records in compliance with any applicable state laws, federal laws, contractual agreements, or institutional policies.
4.2.1.7. The PI ensures that retained records are accessible for inspection and/or copying by authorized representatives of institutional or regulatory agencies.
4.2.1.8. Protocol records will be communicated and memorialized by a reliance agreement to the PI created by the Regulatory Compliance Administrator.

4.2.2. The ORIO maintains protocol records for a minimum period of time as follows:

4.2.2.1. The ORIO maintains IRB records for expedited or full board reviewed protocols for at least three (3) years (or six (6) years if PHI is involved) after Study Closure.
4.2.2.2. For research under the authority of FDA or other regulatory agency, ORIO retains IRB records for the period specified in the applicable regulations if the requirements are longer than three (3) years (or six (6) years if PHI is involved) after Study Closure
4.2.2.3. For multi-site studies that received expedited or full board review, ORIO retains IRB records for a minimum of three (3) years (or six (6) years if PHI is involved) after Study Closure or longer if required by the study sponsor.
4.2.2.4. Withdrawn or Disapproved protocols will be retained for a period of one (1) year after withdrawal or disapproval notice is given;
4.2.2.5. For study protocols granted a not research with human subjects determination or exemption from IRB review determination, ORIO retains records for at least three (3) years (or six (6) years if PHI is involved) from the most recent submission date.
4.2.2.6. ORIO ensures that retained records are accessible for inspection and/or copying by authorized representatives of institutional or regulatory agencies.

4.3. Storage of Other Records

4.3.1. In addition to protocol files, the ORIO maintains information and records, including but not limited to the following:

4.3.1.1. Standard operating procedures;
4.3.1.2. IRB membership rosters;
4.3.1.3. Meeting minutes, which include documentation of convened IRB meetings;
4.3.1.4. Federalwide Assurances;
4.3.1.5. Computerized research protocol tracking system;
4.3.1.6. Other IRB correspondence;
4.3.1.7. Agendas for IRB meetings, which include all items to be reviewed and documentation of expedited and exempt reviews;

4.3.1.8. Alleged noncompliance case records;
4.3.1.9. Mandated reports;
4.3.1.10. Resumes of currently active IRB members; and
4.3.1.11. Electronic records documenting completion of mandatory IRB training for study personnel, IRB members, and ORIO staff.

4.3.2. ORIO staff maintain records that are not part of specific protocol files such and periodically, destroys them as appropriate and determined by the RCA.

4.3.3. The ORIO also maintains communications to and from the IRB and keeps any relevant communication related to a specific research protocol in the protocol record.

4.4. Protocol Records

4.4.1. ORIO staff maintain a separate record for every research application.

4.4.2. The Full Review Protocol IRB record includes (when applicable) but is not limited to:

4.4.2.1. Initial IRB application;
4.4.2.2. Scientific evaluations of the proposed research, if any;
4.4.2.3. Study drug information (i.e., investigator's brochure, monograph, labeling);
4.4.2.4. Study device information (i.e., prior investigation, operations manual, labeling);
4.4.2.5. Data Safety and Monitoring Board reports, if any;
4.4.2.6. Results of Quality Improvement Program (QIP) reviews, if any;
4.4.2.7. Investigator Assurance;
4.4.2.8. IRB approved informed consent document and assent document with the approval date stamp;
4.4.2.9. Documentation of all IRB review and approval actions, modifications, and all relevant correspondence to and from the investigator, including initial, continuation, modification, deviation, and exception review;
4.4.2.10. Documentation of type of review;
4.4.2.11. Documentation of study close-out;
4.4.2.12. Specific findings (federal and institutional requirements);
4.4.2.13. Continuation/final review materials;
4.4.2.14. Significant new findings provided to human subjects, if any;
4.4.2.15. Reports of unanticipated problems/adverse events involving risks to subjects or others;
4.4.2.16. Reports of protocol violations;
4.4.2.17. All relevant correspondence to and from the investigator and any other correspondence related to the protocol;
4.4.2.18. IRB Authorization Agreements;
4.4.2.19. Any existing contractual agreements for off-site research;

4.4.2.20. Applications for funding/sponsorship;
4.4.2.21. Advertising or recruiting materials;
4.4.2.22. Protocol amendments or modifications;
4.4.2.23. Instrument to be used for data collection;
4.4.2.24. Department of Health and Human Services (HHS)/National Institutes of Health (NIH) approved sample informed consent form and protocol;
4.4.2.25. Copy of the package insert, drug monograph, or FDA approved label for drug or device studies using the FDA approved medication/device for approved medical indication;
4.4.2.26. Sponsor's grant, contract, or device proposal if the protocol does not involve the administration of drugs;
4.4.2.27. Evidence of Human subject protection training for principal investigators and study personnel;
4.4.2.28. Health Insurance Portability and Accountability Act (HIPAA) forms;
4.4.2.29. Institutional Biosafety Committee (IBC) correspondence and approval letters;
4.4.2.30. Other committee approvals/correspondence;
4.4.2.31. Mandated reports;
4.4.2.32. Criteria for IRB Approval; and
4.4.2.33. Criteria IRB Continuing Review: Primary Reviewer Checklist(s).

4.4.3. The Expedited Review Protocol IRB record includes (when applicable) but is not limited to:

4.4.3.1. All of the items listed above under full review protocol, as applicable to individual studies;
4.4.3.2. Documentation and determinations required by the regulations and protocol-specific findings justifying those determinations, including that the study presents no more than minimal risk , the study is eligible for expedited review and identification of the applicable expedited review category(ies); and
4.4.3.3. Description of action taken by the primary expedited reviewer.

4.4.4. The Exempt Review Protocol record includes (when applicable) but is not limited to:

4.4.4.1. Initial application for exempt review;
4.4.4.2. Investigator Assurance;
4.4.4.3. Items listed under full review protocol, as applicable to individual studies;
4.4.4.4. Documentation and determinations required by the regulations and protocol specific findings justifying the determinations, including documentation of exempt eligibility and specifying appropriate exemption category(ies); and
4.4.4.5. Description of action taken by the exempt reviewer.

4.5. Database

4.5.1. The ORIO maintains a computerized tracking system. Examples of data included in the computerized system include the following, when applicable:

4.5.1.1. IRB number which identifies the protocol as full, expedited, or exempt;
4.5.1.2. The IRB which provides review and ORIO staff who manage the review;
4.5.1.3. Current status (active/inactive);
4.5.1.4. Protocol type (medical/nonmedical);
4.5.1.5. Title of the research project (protocol);
4.5.1.6. Protocol process type (full, expedited, exempt);
4.5.1.7. Approval stage (pre-approved, approved, suspended, terminated);
4.5.1.8. IRB to which the protocol is assigned;
4.5.1.9. Risk category;
4.5.1.10. Dates of research period (initial approval date and anticipated ending date);
4.5.1.11. Approval period;
4.5.1.12. Names of the PI, co-investigators, study coordinators, and other study personnel as appropriate;
4.5.1.13. Planned Number and age level of subjects;
4.5.1.14. Expected Subject demographics;
4.5.1.15. Enrollment status (open or closed to accrual);
4.5.1.16. Research attributes (e.g., cancer, genetic research);
4.5.1.17. Drug or device information;
4.5.1.18. Other committee approvals (e.g., Institutional Biosafety Committee);
4.5.1.19 Funding source and type;
4.5.1.20. Research sites;
4.5.1.21. Date of initial approval;
4.5.1.22. Date of most recent approval;
4.5.1.23. Date of most recent continuation approval;
4.5.1.24. Prior notice of end of current approval period;
4.5.1.25. Submission and review dates for each protocol event (initial review, continuation review, final review, modification review, extension review, unanticipated problem review);
4.5.1.26. Other information, such as meeting dates;
4.5.1.27. Comment section.

4.5.2. Only ORIO staff have administrative access to the database.

4.5.2.1. Access for investigators, research staff, and IRB members is appropriately limited.

5.0 References

5.1. 45 CFR 46.115;
5.2. 21 CFR 56.115