



SOP: Document Management and Record Retention of Institutional Review Board Records

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1 PURPOSE

- 1.1 This policy describes the requirements for IRB record management, retention, and archiving.
- 1.2 The process begins when an IRB application, an allegation of non-compliance (perceived or confirmed), or a participant complaint is received by the IRB Office, or when a monitoring assessment (routine or for-cause), for-cause directed review, or other investigation is initiated by the IRB Office.
- 1.3 The process ends when the IRB record is archived or destroyed in accordance with institutional record retention policies.

2 PREVIOUS VERSION

- 2.1 Replaces the previous version dated 03/28/2022.

3 POLICY

- 3.1 The IRB Office must maintain records that contain a complete history of all IRB actions related to the review and approval of a protocol, including continuing reviews, modifications, reportable new information submissions, compliance-related services and inquiries, and other administrative actions.
- 3.2 The IRB Office Compliance Team (Compliance Team) is responsible for maintaining these documents for the required time consistent with the institution's record retention practices.
- 3.3 Records are retained according to this policy regardless of whether the submitted IRB application is approved, determined to be exempt, determined to be not human research, or if there is no associated IRB application/study. The records clearly indicate which documents the IRB has approved.
- 3.4 The records must be accessible for inspection and copying by authorized representatives of the funding department or agency, regulatory agencies, and institutional auditors at reasonable times and in a reasonable manner.
- 3.5 Requested documents must be submitted to the appropriate funding entity as required.

4 RESPONSIBILITIES

- 4.1 IRB Office Compliance Team members carry out these procedures.

5 PROCEDURE

Study-Related Document Retention

- 5.1 The IRB Office retains all records regarding an IRB application, regardless of whether it is approved.
 - 5.1.1 If a protocol is canceled without participant enrollment, IRB records are maintained for at least three years after cancellation.
- 5.2 For all applications that are approved and the research initiated, or the submission is acknowledged, the IRB Office must retain all records regarding that research for the appropriate length of time after completion of the research as described in item 3.2.
- 5.3 Adequate documentation of each IRB's activities will be prepared, maintained, and retained in a secure location. Retained documents include but are not limited to:
 - 5.3.1 Copies of all research protocols reviewed, supporting documents, scientific evaluations, if any, that accompany the proposals, consent documents, progress reports submitted by investigators, and other documents classified as "support documents."
 - 5.3.2 Copies of all submitted monitoring reports, site visit reports, progress reports, and other documents required at continuing review activities.



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- 5.3.3 Reports of injuries to participants, adverse events, unexpected adverse events, and unanticipated problems involving risks to participants or others, and reported deviations or violations from the protocol.
- 5.3.4 Copies of IRB system correspondence between the IRB and the investigators.
- 5.3.5 Reviewer sheets, IRB Checklists, and other supplemental review documentation.

IRB Administration Document Retention

- 5.4 Adequate documentation of the Human Research Protection's Program (HRPP) and IRB's internal operations will be prepared, maintained, and retained in a secure location. Documents to be retained include:
 - 5.4.1 Agendas and minutes of all IRB meetings and confidentiality agreements.
 - 5.4.2 Current and obsolete copies of the Standard Operating Policies and Procedures
 - 5.4.3 Delegation of specific functions, authorities, or responsibilities by the IRB Chairperson
 - 5.4.4 Reports of any complaints received from participants or allegations of non-compliance
 - 5.4.5 Reports of any routine monitoring activities, for-cause reviews, or other investigations
 - 5.4.6 Current Federalwide Assurance (FWA) with OHRP
 - 5.4.7 IRB registrations, as required

Duration of Retention

- 5.5 In accordance with the Common Rule and FDA regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)) respectively, IRB records are retained for at least three (3) years after the completion of the research.
 - 5.5.1 In accordance with institutional policy, if any claim or litigation arises out of the study, records shall be kept until all such claims or litigation have been resolved and final action has been taken.
- 5.6 All institutions that are engaged in Department of Defense (DoD)-conducted or DoD-supported human participant research must retain records for at least three (3) years after the completion of the research, or longer if required by DoD Manual 6025.18, the Privacy Act, FDA regulations, or other applicable requirements.
- 5.7 In accordance with federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulations (45 CFR § 164.530(j)), IRB records in which a HIPAA authorization or a waiver of HIPAA authorization was granted for the research must be retained for at least six (6) years after the completion of the research.
- 5.8 If the research is regulated by multiple agencies, the data will be maintained for the longest period.

Manner of Retention

- 5.9 Federal IRB regulations permit records to be stored electronically or in hard copy. As of 2011, Northwestern University began using electronic submission systems, eIRB Legacy, and in 2014 eIRB+, to process IRB applications. Both systems reside on secure servers with password-protected access. The Northwestern University IRB maintains documentation in electronic format but may elect to store files in hard copy format as deemed necessary.
- 5.10 Upon closure or termination of a protocol, files are archived or stored within the appropriate electronic submission systems.
- 5.11 For studies that originated in paper format, hard copies of those IRB approved studies are recorded within the QA Vanguard Storage 10-28-2015 spreadsheet and stored at an off-site location.
 - 5.11.1 Retrieval of off-site records may take between 5-10 business days to obtain.
- 5.12 Paper-based Compliance Unit records are archived three (3) years after the final compliance-related activity is completed. The materials are logged within the archive tracking sheet labeled



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“The New Tracking Sheet (B Boxes)” and stored in the basement of the Arthur Rubloff Building, 375 E Chicago Ave., Chicago, IL 60611.

- 5.13 Electronic Compliance Unit records are archived within the unit's university-managed shared drive (S:\IRB - Quality Assurance and Training\Compliance) and secured by user permissions.
- 5.14 Reliance records are stored in eIRB+ as a part of the record for each associated study. They are archived with the eIRB+ record when the study is closed.
- 5.15 Education records are stored and archived within the unit's university-managed shared drive (S:\IRB - Quality Assurance and Training\Education & Training) and secured by user permissions.

Archiving and Destruction

- 5.16 All documents and materials pertinent to IRB determinations will be archived or destroyed according to institutional policy.
 - 5.16.1 Compliance and Reliance records associated with an IRB approved study or research record will be destroyed in conjunction with the destruction of the associated IRB study.
 - 5.16.2 Compliance and Reliance records that are not associated with an IRB record will be destroyed three years after the final action.
- 5.17 For studies that have a litigation hold, if any claim or litigation arises out of the study, records shall be kept until all such claims or litigation have been resolved and final action has been taken.
- 5.18 At the discretion of the University, Office for Research, or IRB Office, any IRB records pertaining to this policy may be retained for a longer (not shorter) time period, as needed, until all outstanding issues are resolved.

6 MATERIALS

- 6.1 None

7 REFERENCES

- 7.1 45 CFR 46.115(b)
- 7.2 21 CFR 56.115(b)
- 7.3 45 CFR § 164.530(j)
- 7.4 DOD INSTRUCTION 3216.02
- 7.5 GENERAL DOCUMENT: Investigator Manual (HRP-103)
- 7.6 SOP: IRB Records (HRP-070)
- 7.7 NU Policy: Retention of University Records
- 7.8 NU Policy: Research Data: Ownership, Retention, and Access
- 7.9 FSM Administrative Policy: Data Security Plans for Identifiable Information Used in Clinical Research