

## Research Document Retention Requirements for Principal Investigators

The Principal Investigator (PI) of a human research study at Northwestern University must maintain research records in accordance with the [Policy on Retention of University Records](#). The length of time a PI must retain research records varies according to several factors, including funding source, oversight, and record type. In cases where the sponsor or other applicable requirements conflict, the PI must follow the longest retention period.

The PI's records are considered the official research file. According to [Document Management and Record Retention of Institutional Review Board Records \(HRP-072\)](#), the IRB Office maintains copies of documents sent to the investigator (e.g., eIRB+; legacy eIRB), but these do not constitute the PI's official record. The PI's responsibility is to maintain adequate documentation of research procedures/processes. In the event of a request to review a research record, such as an audit or routine monitoring, all information must be readily available to be reviewed by the appropriate entity or individual in a reasonable manner.

There could be other retention requirements, for example, longer periods of retention that may result from litigation or questions or allegations about the validity of the data or conduct of the research. Please refer to other department requirements and the University's [Retention Schedule](#). In addition, investigators conducting research at Northwestern Memorial HealthCare (NMHC) should refer to the Northwestern Medicine Policy Manager site to view [Records Management](#) (must be logged in to NM first to access this policy).

Researchers must follow their own school's or unit's requirements in alignment with [School and Unit Policies: University Policies](#).

Shirley Ryan Abilitylab (SRALab) Researchers should refer to SRALab policy, titled "Record Retention (Medical and Administrative)," located in SRALab's internal policy system, PolicyStat.

Refer to NU Information Technology's [Data Management and Storage](#) page.

The following table outlines some required retention periods:

Category	Minimum Retention Period
Research Records/Study Files	Research records/study files must be retained for at least three (3) years after completing the research. Records must be accessible for inspection & copying by authorized representatives of HHS/FDA at reasonable times and in a reasonable manner. [45 CFR 46.115(b); 21 CFR 56.115(b)]
Research Data/Source Documentation	Research data/source documentation must be retained for at least three (3) years after completing the research.

HIPAA Authorization	<p>If the consent form contained a HIPAA Authorization, the documents must be retained for six (6) years. If a stand-alone HIPAA Authorization or a verbal HIPAA authorization were used, the documentation must be retained for six (6) years.</p> <p>If the consent form did not include a HIPAA authorization, three (3) years is sufficient.</p>
HIPAA Authorization Waiver	Documentation must be retained for six (6) years after completing the research.
FDA Regulated Studies	An investigator involved in research on drugs, devices, or biologics being tested in humans for FDA approval must retain records for two (2) years following the date the FDA approves a marketing application for the drug, device, or biologic for the indication for which it was investigated; or, if the responsible party will not file a marketing application or if the application is not approved for such indication, the investigator must retain records for two (2) years after the investigation is discontinued and FDA is notified.

- **Research Records/Study Files** include but are not limited to: Protocols and Amendments; Correspondence with sponsors; Other study instruments such as surveys, questionnaires, and recruitment materials; Interview recordings and transcripts; Study team qualifications and training; all records of communications (including applicable emails) with the IRB, and all IRB approval and acknowledgment documentation.
  - The eIRB+ system is the IRB Office's tool for keeping and maintaining records; it does not meet the institutional requirements for PI documentation. The [IRB Office provides](#) the Regulatory Binder Checklist and Research Record Components tools to assist investigators in maintaining research documentation in compliance with best research practices, IRB standards, and applicable regulatory and institutional requirements. Investigators may maintain research records electronically or with hard copies in a physical binder.
  - Investigators must store research records on or in facilities under the auspices of Northwestern University, Northwestern Memorial HealthCare, Shirley Ryan AbilityLab, or other appropriate entity. If Northwestern University is engaged in the research, the investigator must maintain records following Feinberg School of Medicine's [Hardware and Software Standards](#).
  - For studies that involve [Protected Health Information](#) (PHI), identifiable data must be destroyed at the earliest opportunity, as described in the study protocol.
- **Research Data/Source Documentation** includes records necessary for the reconstruction and evaluation of the reported results of research, which includes but is not limited to: Consent forms, Medical History, Participant Diaries, Participant Files, Data sets and analyses of data, and Laboratory, MRI or any other reports. Documentation of source data is necessary to reconstruct,

evaluate, and validate clinical findings, observations, and other activities during a clinical trial. All data must be verifiable, and all documentation must have an audit trail.

- **HIPAA Authorization** means either (1) the copy of the signed informed consent form and authorization, or (2) the stand-alone signed authorization, or (3) documentation of verbal authorization.
- **Consent Forms:** The Investigator must retain copies of signed consent forms in a manner that maintains the participants' confidentiality and must restrict access to the forms to only those listed as study team members in eIRB+. At the conclusion of the retention period, the signed informed consent forms must be effectively destroyed and no longer accessible to anyone.
  - Additionally, if the informed consent document or protocol states that the forms will be stored for periods exceeding three (3) years, this must be fulfilled.
- **HIPAA Waiver** means the documentation that the IRB, acting as the Privacy Board, waived the requirement for the investigator to obtain the participants' authorization to access or use Protected Health Information (PHI).
- **FDA:** Please note that the date of last marketing approval will not be known when the research is completed and can take time. Investigators are advised to ensure that their study budgets include funds for storage. The PI should retain the records until the sponsor or FDA grants permission to destroy the records in writing.
- **For data collected in other countries/states:** Investigators must follow local/state/institution laws and requirements and abide by whichever policy is more stringent for record retention.
- **GDPR** (General Data Protection Regulation) is a set of European Union (EU) and the European Economic Area (EEA) rules on data protection and privacy that contains additional requirements for data retention and destruction. Please email [privacy@northwestern.edu](mailto:privacy@northwestern.edu) with questions about GDPR data retention requirements.
- Please refer to the [Policy on Retention of University Records](#) for **Record Destruction** guidelines.