Paper Trails and Digital Details: Records Retention Made Simple

IRB Brown Bag

June 18, 2025

Presented By: **Kim Rowan, MBA, CIP**
Senior Education and Communication Analyst
Institutional Review Board (IRB) Office

Northwestern | INSTITUTIONAL REVIEW BOARD

🗂️ What is Research Records Retention?

- Maintaining the required study documents for a set period of time
- Ensures the Principal Investigator's (PI) study is in compliance with regulations and institutional policies
- Allows for monitoring, auditing, or inspection
- Applies to all study types – even exempt research
- ⏳ Retention requirements vary based on record type and study oversight
  - Typically kept for at least 3 years, but some studies require longer retention (e.g., FDA-regulated, sponsor requirements, HIPAA)

📈 Baseline Poll

How confident are you in your knowledge of each of the following?

1 – Not confident
2 – Somewhat confident
3 – Confident

1. How long research records must be retained
2. Which retention rules apply to your research and where to find them
3. Whether electronic storage of research records is permitted
4. Who is responsible for maintaining research records if the PI leaves Northwestern University

Why Records Retention Matters

- ✅ Safeguard participant rights and privacy
- ✅ Protect research integrity
- ✅ Comply with federal, institutional, and sponsor regulations
- ✅ Support audits, investigations, or future study questions
- ✅ Provides documentation for publications and future research

What Records Must Be Retained?

- **Study Documents**
  - Protocols, amendments, recruitment materials, IRB approval letters, correspondence with the IRB, federal oversight agencies, and sponsors
- **Research Data/Source Documentation**
  - Signed consent forms, participant diaries, medical histories, lab/MRI reports, datasets, analysis files
- **Training and Compliance Records**
  - Study team qualifications, human research protection training certifications, study training and delegation logs
- **HIPAA Documentation**
  - Signed HIPAA Authorizations
  - Stand-alone or verbal HIPAA Authorizations
  - HIPAA Waivers approved by the IRB

How to Store Your Research Records

- Proper storage is essential for protecting study information and meeting regulatory requirements
- Records can be kept in secure paper files or approved electronic systems
- Ensure confidentiality and data security at all times
- Organize documents so they are easy to locate and retrieve when needed
- Storage methods must allow for **inspection** and copying by authorized representatives
- Follow institutional policies on access control, backups, and retention schedules, including Northwestern University Information Technology Policies, Standards, and Guidelines

 Records Must Be Accessible for Inspection

What does this mean?

- **Study records** must be available for **review, inspection, and copying** by:
  - The Office for Human Research Protections (OHRP) – part of HHS
  - The Food and Drug Administration (FDA) (if applicable)
  - Northwestern University or other authorized entities

What You Need to Do

- **Keep records organized** and **securely stored** (paper or electronic)
- **Ensure records are retrievable** within a reasonable time if requested
- Maintain access until the **required retention period** is over

Why It Matters

- Verifies **compliance with federal regulations**
- Ensures **participant protections** and **research integrity**

🤔 When Should You Start Thinking About Record Retention?

🌼 **Start Early — Include in protocol planning phase**

❗ Once you have obtained **IRB approval, you must retain research records** following regulatory and institutional requirements.

🛠️ To help you maintain **complete and compliant records**, be sure to use the **IRB Office Study Support Resources and Templates**.

⏳ How Long is the Principal Investigator Required to Keep Records?

Record Type	Minimum Retention Period
General Research Records*	3 years post-completion
HIPAA Authorization	6 years post-completion
HIPAA Waiver	6 years post-completion
FDA-Regulated Research	2 years after approval or discontinuation
Data with PHI	Until destroyed per protocol
Sponsor-specific requirements	May vary: Use longest requirement

*Northwestern University Requirement for Research Records

*NMHC, SRALab, or your department may have different requirements

🔍 Always follow the **longest** applicable retention period.

⏱️ When Does the Retention Period Clock Start?

📌 The retention period **does not start at IRB closure**—it starts at **study completion**.

📄 **Retention Timelines Start:**

- **When the study is completed**, as defined by:
  - **All data collection and analysis are finished**
  - **Study is officially closed with the sponsor (if applicable)**
  - **Final report or publication is issued**

- 🛑 *"Completion" ≠ "IRB closure" if analysis/publication continues after closure.*

Retention Period by Record Type

Record Type	Retention Period	Retention Clock Starts
General research records	3 years	From study completion
HIPAA Authorizations	6 years	From date of signature/use
HIPAA Waivers	6 years	From date waiver granted
FDA-regulated studies	2 years	From FDA approval or notice of discontinuation
Sponsor-specific requirements	May vary: Use longest requirement	May vary: Use longest requirement
Data with PHI	Until destroyed per protocol	Until destroyed per protocol

HIPAA Documentation Retention

🔐 HIPAA Authorization

✓ Participant gives explicit permission to use their PHI

Includes:

- Signed informed consent with HIPAA language
- Stand-alone HIPAA authorization
- Documented verbal authorization

📂 **Retention: 6 years** from date of signature or use

📘 [45 CFR §164.530(j)(2)]

🛑 HIPAA Waiver

✓ IRB/Privacy Board waives the requirement for participant authorization

Includes:

- Documentation that the IRB approved a waiver

📂 **Retention: 6 years** from date waiver granted

📘 [45 CFR §164.530(j)(2)]

📌 **Tip:** Store both authorizations and waivers securely and separately from the research dataset.

💡 *Even if a study closes earlier, HIPAA documentation must still be retained for the full 6 years.*

🗂️ Data with PHI

- Health information is considered Protected Health Information (PHI) if it includes any of HIPAA's 18 Identifiers
- If a study involves PHI, then the data must be destroyed **at the earliest opportunity stated in the study protocol or data management plan**.

✅ Key Points:

- PHI must **not** be retained longer than necessary, per **HIPAA privacy standards**.
- The protocol should include a **defined data destruction plan** (e.g., “PHI will be destroyed 6 months after study closure”).
- If no specific timeline is defined, default HIPAA requirements (e.g., 6 years retention for authorization) apply.
- Data destruction must be **secure and verifiable** (e.g., shredding physical records, deleting encrypted files using secure wipe tools).

📌 Best Practice for Researchers:

Ensure the **protocol specifies** when PHI will be destroyed and **document the destruction** process when completed.

🛡️ Why Should PHI Be Destroyed at the Earliest Opportunity?

🔐 Protect Participant Privacy
•Reduces risk of unauthorized access or data incidents
•Limits exposure of sensitive health information

📜 Ensure HIPAA Compliance
•HIPAA requires PHI retention only as long as necessary
•Secure destruction once data is no longer needed for research or oversight

⚖️ Meet Institutional and Sponsor Requirements
•Aligns with data use agreements, protocols, and institutional policies
•Fulfills commitments made in consent documents

✅ Follow Best Research Practices
•Demonstrates responsible data stewardship
•Timely destruction reinforces an ethical commitment to safeguarding participant rights and well-being

💻 Electronic or 📄 Hard Copy?

✅ Electronic records **are allowed**, but must be:

- Secure
- Readily accessible
- Stored under NU/NMHC/SRAlab-approved systems
- Compliant with IT and PHI handling policies
- If FDA-regulated, must be Part 11 Compliant

🖨️ Can I Scan and Destroy Signed Consent Forms?

✅ **Yes — if all the following are true:**

- The **electronic version is an exact, legible copy** of the signed document (e.g., PDF scan)
- The file is **stored securely** in accordance with institutional and departmental data storage policies (e.g., encrypted, access-controlled)
- The electronic record **retains the signature** and meets requirements for **auditability and access**
- The protocol, IRB submission, or sponsor **does not explicitly require paper copies**
- Your study **does not involve** additional legal or regulatory restrictions (e.g., some FDA-regulated studies)

❗ **Check Before You Shred:**

- Your school/unit's **document retention policy**
- Any **sponsor-specific** requirements
- Whether a **wet ink signature** is required for legal or regulatory reasons

💡 When in doubt, confirm with the IRB Office or your research compliance contact.

🖨️ Can I Scan and Destroy Signed Consent Forms for FDA-Regulated Studies?

⚠️ **Be cautious — generally, keep paper copies unless you meet strict criteria**

To store informed consent forms **electronically only**, you must comply with:

- **21 CFR Part 11** (Electronic Records and Signatures)
  - Systems must ensure **authenticity, integrity, and security** of records
  - Must maintain an **audit trail** and **system validation**
- FDA must accept **electronic source documentation** in place of paper
  (see FDA guidance: *Use of Electronic Informed Consent*)
- 💡 **If Part 11 compliance is uncertain, retain paper copies.**

🗂️ ❓ Responsibilities for Research Records at Study Closure or PI Transition

1. **Study activities have concluded and the PI submits the study for closure with the IRB Office**
   - The PI is responsible to retain their research records according to institutional and regulatory requirements.
2. **The PI is leaving Northwestern**
   a) **The study will continue.**
      - The PI must transfer research oversight to another eligible faculty researcher at Northwestern.
      - The retention requirements are transferred to the new PI.
   b) **The study will not continue.**
      - The PI should submit the study for closure with the IRB Office.
      - Retention requirements fall to the PI's department.

Special Retention Situations

Data with PHI = must be destroyed per protocol and securely

Litigation or allegations = longer retention

Multi-site or international studies = check local laws

FDA approval timelines = may exceed PI's term at Northwestern University

🏆 Best Practices for Records Retention

- **Ensure Compliance with all applicable retention requirements**
  - Check with your department or sponsor to confirm they don't require a longer retention period for certain records.
- **Include a Detailed Data Safety and Destruction Plan in Your Protocol**
  - Clearly specify *how* and *when* data will be securely destroyed (e.g., encrypted deletion for electronic files, shredding for physical records)
- **Maintain a retention log that includes each record type, applicable rules, and planned destruction date.**
- **Document All Data Destruction Activities**
  - Document what you destroy (what, when, and why) for accountability and audit purposes

🏆 Best Practices for Records Retention

📝 For ongoing **compliance and quality assurance (QA)**, use the **IRB Office Post-Approval Monitoring checklists** as practical tools to support proper retention and management of research records throughout the life of the study.

💭 **Remember to think about retention early and often** — conducting regular reviews using the **PAM checklists** helps ensure your research records remain compliant from start to finish.

Resources

Northwestern University

1. Northwestern's research data policy; Northwestern's Retention of University Records policy and its associated records retention schedule
2. Northwestern Information Technology Policies, Standards, and Guidelines, Archiving Data When a Project Is Completed, Protecting Sensitive Information

IRB Office

1. **Research Document Retention Requirements for Principal Investigators (HRP-1914)**
   How long to keep records, acceptable formats, and PI responsibilities
   irb.northwestern.edu → Policies & Guidance
2. **Study Support Resources**
   Templates and tools to support compliant recordkeeping throughout the study lifecycle, including:
   Regulatory Binder Checklist and Research Record Template
   irb.northwestern.edu → Study Support Resources
3. **Post Approval Monitoring (PAM) Checklists**
   Complete these after enrolling your first participant to ensure study records are compliant and set your study up for success.
   irb.northwestern.edu → Checklists & Worksheets

These resources can help you stay organized, meet institutional requirements, and prepare for study closeout.

Be aware that your department, unit, sponsor, or regulatory oversight agency may have additional requirements.

👋 Exit Poll

How confident are you in your knowledge of each of the following?

1 – Not confident
2 – Somewhat confident
3 – Confident

1. How long research records must be retained
2. Which retention rules apply to your research and where to find them
3. Whether electronic storage of research records is permitted
4. Who is responsible for maintaining research records if the PI leaves Northwestern University

Questions?

Contact Us: Institutional Review Board (IRB) Office - Northwestern University

IRBTraining@northwestern.edu