Research Record Retention & Destruction: Tips and Best Practices

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Disclaimer

The authors of this presentation are not representative of UMB or UMMC as compliance subject matter experts. The materials provided were collected from policies, regulations, and guidance from various leadership bodies throughout the respective institutions.

Poll:

Do you feel comfortable destroying your research records?

What is a record?

UMB Sponsored Programs Administration Definition:

- “Records” includes any documentary material made or received in connection with the application for, or conduct of, a sponsored activity.
- “Records” includes paper, electronic records, and records, reports, or data in other media.

Poll:

Do you feel confident that you know **how long to keep** your research records?

Best Practice: Data Management Plan

- Many funders are requiring one (NSF, NIH, etc.)
- Considerations for development:

  FAIR Data Principles: Findability, Accessibility, Interoperability, and Re-usability.
  - Descriptive information (metadata)
  - Organization (file naming, consistent coding, version control, formatting, etc.)
  - Storage (legal, security, open data, local, commercial, registries, long term, etc.)
  - Sharing (confidentiality, intellectual property, licensing, registries, open data, regulations, etc.)
  - Citations (digital curation, DOIs, formatting, standards, etc.)
- Resources are available:
  - DMPTool (free)
  - Examples

Key Players

- ❑Funders
  - ❑Internal
  - ❑External
- ❑Publishers
- ❑Repositories
- ❑Participants

- ❑Regulatory bodies
  - ❑Federal (VA/HHS/etc.)
  - ❑State
  - ❑Institution (private)
  - ❑Controller (state)
  - ❑IRB (academic/for-profit)
  - ❑Office of Accountability and Compliance*
  - ❑School (public/private)
  - ❑Department (local)
  - ❑QA office* (local)


Research Record Retention

Funders

Retention time frame is funder specific

(internal/external, private/gov't, etc.)

Typically described in the contract/data agreement

Per UMB Investigators Manual: "If your human research is sponsored, contact the sponsor before disposing of human research records."

Federal Regulatory Bodies

VA/ HHS/ etc.

Federal (ex. VA)

UMB HRPO Investigators Manual Appx A-7

Research Records. All written information given to subjects must be in the investigator's research file along with the consent form(s). All records regardless of format (paper, electronic, electronic systems) must be managed per NARA approved records schedules found in VHA RCS 10-1 and therefore must be retained until disposition instructions, as approved by NARA, are published in VHA RCS 10-1. NOTE: Once the disposition schedule is determined, records should be disposed in accordance with VHA RCS 10-1. If the investigator leaves VA, all research records must be retained by the VA facility where the research was conducted.

Federal (ex. FDA): PI Record Retention

21CFR 312.62

(c) Record retention. An investigator shall retain records required to be maintained under this part [i.e., disposition or drug & case histories] for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

UMB HRPO Investigators Manual Appx A-2 cites PI requirement to comply with 21CFR 312.62

Federal (ex. HHS)

Offices of the Secretary:

Assistant Secretary for Administration (ASA)
Assistant Secretary for Financial Resources (ASFR)
Assistant Secretary for Health (OASH)
Assistant Secretary for Legislation (ASL)
Assistant Secretary for Planning and Evaluation (ASPE)
Assistant Secretary for Public Affairs (ASPA)
Office for Civil Rights (OCR)- *HIPAA*
Departmental Appeals Board (DAB)
General Counsel (OGC)
Office of Global Affairs (OGA)
Office of Inspector General (OIG)
Office of Medicare Hearings and Appeals (OMHA)
National Coordinator for Health Information Technology (ONC)
HHS Chief Information Officer

Operating Divisions:

Administration for Children and Families (ACF)
Administration for Community Living (ACL)
Agency for Healthcare Research and Quality (AHRQ)
Administration for Strategic Preparedness and Response (ASPR)
Agency for Toxic Substances and Disease Registry (ATSDR)
Centers for Disease Control and Prevention (CDC)
Centers for Medicare & Medicaid Services (CMS)
Food and Drug Administration (FDA)
Health Resources and Services Administration (HRSA)
Indian Health Service (IHS)
National Institutes of Health (NIH)
Substance Abuse and Mental Health Services Administration (SAMHSA)

NIH Data Sharing Policy (2003)

Grant applicants seeking >$500K in direct support in any given year must submit a data sharing plan or rationale if not possible.

- Include: “Recorded factual material… of sufficient quality to validate and replicate research findings…”
- When to share: no later than publication or end of award
- Best practice: De-identify to the greatest extent while maintaining scientific utility and regulatory compliance

> “Researchers may propose longer time periods for making scientific data available that may be informed by other factors, such as anticipated value of the dataset for the scientific community and the public. “
>
> –Taunton Payne, MA Director, Scientific Data Sharing Policy Division Office of Science Policy, National Institutes of Health

Federal (HIPAA)

Per UMB Investigators Manual:

"Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least SIX YEARS after **completion** of the research."

-UMB HRPO Investigators Manual v.Apr2021 p.25

What defines completion?

Best Practice: final project report, financial report and patent report are submitted

Local Regulatory Bodies

- ❑State
- ❑Institution (private)
- ❑Controller (state)
- ❑IRB (academic/for-profit)
- ❑Office of Accountability and Compliance
- ❑School (public/private)
- ❑Department (local)
- ❑QA office* (local)

UMB Institutional Review Board (State/Academic)

Per the UMB Investigators Manual:

"Maintain your human research records, including signed and dated consent documents, for at least THREE YEARS after **completion** of the research."

Pop Quiz! Funder requirements aside, if you are conducting a study at UMB and it involves the use of HIPAA covered data, do you only need to retain records for 3 years?

-No, 6 years per HIPAA requirement

Best practice: most conservative timeframe

UMB Office of Research & Development (ORD) Policies and Procedures

Per ORD's Guidelines for Record Retention

- In general, UMB records must be retained and protected for the longest period required by the State of Maryland, applicable Federal laws and requirements, the sponsor, and the foreign country (as applicable for international activities).
- Electronic records should be backed up regularly in a way that would prevent a catastrophic loss and ensure the quality and integrity of the data.
- Records should not be retained longer than required. This minimizes unnecessary administrative burden and expense, and records discarded in accordance with regulation and policy are no longer available for audit.

UMB Office of Research & Development Guideline for the Retention of Fiscal Records

Funding Source	Guidance
Federal awards	Retain records for three years after submission of the fiscal status report (annual or, if annual is not required, competitive segment) or after final payment under a federal contract. If any litigation, claim, or audit is started before the expiration of the three-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. Record retention under federal grants is governed by the Uniform Guidance, 2 CFR 200.334-338. Record retention under federal contracts is governed by the Federal Acquisition Regulation, FAR 52.215-2 Alt II.
U.S. state and city awards	Check the award terms. A number of these awards require that UMB retain fiscal records for six years; it is recommended that all records for projects funded under state and city awards be retained for six years.
International activities	Check the award terms.
Other	Check the award terms and conditions or the sponsor's written policies. If the sponsor or award document does not specify a specific time period to retain project records, follow the federal requirement (retain for three years after final payment under the award).

UMB Office of Research & Development
Guideline for the Retention of Program Records

Record Type	Guidance
Scientific and other technical records	Program reports: Retain programmatic/technical progress and final reports for at least three years after submission of the final report. Scientific data: Retain the original data and all project records for at least three years after submission of the final report or award termination. Most such records are retained for many years. After the required retention period, the principal investigator/project leader may make the decision to retain the records or to discard them when the records are determined to be no longer useful for research or educational purposes. Projects that resulted in an invention or discovery: When an invention has resulted from the project, check with the Office of Technology Transfer for advice on retention of relevant records.
Clinical study records	Corporate clinical study agreements specify the required period of record retention for source documents, which may differ depending on the type of study and, ultimately, the success of the test product. The source (essential) documents must be maintained according to FDA regulations. The sponsor should notify UM and the investigator when the records are no longer required. [ICH GCP] is a good resource regarding essential documents, retention, and audit. For studies involving children, records are to be retained indefinitely.

What if you leave the institution?

UMB Research and Development Policies and Procedures: Record Retention, Program Records

Faculty transfers

- Project records (non-clinical study data, etc.) generated at UMB are to be retained at UMB for at least the required retention period. The departing faculty member (with a signed agreement) may take copies of these records.
- Clinical study data must remain at UMB. Confidentiality provisions of the award as well as HIPAA regulations will generally prohibit the departing faculty member from retaining copies of these data.

Should records be kept forever?

FUNDER/

REGULATORY REQUIREMENTS

OPEN SCIENCE/

DATA SHARING

LEGAL REQUIREMENTS

AUDITS

PUBLIC TRUST

What are the risks with keeping records forever?

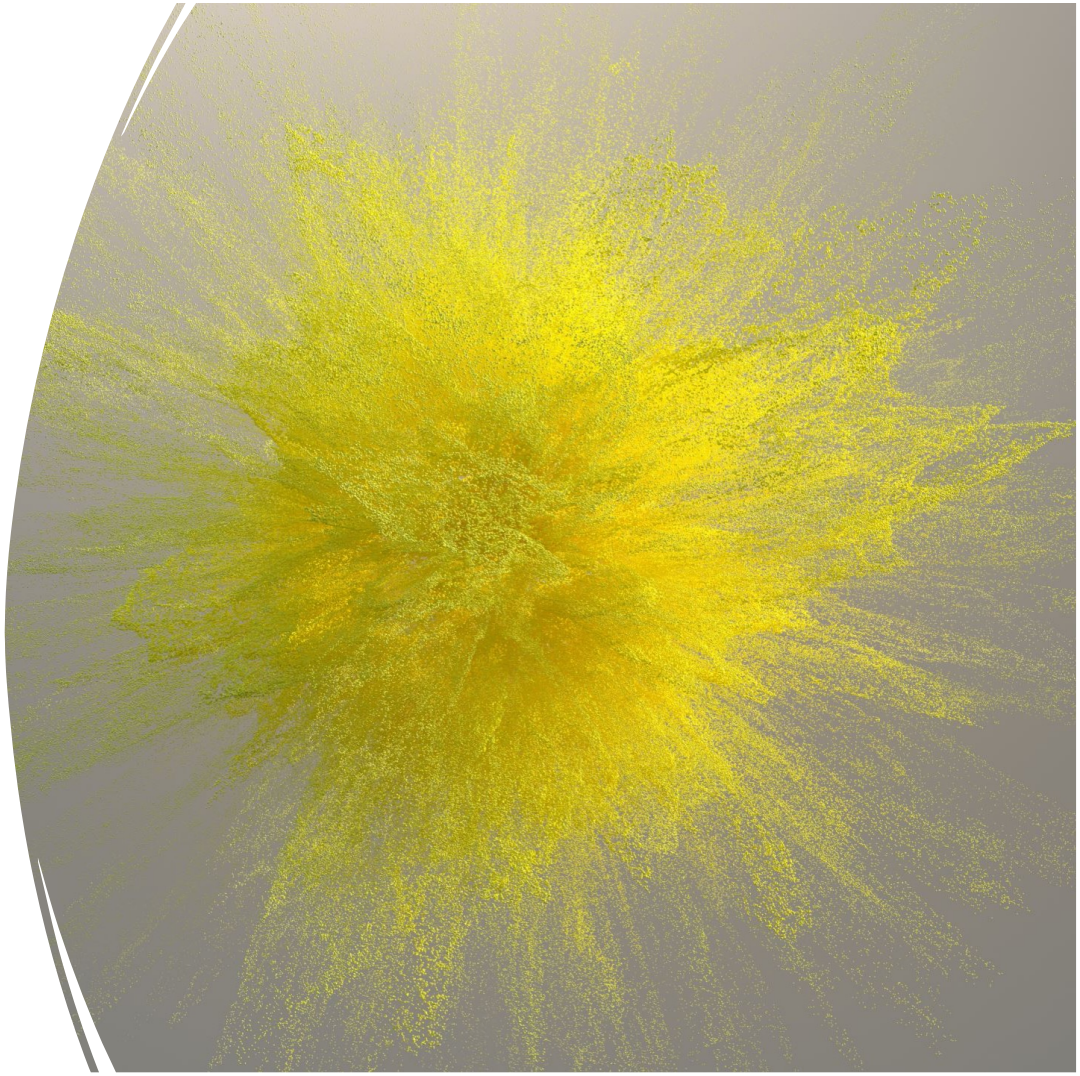
- Physical resources
- Fiscal resources
- Tech resources/advances
- Confidentiality
- Potential for audit

Best Practice: Records should not be retained longer than required

Poll:

What research records may be destroyed?

Research Record Destruction



CICERO Institutional Review Board Application

6 * Will any data be destroyed? [redacted]

◯ Yes ● No Clear

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

Who is responsible for record and/or storage device destruction?

1. Principal Investigator/Designee
2. Appropriate Information Technology (IT) Personnel
3. Department Leadership/Designee

Best practice: Have an SOP/DMP!

Keep these in Mind...

- Be aware of confidentiality and the inclusion of personal information in the records.
- Destroyed so there is no possibility of reconstructing the information.
- Appropriate methods for destroying different types of data records should be used.
  - Deleting a file does not destroy the data; it only deletes the filename from the directory.
  - Deletion of an electronic record may not eliminate all remnants of the record.

Best practice: document the destruction/sanitization

From UMMC policy 9367693 and OAC

Appropriate Methods for Destroying Paper and Microform Records

- Shredding using a cross-cut shredding device
- Burning
- Pulping
- Pulverizing

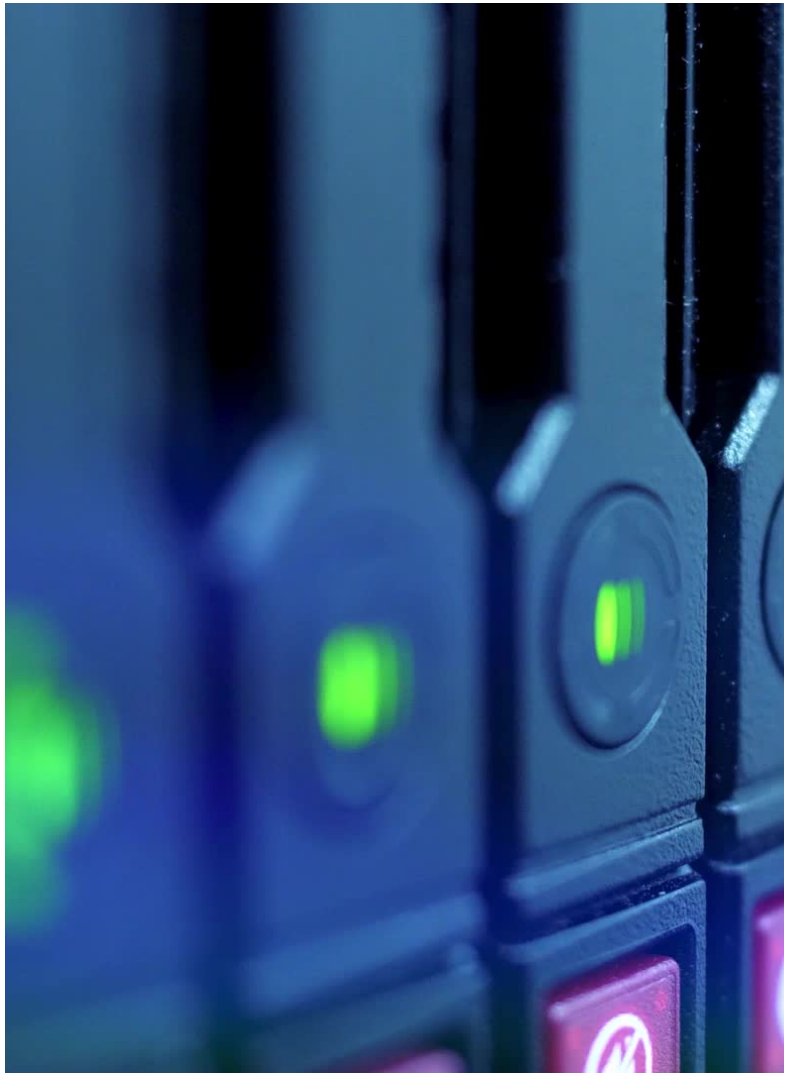
Appropriate Methods for Destroying Electronic Data Records

- Electronic data must be securely removed from any media device with electronic storage before the device is transferred or discarded.
- Electronic data can be securely removed from media devices using sanitation methods
  - Clear: Overwriting/rewrite data or reformatting the disk.
  - Purge: Incineration, shredding, disintegrating, degaussing, and pulverizing
  - Destroy (device): if not be reused

"Clear – Purge – Destroy“

Appropriate Methods for Destroying Electronic Media Devices

- Electronic media devices include copy/fax machines, hard drives, USB drives, mobile devices, etc.
- Destroying media devices with ePHI or sensitive data ("personal, confidential, legal, etc.) require special handling.
    - Considering whether the media device will be reused and/or leave the institution
- Specific, assigned Inventory Disposal Personnel are the key points of contact when disposing of Data Storage Devices.
    - Inventory Disposal Personnel assigned to that area should be contacted to assist with preparations



What About Deleting Research Records in the Medical Record?

What we have found so far:

Formal, documented information on research data removal from the EMR doesn't exist. UMB OAC recommends SOP for retention of research related data in the medical record.

Per Joanne Marshall, MS, BSN, RN, CHRC (UMMS Human Protections Administrator):

"scanned documents (e.g. the signed informed consent) are managed by UMMS Health Information Management (HIM) which can attach or remove the scanned documents from the Epic EMR"

Per EPIC:
Patient-study enrollments can be soft-deleted, meaning they can become available for an audit after the fact.
Studies can only be hard-deleted, so there will be no way to provide records if an audit occurs after the fact.

Deleting research records into workflows is not recommended because study related activities may have long-lasting contraindications that users should be aware of.

There are no documented "best-practices" around record deletion because we [EPIC] don't recommend it. It should only be done out of necessity.

Main Take-Away

Funders and regulators hold the weight behind retention and destruction rules, however, additional considerations for data management plan and ethics:

- ❑Publishers
- ❑Repositories
- ❑Participants

Other Take-Aways

"Records" includes any documentary material made or received in connection with the application for, or conduct of, a sponsored activity.

Research records should be kept for the longest period required.

- Often 7 years unless otherwise specified by the funder (e.g., FDA or VA)
- Some records should not be destroyed (clinical study data that is part of a permanent record)

Eventual record destruction is advised, so develop a data management plan (DMP) early

- Administrative burden, expense, institutional audits for any retained data records

When destroying data records...

- Be aware of the inclusion of personal information
- Select the most appropriate methods of destruction based on the record type
- Coordinate with Inventory Disposal Personnel regarding media storage devices containing sensitive data
- Keep a log

The PI is responsible for adhering to record retention and destruction guidelines and requirements, but should advise with appropriate personnel on document destruction decisions

- **NIST:** https://csrc.nist.gov/publications/detail/sp/800-88/rev-1/final
- **HHS:** https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
- **FDA:** https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
- **GCP:** PDF ICH-E6 Good Clinical Practice (GCP)
- **UMB:**
  - https://www.umaryland.edu/spa/policies-and-procedures/record-retention/
  - https://www.umaryland.edu/spa/policies-and-procedures/record-retention/discarding-and-destroying-records/
  - https://www.umaryland.edu/policies-and-procedures/library/information-technology/information-technology-procedures/umb-procedure-for-disposal-of-media-containing-sensitive-data.php
    - X-99.08(A) UMB Policy on Disposal of Media Containing Data
  - https://www.umaryland.edu/hrp/for-researchers/investigator-manual/
- **UMMC:**
  - UMMC Midtown PolicyStat ID 9367693
  - UMMC Downtown PolicyStat ID 8261108

Contacts

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Thank You!

Questions?