

Clinical Research Education Series

08/11/2023

Accreditation

The University of Virginia School of Medicine and School of Nursing designates this live activity for a maximum of **1.0 AMA PRA Category 1 Credits**.™

Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The University of Virginia School of Medicine and School of Nursing awards **1.0 contact hour** for nurses who participate in this educational activity and complete the post activity evaluation.

The University of Virginia School of Medicine and School of Nursing awards **1.0 hour of participation** (consistent with the designated number of *AMA PRA Category 1 Credit(s)*™ or ANCC contact hours) to a participant who successfully completes this educational activity. The University of Virginia School of Medicine and School of Nursing maintains a record of participation for six (6) years.

Disclosures

The speaker, Caroline Walters, has no personal or professional financial relationships with a commercial entity producing healthcare goods or services.

The planning committee members, Katie Rea, MSCR, BSN, RN, CCRC; Lori Elder, RN, BSN, CCRA; Kimberly Underwood, BS, CCRC; and Maria Davenport, MPH, CCRP; have no personal or professional financial relationships with a commercial entity producing healthcare goods or services.

Activity Code: **148330**

CLINICAL TRIAL RECORDS MANAGEMENT

Caroline J. Walters, CRM
University Records Officer
Records & Information Management
University of Virginia



AGENDA

UVa Records Management Policy

Virginia Public Records Act

Clinical Trial Records Retentions

Records Storage

University Records Management Application (URMA)

Records Management Office Services

Questions?



UVA RECORDS MANAGEMENT POLICY

<https://policy.itc.virginia.edu/policy/policydisplay?id=IRM-017>

- Comply with retention and disposition per the Virginia Public Records Act.
- Store physical records in compliance with the Physical Records Storage Standards.
- Store electronic records in compliance with the Institutional Data Protection Standards.
- Complete Certificates of Records Destruction (RM3) – approval for destruction as required by the Virginia Public Records Act.

UNIVERSITY RECORD

Recorded information that documents a transaction or activity by or with any appointed board member, officer, or employee of the University. Regardless of physical form or characteristic, the recorded information is a University Record if it is produced, collected, received or retained in pursuance of law or in connection with the transaction of university business. The medium upon which such information is recorded has no bearing on the determination of whether the recording is a University Record.

VIRGINIA PUBLIC RECORDS ACT

§ 42.1-86.1. Disposition of public records.

A. Before destroying records, confirm:

- the retention period in the records retention schedule has expired;
- permission is obtained from the agency's records officer;
- there are no pending issues (audit, legal, FOIA).

B. DO NOT DESTROY IF:

- Document is dated or known to have been created before 1912.

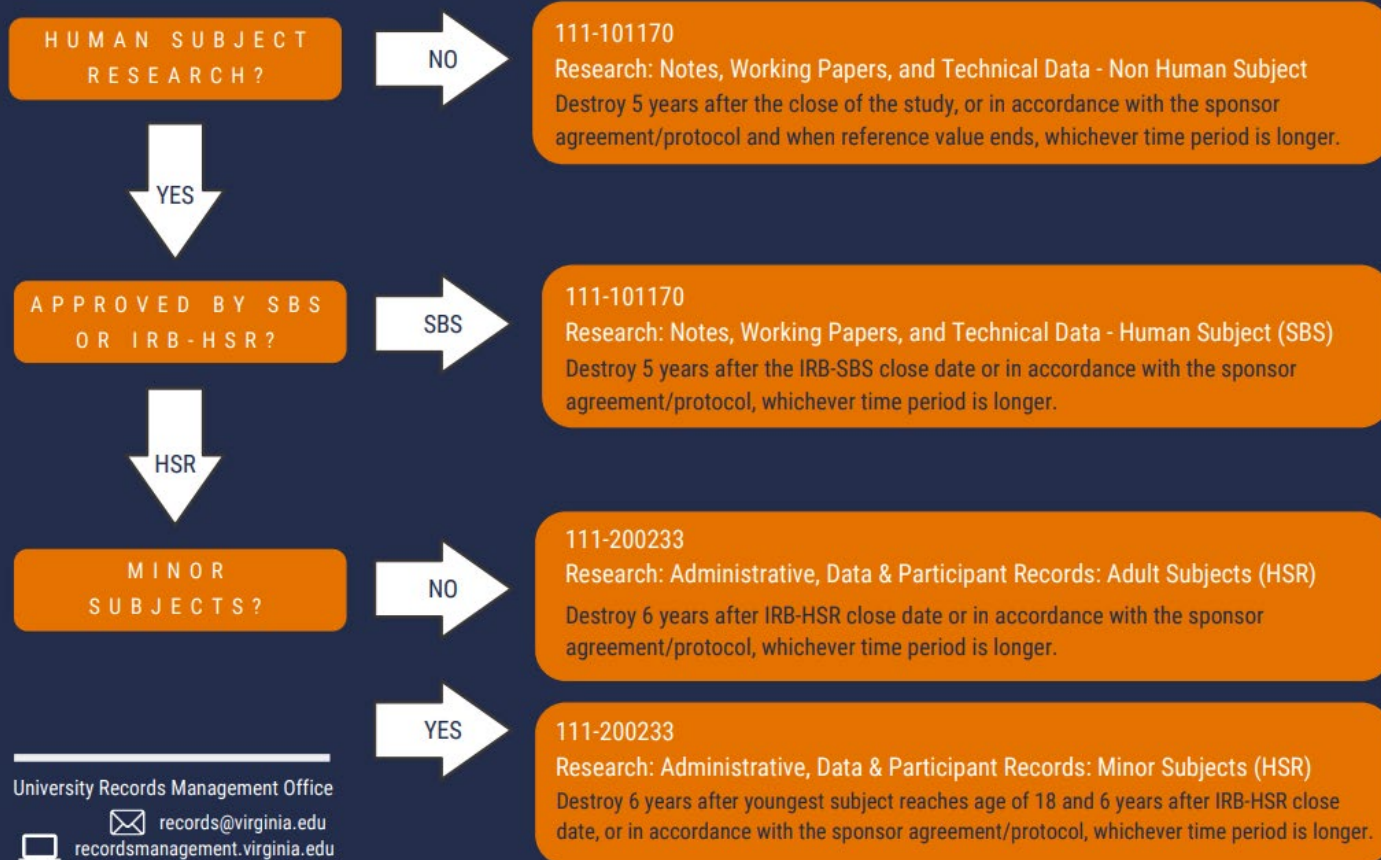
VIRGINIA PUBLIC RECORDS ACT

§ 42.1-86.1. Disposition of public records.

C. Records should be destroyed within :

- A timely manner (12 months) of the expired retention period,
- Or within 6 months of the expired retention period if the records contain “personal identifying information.”

Research Records Classification



CLINICAL TRIAL PROJECTS - ADULTS (111-200233)

Record Series Name: Research: Administrative, Data & Participant Records: Human Subjects - Adult Subjects (HSR)

Record Series Description: Includes all administrative records such as contracts, agreements, correspondence, protocols, and IRB approvals, and data such as collection tools, data sets, participant information, and consents, related to the data collection and management of adult human subject research approved by IRB-HSR.

Disposition Description: Destroy 6 years after IRB-HSR close date or in accordance with the sponsor agreement/protocol, whichever time period is longer.

CLINICAL TRIAL PROJECTS - MINORS

(111-200233)



Record Series Name: Research: Administrative, Data & Participant Records: Human Subjects - Minor Subjects (HSR)

Record Series Description Includes all administrative records such as contracts, agreements, correspondence, protocols, and IRB approvals, and data such as collection tools, data sets, participant information, and consents, related to the data collection and management of minor human subject research approved by IRB-HSR.

Disposition Description: Destroy 6 years after IRB-HSR close date and date youngest subject reaches age 18, or in accordance with the sponsor agreement/protocol, whichever time period is longer.

UNFUNDED CLINICAL TRIALS (111-200232)

Research proposals denied or not funded.
Includes proposals, drafts, budgets, and all
information and working papers in the
preparation of the proposal, including final
correspondence.

Destroy 1 year after notification of denial and
when reference value ends.



RESEARCH FINANCIAL RECORDS (111-101168)

Contract and Grant Funds (includes financials for clinical trials)
managed via OSP

- Destroy 5 closed fiscal years after the end date or the contract/grant, or as stipulated in agreement/protocol.

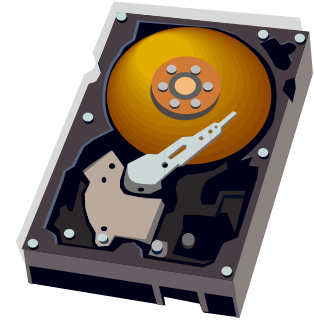
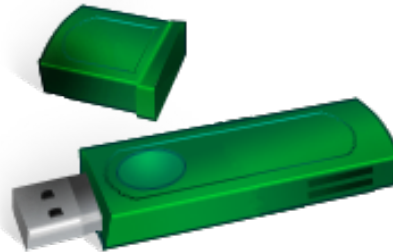
Accounts Payable
Accounting Reports
Cash (Settlements)
Checking & Checks
Purchase Orders

Receiving Reports
Accounts Receivable
Bank Records
Cash Deposits
Credit Card Receipts

ELECTRONIC RECORDS

Retention time periods are the same for electronic and paper records.

Do not retain electronic records beyond the retention periods in the schedules.



WHERE TO STORE?

All formats

- Must meet requirements for the storage of highly sensitive data.
- Must be accessible during the entire retention period.

Electronic

- May need some action during retention period – migration, reformatting, etc.

Paper

- Needs to meet RIM Storage Standards:
<https://recordsmanagement.virginia.edu/physical-records-storage>

UVA MANAGED STORAGE - PHYSICAL

RECORDS & INFORMATION MANAGEMENT

[Home](#)[About +](#)[Services +](#)[Records Retention & Disposition +](#)[Records Storage +](#)[URMA +](#)[Training & Reso](#)

Records Storage

[Overview](#)[Physical Records Storage](#)[Electronic Records Storage](#)[> Off-Site Storage Vendor](#)[Services & Pricing](#)[Create a Storage Account](#)[Prepare Records for Storage](#)[Transfer Records to/from Storage](#)[Submit a Scan-On-Demand Request](#)[Ordering Boxes](#)[HOME](#) / [RECORDS STORAGE](#) / [OFF-SITE STORAGE VENDOR](#)

Off-Site Records Storage

The University has an agreement with [Patterson Pope](#) for off-site storage of paper and other physical records. This vendor meets UVA's [Physical Records Storage Standards](#) for off-site locations.

The Records & Information Management Office serves as an intermediary with the vendor by coordinating the pick-up and delivery of boxes as well as final disposition (typically destruction) once records have met retention.

Users must have an [URMA account](#) to use off-site storage. Departments must have an account with the vendor and make payments monthly using a University travel and expense card.

For information on Medical Center records storage, contact the [UVA Health Records Management office](#).



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CLOSED STUDIES: ORGANIZE AND STORE

Take stock of what you have

Determine retention

- Don't know how? Ask RM!
- Retention met? Destroy with RM3!
- Not yet? Box it up!

Enter into University Records Management Application (URMA)

Send boxes to storage

CURRENT/FUTURE STUDIES: PLAN AHEAD!

Budget for storage costs

- Offsite storage vendor costs:
<https://recordsmanagement.virginia.edu/services-pricing>
- If possible, build projected costs into contract

Gather critical info at closeout

- Confirm retention requirements
- Enter all into URMA

UNIVERSITY RECORDS MANAGEMENT APPLICATION URMA

- Track storage of both physical and electronic records.
- Manage storage of physical records with storage vendors.
- Records connected to the department, not the person.
- URMA let's you know when records have met retention.
- Completes the destruction approval process (RM3 Form) online.
- Manages legal holds on records in storage.
- Provides more functionality to search records retention and disposition schedules.

BEFORE USING URMA

RECORDS & INFORMATION MANAGEMENT

[Home](#)[About +](#)[Services +](#)[Records Retention & Disposition +](#)[Records Storage +](#)[URMA +](#)

URMA

Overview

> Account Creation

New to URMA

Instructions & Guidance

Login to URMA

[HOME](#) / [URMA](#) / [ACCOUNT CREATION](#)

Create an Account

To use URMA you must first do the following:

1. Complete [Records & Information Management Basics](#), available in Workday.
2. Submit the [URMA Supervisor Authorization Form](#). The request will be emailed to your supervisor, who must review the information and reply to RIM indicating approval.
3. Attend a virtual URMA one-on-one training session with RIM staff.



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URMA



 Home  Preferences  Labels  Reports  Requests  Admin  Dashboard  Help  Print

 Records Series  Users  Records  Disposition Notices  Locations  Files  Shelves  Legal Holds

 Organizations  Research Projects  Research Sponsors  Attachments

Records Barcode

Organization

Primary Contact

Vendor Barcode

Legacy Box Number

Description of Records

Scheduled Destruction Date

(Rollover for Current Search)

Page 1 [\[2 \]](#) [\[3 \]](#) [\[4 \]](#) [\[5 \]](#) [\[6 \]](#) | Jump to Page:  The search found 510 Records

☐

Record Quick Description

☐

0000279127 - Research: Administrative, Data & Participant Records: Human Subjects - Adult Subjects (HSR) [CC1101 - MD-OBGY Ob & Gyn-Admin (40860): 

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0000279126 - Research: Administrative, Data & Participant Records: Human Subjects - Adult Subjects (HSR) [CC1101 - MD-OBGY Ob & Gyn-Admin (40860): 

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0000279125 - Research: Administrative, Data & Participant Records: Human Subjects - Adult Subjects (HSR) [CC1101 - MD-OBGY Ob & Gyn-Admin (40860): 

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0000279124 - Research: Administrative, Data & Participant Records: Human Subjects - Adult Subjects (HSR) [CC1101 - MD-OBGY Ob & Gyn-Admin (40860): 

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0000279123 - Research: Administrative, Data & Participant Records: Human Subjects - Adult Subjects (HSR) [CC1101 - MD-OBGY Ob & Gyn-Admin (40860): 

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0000279122 - Research: Administrative, Data & Participant Records: Human Subjects - Adult Subjects (HSR) [CC1101 - MD-OBGY Ob & Gyn-Admin (40860): 

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0000279121 - Research: Administrative, Data & Participant Records: Human Subjects - Adult Subjects (HSR) [CC1101 - MD-OBGY Ob & Gyn-Admin (40860): 

BEFORE STORAGE

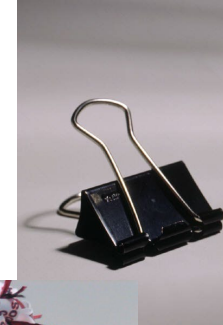
Order standard records storage boxes (10"x 15" x 12")

Remove:

- Binders
- Binder clips
- Hanging files
- Plastic sleeves

Create inventory by file for each box

Use URMA Clinical Trial entry form



RIM ONLINE RESOURCES

RECORDS & INFORMATION MANAGEMENT

[Home](#)[About +](#)[Services +](#)[Records Retention & Disposition +](#)[Records Storage +](#)[URMA +](#)

Training & Resources

[Events Schedule](#)[General Records Management](#)[Electronic Records](#)[Email](#)[> Research Records](#)[Leaving the University](#)

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Research Records

Research records generally require approval from the sponsor before they can be destroyed. RIM recommends using the [University Records Management Application \(URMA\)](#) to track the location and retention of research records.

- [Research Records Classification](#) (flowchart)
- [Managing Research Records](#) (Workday course)

URMA

- [Research Records Inventory Form \(Data and Participant Records\)](#) (fillable form)

NEED HELP?

Records & Information Management to the rescue!

- Website: recordsmanagement.virginia.edu
- Email us: records@virginia.edu
 - Department/School training sessions
 - Site visits
 - URMA one-on-one training





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