

Research Records Management

SOP SD-005

VA Northeast Ohio Healthcare System
Cleveland, Ohio 44106

Service Line(s):
Research Service

Signatory Authority:
Neal Peachey, Ph.D. ACOS/Research

Effective Date:
July 7, 2022

Responsible Owner:
Program Specialist Policy and
Education

Recertification Date:
July 7, 2027

1. PURPOSE AND AUTHORITY

a. The purpose of this standard operating procedure (SOP) is to describe requirements and procedures for storage and disposition of research records.

b. This SOP sets forth mandatory procedures and processes to ensure compliance with VHA Records Control Schedule 10-01, January 2021.

2. PROCEDURES:

a. How to Identify Records

(1) If you answer “yes” to any of these questions, you may have a record:

- (i) Was it created while conducting business (e.g., correspondence, agreements, studies, etc.)?
- (ii) Was it received for action (e.g., FOIA requests, controlled correspondence, grant applications, etc.)?
- (iii) Does it document VA activities and/or actions (e.g., calendars, meeting minutes, project reports, etc.)?
- (iv) Is it mandated by statute or regulation (e.g., administrative records, dockets, etc.)?
- (v) Does it support financial obligations or legal claims (e.g., contracts, litigation case files, IPAs, etc.)?

(2) If you answer “yes” to any of these questions, you may have a non-record:

- (i) Is it reference material (e.g., vendor catalogs, phone books, technical journals, etc.)?
- (ii) Is it a convenience copy (e.g., duplicate copies of correspondence or directives, etc.)?
- (iii) Is it a stock copy (e.g., VA publications, etc.)?
- (iv) Is it a draft or working copy (e.g., draft with no substantive comments, rough notes, calculations, etc.)?

July 7, 2022

PLEASE NOTE: Some drafts are needed to support the decision trail or are required by a records schedule.

(3) If you answer “yes” to this question, you may have a personal paper:

(i) Is it only related to your own affairs (e.g., soccer schedule, PTA roster, restaurant menus, etc.)?

PLEASE NOTE: Personal planners and calendars might be records if they document your activities for the VA.

b. Record Storage

(1) Mobile devices and hard copies of VASI. These must be stored securely when not in use. Mobile devices and hard copies of VASI must be secured behind two locks. Examples of secure storage when not in use would include locking mobile devices and/or VASI in cabinets or drawers within a locked room. Examples of mobile devices include digital recorders, iPods, smartphones, etc. Hard copies of VASI includes cassettes tapes, VHS tapes, glass slides, memory cards, floppy disks, CDs/DVDs, zip discs, etc.

(2) Electronic records. Electronic records must be stored on approved servers. Electronic records include all committee/subcommittee correspondence, project related information and/or data, amendments/modifications, case report forms, databases, excel spreadsheets, etc.

c. Record Retention Requirements

(1) Accreditation records.

(i) Records related to acquiring and maintaining accreditation for components of the facility's research program. The accreditations are for such components as the HRPP and the animal research program. Records include, but are not limited to, initial and renewal applications; annual and interim reports; tracking of accreditation visits and outcomes; and correspondence to/from the Accrediting Organization.

(ii) **Destruction is allowed 2 years after the cutoff.** For these types of records, cutoff is at the end of the fiscal year in which the accreditation cycle ends.

(2) Committee/Subcommittee files for Approved projects.

(i) Research Review Committee and Subcommittee Protocol Files
Committee and subcommittee files related to the review and oversight of research protocols submitted by VA investigators for research conducted at the field facility. The committees and subcommittees include, but are not limited to, the Research & Development (R&D) Committee, the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), the Subcommittee on Research Safety, and the Institutional Biosafety Committee. Records include, but are not limited to, the application to the VA Central IRB; research protocol and amendments; case report forms; reports of adverse events, complaints, and deviations from the approved protocol; data and safety monitoring reports; research findings to date; and all relevant documents and related correspondence between the committee and the investigators in the review of an associated protocol.

(ii) **Destruction is allowed 6 years after cutoff.** For these types of records, cutoff is at the end of the fiscal year in which the research project has been finalized or

July 7, 2022

terminated.

(3) Committee/Subcommittee files for Disapproved or Withdrawn projects.

(i) Protocols Disapproved by the Committee or Subcommittee or Withdrawn by the Investigator

Committee and subcommittee files related to the review of research protocols submitted by VA investigators for research that was disapproved by the committee or subcommittee or was withdrawn by the investigator, committee, or subcommittee. The committees and subcommittees include, but are not limited to, the Research & Development (R&D) Committee, the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), the Subcommittee on Research Safety, and the Institutional Biosafety Committee. Records include, but are not limited to, the application to the VA Central IRB; research protocol and amendments; case report forms; and all relevant documents and related correspondence between the committee\subcommittee and the investigators in the review of an associated protocol.

(ii) **Destruction is allowed 3 years after cutoff.** For these types of records, cutoff is at the end of the fiscal year in which the research project has been disapproved or withdrawn.

(4) Committee/Subcommittee Membership files.

(i) Records include, but are not limited to, membership rosters, appointment letters, curriculum vitae, training records, meeting minutes and related documentation.

(ii) Destruction is allowed 6 years after cutoff. For these types of records, cutoff is at the end of the fiscal year in which final action occurred, including expiration, or when superseded.

(5) Committee/Subcommittee Operations files.

(i) Records include, but are not limited to, agreements by VA facilities to use a review committee or subcommittee from the affiliated university or other entity; standard operating procedures, policies, and educational materials; documents assessing the effectiveness of the review committees or subcommittees and compliance with all regulatory requirements; and related correspondence not related to specific protocols received or created during VA Central IRB operations.

(ii) **Destruction is allowed 3 years after cutoff.** For these types of records, cutoff is at the end of the fiscal year in which final action, expiration, or when superseded.

(6) Investigator's Records.

(i) Research records maintained by the investigator that span the entire lifecycle of the project and the records required by regulations such as the investigator's regulatory file. Records include but are not limited to research protocol and all amended versions of the protocol; grant application; review committee correspondence (e.g., Institutional Review Board, Institutional Animal Care and Use Committee, Research & Development Committee) including documents approved by the review committees.

1. correspondence with ORD, regulatory entities, sponsor and/or funding source, correspondence.

July 7, 2022

2. case report forms and supporting data (including, but not limited to, signed and dated informed consent forms and HIPAA authorization forms).
3. documentation on each subject including informed consent, interactions with subjects by telephone or in person, observations, interventions, and other data relevant to the research study.
4. data collected during the research including photos, video recordings, and voice recording, all derivative data, and derivative databases.
5. list of all subjects entered in the study and the crosswalk connecting the subjects name with the code used for each subject.
6. subject compensation records.
7. reports of adverse events, complaints, and deviations from IRB-approved protocol.
8. data analyses.
9. codes and keys used to de- identify and re-identify subjects' PHI.
10. reports (including, but not limited to, abstracts and other publications).
11. research study correspondence not involving Office of Research and Development (ORD), Office of Research Oversight (ORO), sponsor, or funding source.
12. correspondence and written agreements with the funding source or sponsor, ORD and applicable oversight entities such as IRB, Research and Development (R&D) Committee, ORO, VA Office of Human Research Protections (OHRP) and FDA.
13. signed and dated forms submitted to regulatory agencies.
14. investigator's brochure.
15. records related to the investigational drugs such as drug accountability records.
16. monitoring and audit reports such as Data Safety Monitoring Board Reports and audits by oversight entities.
17. documents related to budget and funding; and
18. other forms required by policy and regulation.

PLEASE NOTE: If the investigator leaves the VA, all research records are retained by the VA facility where the research was conducted. If the grant is ongoing and the investigator leaves one VA facility to go to another VA facility, the investigator must obtain approval for a copy of relevant materials to be provided to the new VA facility's research office. The investigator is not the grantee, nor does the investigator own the data.

(ii) **Destruction is allowed 6 years after cutoff.** For these types of records, cutoff is at the end of the fiscal year in which the research project was finalized by the last of all approving committees and/or subcommittees of oversight for the study.

(7) Local publications.

(i) Copies of publications resulting from funded and approved research activities.

July 7, 2022

(ii) **Destruction is allowed 6 years after the cutoff.** For these types of records, cutoff is at the end of the fiscal in which after publication.

(8) Research Administration Office files.

(i) This section covers records relating to the administration of intramural research programs and conduct of individual research projects at VA field facilities, some of which are funded by VA research appropriation. The research programs at each VA field facility are a decentralized program under the facility's direction. Policies for the administration of research programs and conduct of research are set by ORD.

(ii) **Destruction is allowed 6 years after the cutoff.** For these types of records, cutoff is the end of the fiscal year in which final action or when superseded.

(9) Veterinary Medical Unit Files.

(i) Records include, but are not limited to, sanitation records, daily room checks, feed/bedding invoices, temperature tapes (for the cage washes and autoclaves), health surveillance reports, HVAC performance data, cage cards, mortality reports, pest control reports, animal order invoices, quality assurance records and related documentation.

(ii) **Destruction is allowed 3 years after the cutoff.** For these types of records, cutoff is at the end of the fiscal year in which final action occurred.

(10) Biosafety Program files.

(i) Records related to research laboratory inspections, emergency response planning, information on chemicals or other hazardous substances, inventory of chemicals and other agents in use in research laboratories, and laboratory safety and security policies.

(ii) **Destruction is allowed 3 years after the cutoff.** For these types of records, cutoff is at the end of the fiscal year in which final action.

d. Archiving

(1) Hard copy records. PIs or their designees may archive their records using the following process:

- (i) ordering archive boxes from the Research Records Management Liaison
- (ii) packing records in properly labeled boxes, according to instructions provided by the Records Management Liaison
- (iii) completing a content sheet for each box that lists the PI's name, study number, and a description or listing of the contents.
- (iv) coordinating with the Research Records Management Liaison for pickup of boxes.

(2) The Records Management Liaison will return a copy of the Archiving Request Form with the location and naming convention of the archived boxes to the requestor.

3. ASSIGNMENT OF RESPONSIBILITIES

July 7, 2022

e. The **Associate Chief of Staff /Research and Development (ACOS/R&D) or designee** is responsible for:

(1) ensuring appropriate documentation of all research records stored at the VANEOHS records management program.

(2) ensuring that all research committee and other Research Administration Office records are retained in accordance with VHA's RCS 10-1.

f. The **Facility Records Officer** is responsible for implementing and managing the VANEOHS records management program.

c. The **PI** is responsible for:

(1) storing their electronic and hard copy research records securely, in accordance with the VHA's RCS 10-1, VA regulations and any applicable research committee/subcommittee approval(s).

(2) maintaining their records for any closed study until it has been audited as required by the Research Compliance Officer (i.e., at least once every 3 years, even if open less than 3 years) before preparing the records for archiving.

(3) sending a list of human subjects or a code key to the ACOS/R&D or designee at the time of IRB-approved study closure when the study team would like to continue with de-identified data analysis.

(4) contacting the Research Records Management Liaison to coordinate archiving of closed studies (after the final RCO audit is complete); and

(5) contacting the Research Records Management Liaison in the event of a need to retrieve any records from archiving.

d. The **Records Management Liaison for R&D** is responsible for:

(1) maintaining and updating the aggregated file plans for R&D Service.

(2) providing the archive tracking spreadsheet template to individuals requesting to archive.

(3) providing guidance documents on how to archive.

(4) ordering, when necessary, and providing archive boxes to requesting individuals.

(5) documenting and tracking the location of archive boxes.

(6) responding to information requests from the Facility Record's Management Officer.

(7) attending any meetings at the facility or national level regarding records management for R&D Service.

4. DEFINITIONS

a. **Record:** Recorded information can be in any format and is: 1) created during business; 2) received for action; or 3) needed to document VA activities.

b. **Record Keeping System:** A system, paper-based or electronic, that: 1) collects,

July 7, 2022

organizes,

c. **Records Control Schedule:** A document that describes a group of records and mandates: 1) how long the records are kept (retention); and 2) what happens to them at the end of the time (disposition).

d. **VA Sensitive Information and Data.** VA sensitive data means all VA Data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information and includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, and records about individuals requiring protection under applicable confidentiality provisions VHA Directive 1200.01 (see 38 U.S.C. 5727)

5. REFERENCES

[VA Directive 6500](#), “Managing Information Security Risk: VA Information Security Program.”

[VHA Directive 6300](#), “Records Management”.

[VA ORO Guidance](#), “Compliance Oversight Procedures for Use and Storage of VA Sensitive Research Information”

[Records Control Schedule 10-1 \(va.gov\)](#)

6. REVIEW

At recertification or when there are changes to the governing documents.

7. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of July 7, 2025. In the event of contradiction with national policy, the national policy supersedes and controls.

8. SIGNATORY AUTHORITY

Neal Peachey
Associate Chief of Staff/ Research
Date Approved: July 21, 2022

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: This will be posted on the Research website:
<https://www.clevelandvaresearch.org/>