RESEARCH RECORDS MANAGEMENT

1. **POLICY:** All research records must be securely stored until their applicable disposition date, as per the disposition instructions approved by the National Archives and Records Administration (NARA) and published in VHA's Records Control Schedule (RCS) 10-1. This includes all research field facility records, including investigator's records and committee and subcommittee review records for basic, animal and human research.

   The NARA maintains secure storage at Federal Records Centers (FRCs) of all federal records that are no longer in active use but that must be stored until destruction is allowed, based on the VHA's RCS 10-1. The Seattle FRC serves the VA Portland Health Care System (VAPORHCS).

2. **DEFINITIONS:**
   a. **File Plan:** A document that lists all of the records that are part of a Principal Investigator's (PI's) research program and/or the Research and Development program, and describes: 1) how they are organized (file structure); and 2) how they are maintained (procedures).
   b. **Record:** Recorded information can be in any format, and is: 1) created in the course of business; 2) received for action; or 3) needed to document VA activities.
   c. **Record Keeping System:** A system, paper-based or electronic, that: 1) collects, organizes and categorizes records; and 2) facilitates their preservation, retrieval, use and disposition.
   d. **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 period (disposition).
   e. **VA Sensitive Information (VASI):** All 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. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the HIPAA Privacy Rule, and information that can be withheld under the Freedom of Information Act. Examples of VA sensitive information include the following: individually-identifiable medical, benefits, and personal information; VA personnel information; financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, investigatory, and law enforcement information; information that is confidential and privileged in litigation such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege; and other information which, if released, could result in violation of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of federal programs. **PLEASE NOTE:**

Data which is de-identified (as defined in VHA Handbook 1605.1, Appendix B) is not VA Sensitive Information.

3. **RESPONSIBILITIES:**
   a. The **VA Portland Health Care System Director** is responsible for the contract, expense and storage of all research records in accordance with the RCS 10-1.

   b. The **Associate Chief of Staff /Research and Development (ACOS/R&D) or designee** is responsible for:
      (1) maintaining appropriate documentation of all research records shipped and stored at the Seattle FRC; and
      (2) ensuring that all research committee and other Research Administration Office records are retained in accordance with VHA's RCS 10-1.

   c. The **Facility Records Manager** is responsible for:
      (1) completing and submitting the Standard Form (SF) 135 (http://www.archives.gov/frc/forms/sf-135-intro.html) for approval to the Seattle FRC;
      (2) completing a bill of lading and arranging for shipping to FRC in Seattle after confirmation of receipt of the SF-135;
      (3) contacting Seattle FRC with instructions for destruction of records, when applicable; and
      (4) contacting Seattle FRC for record retrieval, when needed.

   d. 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) requesting new folders be created on the Research network server for all new studies that will accumulate electronic documents (to include regulatory documents, committee and/or subcommittee correspondence, etc.) and research data;
      (3) creating and annually updating a file plan;
      (4) 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;
      (5) 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;
      (6) contracting the Research Records Management Liaison to coordinate archiving of closed studies (after the final RCO audit is complete); and
      (7) contacting the Research Records Management Liaison in the event of a need to retrieve any records from archiving.

   e. 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) coordinating the shredding and off-site storage of archive boxes for R&D Service; and

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

4. **PROCEDURES:**

   a. **How to Identify Records**

   (1) If you answer "yes" to any of these questions, you may have a <u>record</u>:

     (i) Was it created in the course of 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 <u>non-record</u>:

     (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.)?

   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 <u>personal paper</u>:

     (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 actually be records if they document your activities for the VA.

   b. **Record Storage**

(1) <u>Mobile devices and hard copies of VASI</u>. 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) <u>Electronic records</u>. Electronic records must be stored on the committee and/or subcommittee approved network server with access restricted to only those individuals that have committee and/or subcommittee approval to work on the study and see study related information and data. Electronic records includes all committee/subcommittee correspondence, project related information and/or data, amendments/modifications, case report forms, databases, excel spreadsheets, etc.

c. **Record Retention Requirements**

(1) <u>Accreditation records</u>.

(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) <u>Committee/Subcommittee files for Approved projects</u>.

(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 terminated.

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

(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) <u>Committee/Subcommittee Membership files</u>.

(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) <u>Committee/Subcommittee Operations files</u>.

(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 the course of 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) <u>Investigator's Records</u>.

(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:

1. 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;

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

3. case report forms and supporting data (including, but not limited to, signed and dated informed consent forms and HIPAA authorization forms);

4. 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;

5. data collected during the research including photos, video recordings, and voice recording, all derivative data, and derivative databases;

6. list of all subjects entered in the study and the cross-walk connecting the subjects name with the code used for each subject;

7. subject compensation records;

8. reports of adverse events, complaints and deviations from IRB-approved protocol;

9. data analyses;

10. codes and keys used to de- identify and re-identify subjects' PHI;

11. reports (including, but not limited to, abstracts and other publications);

12. research study correspondence not involving Office of Research and Development (ORD), Office of Research Oversight (ORO), sponsor, or funding source;

13. 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;

14. signed and dated forms submitted to regulatory agencies;

15. investigator's brochure;

16. records related to the investigational drugs such as drug accountability records;

17. monitoring and audit reports such as Data Safety Monitoring Board Reports and audits by oversight entities;

18. documents related to budget and funding; and

19. 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.

(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 (RODAC plates, ADP tests, etc.) 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; by completing an Archiving Request Form to be submitted to the Records Management Liaison

(ii) retrieving requested number of archive boxes from the Records Management Liaison

(iii) packing records in properly labeled boxes, according to instructions provided by the Records Management Liaison upon submission of Archiving Request Form

(iv) completing a content sheet for each box that lists the PI's name, study number, and a description or listing of the contents;

(v) delivering labeled boxes, with the appropriately completed content sheet, to the Records Management Liaison in the Research Administration Office.

(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.

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"

VHA Record Control Schedule (RCS 10-1)

6. **CONCURRENCES:** Endorsed by the R&D Committee, 09/16/2016.

7. **FOLLOW-UP RESPONSIBILITY**: ACOS/R&D

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