

SUBJECT: Research Data Requirements

1. PURPOSE:

This SOP establishes the procedures for storing, archiving, and disseminating data from VA-approved research projects.

2. DEFINITIONS:

PI: Principal Investigator

R&D: Research and Development

PHI/PII: Protected Health Information/Personally Identifiable Information as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191

Data: Any information (hard copy or electronic) collected or generated as part of a VA-approved research project for purposes of scientific study and/or analysis, including but not limited to primary (raw) data, de-identified data, and data generated by analysis/meta-analysis of other information sources.

DMAP: Data Management & Access Plan

3. OVERVIEW:

Data generated in the course of VA studies falls under multiple requirements intended to ensure integrity of research data, accessibility to the public, and privacy for study participants. These include:

- a) Executive Order 13642 (Making Open and Machine Readable the New Default for Government Information) established an Open Data Policy (Office of Management and Budget Memorandum M-13-13) requiring a system of tracking and disseminating data generated by Federally-funded institutions such as the VA.
- b) The VA Office of Research and Development (ORD) requires a Data Management and Access Plan (DMAP) for each study protocol and/or VA-funded grant.
- c) VHA Handbook 1200.19 requires that VA investigators comply with NIH Open Access rules for all peer-reviewed publications, without exception.
- d) National Archives and Records Administration (NARA) Records Schedule DAA-0015-2015-0004 sets minimum time frames for retention of data and records collected during the course of a VA research project.

The procedures outlined below are intended to aid in understanding and adhering to these requirements.

4. PROCEDURES:

- a) **Data Management & Access Plan (DMAP):** When submitting a grant proposal to the VA Office of Research & Development, or when filing a new study protocol for an unfunded or non-VA funded study, PI must include a Data Management & Access Plan.
 - i) DMAPs for VA-funded studies are reviewed and approved by ORD, and should use the ORD DMAP template.
 - ii) DMAPs for unfunded or non-VA funded studies are reviewed and approved by the local Research Office, and should use the Non-VA DMAP template.

- iii) All research protocols that are tied to the same project (funding source) can use the same DMAP form. For example, all unfunded protocols from one PI can use a common DMAP.
- b) **Data Format:** Whenever possible, primary data should be collected and maintained in an electronic format to facilitate indexing and dissemination of data.
 - i) Records that are collected in hard copy should be digitized unless doing so would conflict with other Federal regulations (e.g., FDA, NIH) or contract/agreement with outside institutions and/or study sponsors (such as patient signatures on FDA-approved trials).
 - ii) Records that cannot be digitized (due to regulations or volume of records) must be maintained on site at the MVAHCS until archived for long-term storage at study closure (see Archiving Records below).
- c) **Data Storage:** Hard copy data that cannot be digitized must be stored in a secure location on site at the MVAHCS. Electronic data must be stored on the VA network.
 - i) Data should be stored in a discrete, predictable location. MVAHCS Research Service requires electronic data to be stored in R:\Data, in a subfolder using the approved protocol number as the folder name as described in “Instructions for Securing and Archiving Research Data”.
 - ii) Hard copy data collected off-site must be transported to the MVAHCS using an approved transport method to ensure security of data.
 - iii) Electronic data collected off-site or on non-networked computers must be copied to the VA network using an approved method (such as an encrypted optical media disk or VA-issued encrypted flash drive).
 - iv) For instances of electronic data that are not considered sensitive (e.g. do not contain PHI/PII, have been certified by Privacy Officer as de-identified, or were not collected from humans or nonhuman primates), a definitive copy of the data must be maintained on the VA network, but “working copies” can also be located outside of the VA network so long as data remains under the control of PI and / or study personnel.
- d) **Data Inventory:** MVAHCS Research Service maintains a Data Inventory to meet requirements for tracking VA data. All data storage locations (electronic or hard copy) for each approved study protocol must be entered into the facility Data Inventory, and kept current until minimum records retention limits have been met.
 - i) Data Inventory submission forms will be sent to PI at first annual or continuing review, and requests to update this information will be sent annually thereafter until study closure. PI and/or study staff must respond to these requests in a timely fashion.
- e) **Open Data Policy:** VA investigators are required to make publications resulting from VA research and final data sets underlying such publications available to the public.
 - i) PIs must ensure that all publications comply with NIH Open Access Guidelines by submitting final accepted copies of all manuscripts to PubMed Central. Instructions can be found at the NIH public access website (<http://publicaccess.nih.gov>).
 - ii) PIs should refer to MVAHCS SOP R&D-002 “Presentation of Research Results” and Research Service “Checklist for Publishing VA Research” for additional guidance.
 - iii) PIs must make final data sets available to others through mechanisms described in detail in the DMAP filed for each VA-approved study. When doing so would require a de-

- identified data set, PI must ensure such a data set is created prior to study closure (see Archiving Records below).
- iv) For de-identified data sets, requests to access data must be submitted to the Privacy Officer. Requests sent directly to the PI should be referred to and approved by the Privacy Officer prior to disclosure of the data.
 - f) **Data Repositories:** Access to data from closed studies is limited and in some cases is not allowed.
 - i) Data from a human subjects research protocol in which PI did not explicitly obtain informed consent for use of data in future studies cannot be accessed after closure of the study in which it was collected. PIs should refer to MVAHCS SOP R&D-003 “Privacy and Confidentiality of Research Data” for additional guidance.
 - ii) Data that is collected or saved in an archive with intent (and informed consent, where necessary) for use in future studies may meet the definition of a Research Data Repository under VHA Handbook 1200.12. Creation of a Research Data Repository requires an approved protocol for the repository itself. Use of data from the repository requires a separate approved study protocol.
 - iii) Data that does not require informed consent for use, such as certified de-identified data sets, or data not obtained from human subjects, may be accessible for use in future studies provided an R&D-only study protocol is submitted and approved for the use case.
 - g) **Archiving Records:** When a study is closed, study records (including data) must be archived for long-term storage following the guidelines listed in “Instructions for Securing and Archiving Research Data”.
 - i) Records must be turned in to the Research Office for archiving within 30 days of the committee-approved study closure date. Studies for which no records have been received may be subject to referral to RDC for evaluation of potential administrative delinquency.
 - ii) Electronic records will be moved or labeled by Research Office personnel to indicate the date in which records may be destroyed (see Records Retention, below).
 - iii) Prior to study closure, PI should work with the Privacy Officer to create a de-identified data set (for human subjects studies) or should archive a copy of all data sets used in publications (for all other studies) as stipulated in the approved study DMAP.
 - iv) PI access to data and records from human subjects studies will end at study closure. Hard copy records must be submitted for archiving, and electronic records will be administratively locked within 30 days post-closure.
 - v) Hard copy records that cannot be digitized must be boxed for long-term archiving following MVAHCS policy. The facility records manager and/or Research Service records liaison should be contacted for guidance.
 - vi) All closed studies with more than eight (8) boxes can be archived and shipped to the federal archive facility. Eight (8) boxes from the same study are needed to be eligible for palletizing and shipping. All other studies that fill 7 or fewer boxes must be digitized. High speed scanners are available for use upon request from the Research Office.
 - h) **Records Retention:** PIs should be aware that federal records retention guidelines cover all records related to a given study, from initial proposal to final publication. All study records,

including data, must be archived in hard copy or electronic format until federally mandated minimum records retention limits have been met. The investigator cannot maintain data containing PHI/PII upon completion of the study.

- i) Electronic records created or maintained in the MVAHCS electronic protocol management system are stored in the system itself and do not need to be backed up, duplicated, or stored by the investigator. All other hard copy or electronic data or records that are generated by or received by the investigator or his/her team must be stored and maintained for the applicable retention period. For notices generated by the electronic protocol management system, such as protocol review outcome or approval letters, the investigator may retain copies if desired for convenience, but is not required to do so.
 - ii) Records stored in an externally hosted site, such as the VA Central IRB Sharepoint, are not considered to be adequately backed up. Records, regulatory documents, and final copies of datasets stored in external sites must be copied to local VA network storage by the investigator and/or study team to adhere to records retention requirements.
 - iii) The PI's responsibility for records retention will be satisfied by placing electronic data into the "R:\Data\00_ArchiveData" folder, and/or by turning in hard copies of study records to the Research Office. Placing data into this folder or turning in hard copies will constitute the PI's acknowledgement that all data have been submitted for archiving, and that no identifiable human subjects data remains in his/her possession per "Archiving Records" above.
 - iv) Research Office will then accept responsibility for tracking, storing, and making records available upon request until expiration of the required records retention limit. In most cases, the records retention limit for data is 6 fiscal years post study closure.
 - v) An investigator who chooses to retain study records in his/her possession without providing a copy to the Research Office will assume full responsibility for maintaining integrity of these records for the full duration of the applicable retention period. This exception applies solely to data and records not originating from human subjects, or to de-identified data sets from human subjects research. Retention of identifiable human subjects data is prohibited.
 - vi) In case of conflict with other Federal regulations (e.g., FDA, NIH) or contract/agreement with outside institutions and/or study sponsors, documents shall be retained for the longest applicable timeframe.
 - vii) PIs should refer to Research Service "ORD/ORO Records Control Schedule Guidelines" for additional guidance.
- i) **Data Retention or Early Destruction Issues:** Per VHA Directive 1058.01, in cases where data retention issues arise or if early destruction of records occur, the ACOS/R or delegate will notify the facility records management official.

5. **REFERENCES:**

- VHA Handbook 1200.12 "Use of Data and Data Repositories in VHA Research" (09 March 2009)
VHA Directive 1200.19 "Presentation of Research Results" (10 May 2019)
VHA Directive 1058.01 "Research Compliance Reporting Requirements" (22 October 2020)
Minneapolis Research Service SOP R&D-002 "Presentation of Research Results" (05 May 2020)

Minneapolis Research Service SOP R&D-003 “Privacy and Confidentiality of Research Data” (04 June 2019)

National Archives and Records Administration (NARA) “Request for Records Disposition Authority” Records Schedule DAA-0015-2015-0004 (13 July 2015)

Executive Order 13642 “Making Open and Machine Readable the New Default for Government Information” (09 May 2013)

Office of Management and Budget Memorandum M-13-13 “Open Data Policy” (09 May 2013)

6. ATTACHMENTS:

VA Office of Research & Development “Checklist for Publishing VA Research” (11 December 2017)

MVAHCS Research Service “ORD/ORO Records Control Schedule Guidelines” (13 May 2019)

MVAHCS Research Service “Instructions for Securing and Archiving Research Data” (26 October 2020)

7. R&D COMMITTEE APPROVAL: 01 February 2022

8. REVISIONS: Minneapolis Research Service SOP R&D-016 “Research Data Requirements” (03 November 2020).

9. EXPIRATION DATE: N/A

10. FOLLOW-UP RESPONSIBILITY: Research and Development (R&D) Committee

**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

Checklist for publishing VA research (*funded by VA or used VA resources*)

Much of this information is covered in VHA Handbook 1200.19: Presentation of Research Results.

Note that the ORD service funding the study may have additional requirements; contact the specific service or review the ORD website for more information.

□ Acknowledge VA support in the manuscript

- If the work was funded by VA, include this statement:
 - “This work was supported [or supported in part] by [type of award, e.g., Merit Review, Career Development Award, Pilot Project] Award # [award/project number, e.g., I01 RX000123] from the United States (U.S.) Department of Veterans Affairs [as applicable, indicate Biomedical Laboratory Research and Development Service; Clinical Sciences Research and Development Service (mention the CSR&D Cooperative Studies Program if applicable); Rehabilitation Research and Development Service; or Health Services Research and Development Service].”
- If VA only provided resources (e.g., facilities or patients), include this statement:
 - “This material is the result of work supported with resources and the use of facilities at the [name and location of VA medical facility].”

□ Acknowledge VA employment in the manuscript

- Acknowledge employment of VA authors with VA title, name of VA medical facility, city, and state.
- Academic affiliate appointments can also be listed, but if research was funded only by VA, the VA affiliation should be listed first.

□ Include VA/U.S. Government disclaimer in the manuscript

- Include this disclaimer: “The contents do not represent the views of the U.S. Department of Veterans Affairs or the United States Government.”

- **Include NCT number in the manuscript**
 - If your publication concerns a clinical trial or observational study that was registered on clinicaltrials.gov, include the NCT number in the publication. This allows the clinicaltrials.gov website to link your paper to the trial registration.

- **Notify VHA Research Publications**
 - Alerting VA Research Communications about upcoming publications or presentations is particularly important when the topic is newsworthy and VA can develop some productive media relations or when the topic is controversial and the assistance of Public Affairs is likely to be needed.
 - Publications can be reported on-line at <https://gov.irbnet.org>.

- **Deposit manuscript in PubMed Central if the research was ORD-funded research**
 - For specific instructions, see: <https://www.ncbi.nlm.nih.gov/pmc/> .
 - Deposited manuscripts must be made available to the public in PubMed Central no later than 12 months after their publication in a journal.
 - Some journals have an arrangement by which they will deposit the paper in PubMed Central automatically. Participating journals are listed here: <https://www.ncbi.nlm.nih.gov/pmc/journals/>.
 - Unless you are sure that the journal is posting, the author must post it. Use the flow chart on NCBI's “How Papers Get Into PMC” page to learn how their paper may be deposited: <https://www.ncbi.nlm.nih.gov/pmc/about/submission-methods/>.

Updated: February 2022

ORD/ORO Records Control Schedule Guidelines

The list below summarizes the types of records investigators are responsible for archiving under current VA guidelines ("Research Investigator Files"). This is provided as a convenience only, and is NOT an authoritative list. Consult with facility ISO, PO, and Records Manager if questions.

Research Investigator Files include (but are not limited to) the following:

- 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;
- Correspondence with ORD, regulatory entities, sponsor and/or funding source, correspondence
- Case report forms and supporting data (including, but not limited to, signed and dated informed consent forms and HIPAA authorization forms)
- 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
- Data collected during the research including photos, video recordings, and voice recording, all derivative data, and derivative databases
- List of all subjects entered in the study and the cross-walk connecting the subjects name with the code used for each subject
- Subject compensation records
- Reports of adverse events, complaints and deviations from IRB-approved protocol
- Data analyses
- Codes and keys used to de- identify and re-identify subjects' PHI
- Reports (including, but not limited to, abstracts and other publications)
- Research study correspondence not involving ORD, Office of Research Oversight (ORO), sponsor, or funding source
- Correspondence and written agreements with the funding source or sponsor, ORD and applicable oversight entities such as IRB, Research and Development (R&D) Committee, VA Office of Research and Oversight (ORO), VA Office of Human Research Protections (OHRP) and FDA
- Research study correspondence not involving ORD, Office of Research Oversight (ORO), sponsor, or funding source
- Signed and dated forms submitted to regulatory agencies • investigator's brochure
- Records related to the investigational drugs such as drug accountability records
- Monitoring and audit reports such as Data Safety Monitoring Board Reports and audits by oversight entities
- Documents related to budget and funding
- Other forms required by policy and regulation

Note: If the investigator leaves 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.

Key Contacts:

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|---|----------------------|
| Information Security Officer (ISO) | VHAMINISO@va.gov |
| Privacy Officer (PO) | VHAMINPrivacy@va.gov |
| Facility Records Manager (Scott Gordon) | scott.gordon@va.gov |

Records Storage instructions can be found on the R drive at R:\All_Staff\Record Storage

Instructions for Securing and Archiving Research Data

Securing Records:

Hard-Copy research records must be kept in a secured location following standard VA practices. Generally, records containing PII/PHI or other sensitive information should be kept in a locked drawer in a locked room, and should never be left unattended. Records that are being discarded (e.g. after making a digital copy) must be placed into Shred-It bins for secure destruction.

Electronic records must be saved to the VA network, with access to the specific folder limited through use of folder permissions. Research Service requires data for all studies to reside in [R:\Data\](#) unless an alternate location has been pre-approved for a research center such as CCDOR. Secure folder access is managed in the VA SFFX system.

Creating a new secure folder:

Investigators and staff have READ ONLY access to the R:\Data\ and R:\Pis\ directories. This is to prevent creation of folders that do not follow expected data security policies.

- Staff can request new folders for R:\Pis\ as needed. Email vhaminresearchfolderadmin@va.gov – include name of PI or lab group, AND names of personnel who will be managing folder access.
- Data folders in R:\Data\ will be created by Research admin when studies are approved by RDC. We will create a security group and add the PI and any identified study coordinator as managers of this group. The identified group managers (PI/coordinator) will need to add all other staff to the group using SFFX (see below).
- If a study does not already have a secure folder, staff can request creation of a folder in R:\Data\ by emailing vhaminresearchfolderadmin@va.gov. Include name of PI, IRBNet number of the study, AND names of personnel who will be managing folder access.

Managing folder access in SFFX:

All VA personnel can access SFFX (<http://oitminhmsmffx01.v23.med.va.gov/SFFX/Select.aspx>) from a VA computer. Any member of the study team who has been given group manager permissions can add or remove personnel from security groups.

For assistance, to request a change in group manager permissions, or to request a new study group for an existing folder, email vhaminresearchfolderadmin@va.gov.

Archiving Records:

ALL RECORDS must be maintained for a minimum of 6 fiscal years post-study closure per National Archiving & Records Administration guidelines.

Electronic and hard copy records containing PHI/PII cannot be retained by the investigator, and must be turned in to the Research Office for sequestration and long-term archiving per Federal records retention guidelines and local SOPs.

For records that do NOT contain PHI/PII or other sensitive information, investigators may retain a copy of the records provided that s/he provide an administrative copy for long-term archiving.

For data turned in either for sequestration or long-term archiving, the following procedures must be observed:

Hard copy records must be placed into archive boxes, and **MUST** include an inventory sheet describing the contents of each archive box. Contact the Research records liaison for assistance.

Electronic records must be turned in to the Research Office. Records may be turned in on VA-approved secure media (e.g., encrypted CD/DVD or VA-approved USB drive), or placed into a network folder (<R:\Data\00 ArchiveData>) for archiving. CCDOR projects can be archived by working with your CCDOR data team to have the electronic data moved to “projects_HOLD” folder within the <R:\CCDOR Data> folder.

- **If using the network folder, ALL RECORDS must be placed into a subfolder using the protocol number as the folder name.**

By placing documents in the required location(s), you are attesting that no other copies of PHI/PII are retained in the possession of the investigator.

Administrative Oversight:

The Research Information Protection & Security working group will perform a periodic check to ensure that closed studies have followed the procedures outlined above. Studies for which procedures have not been followed may result in referral to the Research & Development Committee for failure to adhere to administrative expectations per R&D SOP 004 “MVAHCS Research Investigator Responsibilities”.