IRB REVIEW AND USE OF RESEARCH REPOSITORIES

SOP 001-RES-RD

VA Portland Health Care System
Portland, OR 97219

Service Line(s):
Research and Development Service

Effective Date:
May 3, 2021

Signatory Authority:
Associate Chief of Staff of Research and Development

Recertification Date:
May 3, 2026

Responsible Owner:
Administrative Director, Research and Development Service

1. PURPOSE AND AUTHORITY

a. The purpose of this standard operating procedure (SOP) is to establish procedures on data and/or biological specimens (hereinafter referred to as "specimens") that are derived directly from patients or human subjects or indirectly through accessing databases and are to be maintained for use in future research studies. Such data and/or specimens must be kept in a research repository. This SOP must be followed by investigators who wish to contribute or obtain such data and/or specimens for research use. ***NOTE:*** *This policy does not apply to research data and/or specimens collected under specific research protocols and not maintained for use in future research. Nor does this policy apply to repositories that include non-human subjects data and/or specimens only. Such repositories will have Research & Development Committee (R&DC) oversight, and will not be reviewed by the Institutional Review Board (IRB)*.

b. This SOP sets forth mandatory procedures and processes to ensure compliance with VHA Directive 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019 (amended January 8, 2021) and VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, dated March 9, 2009.

2. PROCEDURES

a. **The establishment of a research repository that will be located at the VAPORHCS.** All research repositories must have a research repository director, who bears overall responsibility for the repository.

b. **The research use of identifiable data and/or specimens obtained from an established research repository.** All requests to obtain such data and/or specimens must be described in a research protocol and approved by the applicable Institutional Review Board (IRB). Such requests must have a Principal Investigator (PI), who is responsible for the use of the data and/or specimens. The research use of de-identified data and/or specimens may be considered exempt from IRB review or may not meet the

definition of human subjects research; the Research Administration Office must be consulted in order to determine what other approval(s) may be required for such uses.

c. **The contribution of research data and/or specimens to an established research repository**. If the data and/or specimens to be contributed will be collected as part of a project where the sole purpose will be contributing to the repository and where a member of the research repository team would be the PI of such a project, that collection may be reviewed as part of the repository submission. If the data and/or specimens to be contributed will be collected as part of a research project with any objectives other than contribution to the repository and/or where the PI will be someone who is not a member of the research repository team, that study must be submitted as a stand-alone project that receives its own required approval(s). If such a study involves any data and/or specimens that are identifiable, IRB approval will be required; if it involves only data and/or specimens that are de-identified and/or do not meet the definition of human subjects, the Research Administration Office must be consulted to determine what other approval(s) may be required.

(1) If non-research data and/or specimens are to be contributed to a repository, the Research Administration Office must be consulted to determine what may be required in order for this to occur.

(2) If the research repository will be accessed and/or information from the repository disclosed for purposes preparatory to research, the research repository director must:

(a) Receive and maintain a copy of the approved Research Preparation Application, which documents that the information in the research repository will only be accessed for the purpose of preparing a protocol, that no Protected Health Information (PHI) will be removed from the VAPORHCS, and that the PHI accessed is necessary for the preparation of the research proposed. If the recipient investigator will directly access the research repository, the approved Research Preparation Application must include an additional statement that only aggregate data will be recorded for the preparatory to research activity and that no individually identifiable information will be recorded.

(b) Initiate and ensure completion of a Data Use Agreement (DUA); the Research Administration Office must be consulted for guidance on current requirements. NOTE: DUA templates are available on the R&D Service website at: https://www.portland.va.gov/Research/piservices/rd_forms.asp

d. Standard Operating Procedures (SOP). A research repository must address at least the following: ***NOTE:*** *Repository SOP template is located at:* https://www.portland.va.gov/research/documents/irb/biorepository-sop-example.doc)

(1) How all records will be maintained.

(2) Whether the specimens and/or data received, kept and released will be identifiable or de-identified. If the research repository includes de-identified specimens and/or data that may be re-identified, VHA Handbook 1200.12, section 6.c, must be followed.

(3) Policies and procedures for receiving specimens and/or data into, and releasing specimens and/or data from, the research repository.

(4) Mechanisms for verifying required approval(s) of the research by the IRB of record for contributing and recipient investigators.

(5) Administrative activities, such as hiring, training and supervising employees.

(6) Conflict of interest.

(7) Tracking of data.

(8) Whether there may be any research data disclosure to participants and conditions under which disclosure may or may not be allowed.

(9) Destruction or transfer of all specimens and/or data due to the research repository's termination or departure of Research Repository Director with no replacement.

(10) Access agreements (i.e., data use agreements).

(11) Requiring and maintaining required committee approval(s).

(12) Security and oversight.

e. Administrative Oversight. The applicable oversight committee(s) (e.g. IRB) must approve any changes to a research repository, including the appointment of a new Research Repository Director, requests to combine research repositories, termination of a research repository, the appropriate destruction of data and/or specimens (in line with the informed consent form and applicable regulations), and change in location of research repositories.

3. ASSIGNMENT OF RESPONSIBILITIES

a. **Research Repository Director** bears overall responsibility for the repository, including submitting a PPQ and a detailed research repository SOP to the Research Administration Office and obtaining the required approval(s) before establishing a research repository at the VAPORHCS. Required components of the SOP are listed in the SOP of this document. Once a research repository is approved by the applicable committee(s), the research repository director is responsible for the acquisition and maintenance of all data and/or specimens, reviewing requests to access/release data and/or specimens, ensuring that any release of data and/or specimens is in compliance with all VA privacy and information security requirements, keeping all required records, maintaining confidentiality for the data and/or specimens, and ensuring data and/or specimens in the research repository are stored and secured according to VA requirements. They are also responsible for initiating and ensuring completion of a DUA with each recipient and every release; the Research Administration Office must be consulted for guidance on current requirements.

b. **Recipient Investigator** located at the VAPORHCS is responsible for submitting a protocol and other required paperwork to the Research Administration Office in order to obtain the applicable approval(s) for each new proposed use of data and/or specimens stored in an approved research repository. The recipient investigator assumes responsibility for assurances given for the proposed study. Recipient investigators who are not at the VAPORHCS must meet the requirements of their institution. If any release is made outside of the VAPORHCS, the VAPORHCS is no longer responsible for reviewing and approving research protocols dealing with the released data and/or specimens.

c. **Contributing Investigator** is responsible for submitting a protocol and other required paperwork to the Research Administration Office in order to obtain the applicable approval(s) for their proposed activities, including contribution of the data and/or specimens to an approved VAPORHCS research repository. When applicable, they are also responsible for initiating and ensuring completion of a DUA with the Research Repository Director; the Research Administration Office must be consulted for guidance on current requirements.

d. **The Institutional Review Board** provides scientific and ethical oversight for research repositories involving data and/or specimens that are derived directly from patients or human research subjects or indirectly through accessing databases. The VAPORHCS IRB is responsible for complying with all applicable requirements of VHA Directive 1200.05 in reviewing and approving:

(1) the standard operating procedures for the establishment and operation of research repositories at the VAPORHCS;

(2) protocols submitted by recipient investigators at the VAPORHCS for the research use of data and/or specimens held in established research repositories;

(3) protocols submitted by contributing investigators at the VAPORHCS for the addition of new research data and/or specimens/ to established research repositories; and

(4) conducting an annual check-in of the research repository.

e. **The Associate Chief of Staff / Research & Development (ACOS/R&D)** is responsible for assisting the research repository director in developing standard operating procedures on the use of the data and/or specimens and for providing technical and scientific recommendations to the director and contributing and recipient investigators.

4. DEFINITIONS

a. **Coded.** Individually identifying information (e.g. initials, last four digits of social security number) have been removed and only a code (e.g. number, letter, symbol or combination thereof) is used to label information and/or specimens, and a key to the code, allowing linkage back to the identifying information, exists.

b. **Contributing Investigator**. An investigator who deposits data and/or specimen(s) into an established research repository, with all applicable approvals obtained.

c. **Data.** Information derived directly from patients or human subjects or indirectly through accessing databases or electronic medical records. For the purposes of this policy, it does not include information derived from research involving animals or other types of research that do not involve human subjects.

d. **Data Use Agreement (DUA).** A written agreement required when data are transferred from a VAPORHCS investigator or research repository director to a recipient investigator. They define what data may be used, how the data will be used, who may access the data, how the data must be stored and secured, and how the recipient will dispose of the data after completion of the research. The Research Administration Office should be consulted for guidance on current requirements.

e. **De-Identified.** Information or specimens that do not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual (i.e. it is not linkable to personal identifiers or has been deemed statistically de-identified, as per VHA Directive 1605.01)

f. **Directly Identifiable**. Information and/or specimens labeled with personal identifiers (e.g., name, medical record number, social security number, laboratory accession number, etc.). Any of the identifiers specified under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) constitute a personal identifier.

g. **Future Research.** Research not covered by the protocol under which the data and/or specimen(s) are originally collected.

h. **Human Subject.** A living individual about whom an investigator conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information.

i. **Intervention.** Physical procedures by which data are gathered (e.g., venipuncture) and/or manipulation of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

j. **Private Information.** Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and/or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

k. **Protected Health Information.** Protected health information (PHI), as defined by the Health Insurance Portability and Accountability Act (HIPAA), is individually

identifiable health information transmitted or maintained in any form or medium by a covered entity, such as VHA (see VHA Directive 1605.01, Privacy and Release of Information). ***NOTE:*** *HIPAA Identifiers + Heath Information = PHI. List of HIPAA Identifiers located:* https://www.portland.va.gov/research/documents/hrpp/18-HIPAA-identifiers.doc

l. **Recipient Investigator.** An investigator who obtains data and/or specimen(s) from a research repository using procedures approved by the applicable committee(s) and/or entity(ies).

m. **Research Repository Director.** Only an employee with a paid VA appointment may be a research repository director. Without Compensation (WOC) employees who wish to establish a research repository must consult with the ACOS/R&D.

n. **Research Repository.** A place or unit that procures, processes, stores and/or distributes data and/or human biological specimens expressly for future use in research.

o. **Research Repository Application.** The set of forms submitted to the Research Administration Office, including a Proposed Project Questionnaire (PPQ) and a detailed standard operating procedure (SOP), for the proposed research repository, which is reviewed and approved by the applicable committee(s).

p. **Human Biological Specimen.** Any materials derived from human individuals. This includes, but is not limited to, fixed, frozen or fresh pathology specimens, blood, urine, saliva, cerebrospinal fluid, semen, hair, and any purified DNA, RNA, proteins, cell lines or clones. Viral, bacterial and fungal samples obtained from human biological specimens are not themselves considered human biological specimens, as long as the human material has been removed.

5. REFERENCES

a. VHA Directive 1080.01(1), Data Use Agreements, January 19, 2021 (amended March 1, 2021), https://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

b. VHA Directive 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019 (amended January 8, 2021), http://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

c. VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016, https://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

d. VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, dated March 9, 2009,

https://vaww.va.gov/vhapublications/publications.cfm?pub=2&order=asc&orderby=pub_Number

6. REVIEW

This SOP must be reviewed, at a minimum, at recertification, when there are changes to the governing document, and any regulatory requirement for more frequent review.

7. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of May 3, 2026. In the event of contradiction with national policy, the national policy supersedes and controls.

8. SIGNATORY AUTHORITY

DAVID M COHEN 386526
Digitally signed by DAVID M COHEN 386526
Date: 2021.11.15 13:09:51 -08'00'

David M. Cohen, MD
Associate Chief of Staff/R&D Service
Date Approved: May 3, 2021

Merritt H Raitt 388523
Digitally signed by Merritt H Raitt 388523
Date: 2021.11.15 12:20:43 -08'00'

Merritt Raitt, MD
R&D Committee Chairperson
Date Approved: May 3, 2021

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

DISTRIBUTION: SOPs are available at:
http://www.portland.va.gov/research/R&D_Forms.asp