

**IRB REVIEW OF RESEARCH REPOSITORIES LOCATED AT
THE PORTLAND VA MEDICAL CENTER**

1. **PURPOSE:** To set policies and procedures for appropriate review and approval of research bio- and/or data repositories (referred to here as “Research Repositories”), located at (“On-Site”) the Portland VA Medical Center (PVAMC), including the **establishment** and **use** of research repositories and the use at the PVAMC of human biological specimens obtained from either on- or off-site biorepositories.
2. **SCOPE:** This policy applies to data and/or human biological specimens collected during the course of a research protocol and maintained for use in future research. Such data/specimens must be kept in a research repository. This policy applies to research repositories established by PVAMC investigators. It also applies to PVAMC investigators who obtain data or specimens for research use from other research repositories (both internal at the PVAMC and all outside repositories).

This policy does not apply to research specimens and/or data collected for specific research protocols and **not** maintained for use in future research (i.e., for studies other than that under which they were collected).

3. **POLICY:**
 - a. The PVAMC IRB must review and approve:
 - 1) The **establishment** of a research repository, including a review of the procedures for placing specimens/data into the research repository. All research repositories must have a principal investigator (PI), serving as the research repository director, who is responsible for submitting a research repository application to the IRB. The research repository director is responsible for the acquisition and maintenance of all specimens and/or data in the research repository.
 - 2) The research **use** of identifiable specimens/data obtained from research repositories. All requests to obtain specimens/data must be described in a research protocol and approved by the IRB. Such requests must have a PI (the recipient researcher) responsible for the use of the specimens/data. The research use of **de-identified** specimens/data may be considered exempt or may not meet the definition of human subjects research, and the Associate Chief of Staff/Research and Development (ACOS/R&D) should be consulted, as other committee reviews may be required in place of IRB review and approval based on the requirements set forth in VHA handbook 1200.01 and/or the Research & Development Committee Standard Operating Procedure.
 - 3) The **contribution** of specimens/data from a new protocol to an established research repository. If the specimens/data being contributed are de-identified and/or do not meet the definition of human subjects, the ACOS/R&D should be consulted to determine which committees must review and approve the contribution of the samples, based on the requirements set forth in VHA handbook 1200.01 and/or the Research & Development Committee Standard Operating Procedure.

- b. If the research repository will be accessed and/or information from the repository disclosed for purposes preparatory to research, the research repository director must:
 - 1) Receive and maintain a copy of the Research Preparation Application approved by the research office, which documents that the access to the information in the research repository is only to prepare a protocol, that no PHI will be removed from the PVAMC, and that the PHI accessed is necessary for the preparation of the research proposed.
 - 2) Initiate a Data Use Agreement (DUA) for limited data sets or Data Transfer Agreement (DTA) for other data sets, when the data are transferred from the research repository to the recipient investigator. If the recipient investigator directly accesses the research repository, s/he must provide the research repository director with a copy of the approved Research Preparation Application with an additional statement that only aggregate data will be recorded for the preparatory to research activity and no individually identifiable information will be recorded.

4. DEFINITIONS:

- a. **Banked Specimen:** A specimen and its related biomaterial (e.g., DNA) collected and stored for future research purposes. Also included in this category are specimens and related biomaterial collected under a particular protocol but reused for a new research protocol, or specimens that remain after the research protocol under which they were collected terminates.
- b. **Coded Specimen/Data:** A specimen/data for which a link (or code) exists to identifiable information about the individual from/for whom the specimen/data was collected.
- c. **Contributing Investigator:** An investigator who deposits specimen(s)/data into an established research repository using a procedure approved by the IRB.
- d. **Data:** Information derived directly from patients or human research 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.
- e. **Data Transfer Agreement/Data Use Agreement (DTA/DUA):** A written agreement between the provider and the recipient of data that are transferred from one to the other. It defines what data may be used, how the data will be used, who may access and use the data, how the data must be stored and secured, and how the recipient will dispose of the data after completion of the research. A data use agreement is used for a limited data set, whereas a data transfer agreement is used when more than a limited data is transferred.
- f. **De-Identified Specimen/Data:** Specimens/data that cannot be linked to a specific individual either because the existing link (such as code key) to the identity of the individual was destroyed or because the specimen/data was completely de-identified at the time of collection. De-identified specimens/data lack all 18 personal identifiers (see [list of 18 HIPAA Identifiers](#)) specified by the Health Insurance Portability and

Accountability Act of 1996 (HIPAA). Information that cannot be used to identify the individual [such as diagnosis, age (below 90), and gender] may be recorded with or linked to the specimen/data.

- g. **Directly Identifiable Specimen/Data:** Specimens/data labeled with personal identifiers (e.g., name, medical record number, social security number, laboratory accession number, or any elements of dates except year alone). Any of the identifiers specified under HIPAA constitutes a personal identifier.
- h. **Excess Clinical/Research Specimens:** Specimens collected for clinical or research purposes that are no longer needed for the original purpose.
- i. **Future Research:** Research not covered by the protocol under which the specimen(s)/data are originally collected.
- j. **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.
 - 1) **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and 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.
 - 2) **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, 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. **Recipient Investigator:** An investigator who obtains specimen(s)/data from a research repository using procedures approved by the IRB. The recipient investigator assumes responsibility for assurances given to the IRB.
- l. **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 should consult with the ACOS/R&D.
- m. **Research Repository:** A place or unit that procures, processes, stores and/or distributes human biological specimens and/or research/clinical data expressly for future use in research. Research repositories may also store linked clinical and demographic data including individually-identifiable health information, or consist of or contain a dataset, database or collection of databases that have been created or organized for research, administrative or clinical purposes (such as the VISN 20 "CHIPS" Data Warehouse.)

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- n. **Research Repository Application:** The set of forms submitted to the research 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 IRB.
- o. **Specimen: Any biological specimen** obtained from patients or human research subjects. This includes, for example, fixed, frozen or fresh pathology specimens, blood, urine, saliva, cerebrospinal fluid, semen, hair or other biological material, and any purified DNA, RNA, proteins, cell lines or clones. Banking of viral, bacterial and fungal samples obtained from human specimens is not considered specimen banking as long as human material is neither co-mingled nor retrievable.

5. RESPONSIBILITIES AND PROCEDURES:

- a. The **Research Repository Director** is responsible for submitting a PPQ and a detailed research repository standard operating procedure (SOP) to the IRB for approval before establishing a research repository at the PVAMC. Required components of the SOP are listed in section 6.b of this document. Once a research repository is approved by the IRB, the research repository director is responsible for the acquisition and maintenance of all specimens and/or data, reviewing requests to access/release specimen(s)/data, keeping records, maintaining the privacy of subjects and the confidentiality of the data, ensuring specimens/data in the research repository are stored and secured according to VA requirements, and initiating data use agreements (DUAs) or data transfer agreements (DTAs) as needed with recipient investigators.
- b. A **Recipient Investigator** located at the PVAMC is responsible for submitting a protocol and other appropriate paperwork to the PVAMC IRB to obtain approval for each new proposed use of specimens/data stored in an approved PVAMC research repository. The recipient investigator assumes responsibility for assurances given to the IRB for the proposed study. Recipient investigators who are not at the PVAMC must meet the requirements of their institution. The transfer of the specimens/data from a PVAMC research repository to a non-PVAMC recipient or non-PVAMC database must be in compliance with all VA privacy and information security requirements, including the establishment of a combined DUA-DTA. (Please consult with the ACOS/R&D for guidance on current requirements). Once such transfer occurs, the PVAMC IRB is no longer responsible for reviewing and approving research protocols dealing with those specimens/data.
- c. A **Contributing Investigator** is responsible for submitting a protocol, PPQ, IRQ (Initial Review Questionnaire), informed consent form and HIPAA authorization to the IRB for each new proposed submission of data/specimens to an approved PVAMC research repository.

- d. The **Institutional Review Board** provides scientific and ethical oversight for research repositories. It is responsible for complying with all requirements of VHA Handbook 1200.05 in reviewing and approving:
- 1) the standard operating procedures for the establishment and operation of research repositories at the PVAMC;
 - 2) protocols submitted by recipient investigators for the research use of specimens/data held in established research repositories; and
 - 3) protocols submitted by contributing investigators for the addition of new research specimens/data to established research repositories.
- The IRB is responsible for conducting a review of the research repository at least once each year.
- e. The **ACOS/R&D** is responsible for assisting the research repository director in developing standard operating procedures on the use of the data/specimens and for providing technical and scientific recommendations to the director and contributing and recipient investigators.

For additional information about research repositories at the Portland VA Medical Center, see the Frequently Asked Questions (FAQ) document at <http://www.portland.va.gov/research/documents/hrpp/repository-policy-FAQs.pdf>

6. ADMINSTRATIVE OVERSIGHT:

- a. The IRB must approve any changes to a research repository, including the appointment of a new director, requests to combine research repositories, termination of a research repository, the appropriate destruction of specimens/data in line with an informed consent form, and location of research repositories.
- b. **Standard Operating Procedures (SOP)** written by the research repository director as part of the application to establish a research repository must address the following. Guidelines for creating SOP are located at <http://www.portland.va.gov/research/documents/hrpp/biorepository-sop-guidelines.doc>
- 1) How records will be maintained.
 - 2) Whether the specimens/data will be identifiable or de-identified. If the research repository includes de-identified specimens/data that may be re-identified, VHA Handbook 1200.12, section 6.c must be followed.
 - 3) Policies and procedures for receiving specimens/data into, and releasing specimens/data from, the research repository.
 - 4) Who may approve release of specimens/data to recipient investigators.
 - 5) Mechanisms for verifying approval of the research by the IRB of record for the recipient investigator.
 - 6) Administrative activities, such as hiring, training and supervising employees.
 - 7) Conflict of interest.
 - 8) Tracking of data.
 - 9) Disclosure to subjects and conditions under which disclosure is or is not allowed.
 - 10) Destruction of specimens/data due to the research repository's termination.
 - 11) Access agreements (i.e., data use agreements).

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- 12) Requiring and maintaining IRB and other committee approvals.
- 13) Security and oversight.

7. REFERENCES:

VHA Handbook 1200.05

VHA Handbook 1200.12

VA Tissue Banking web site:

http://www.research.va.gov/programs/tissue_banking/default.cfm

8. CONCURRENCES: endorsed by the Research & Development Committee 10/3/2011.

9. RESCISSION:

IRB Review of Biorepositories Located at the Portland VA Medical Center, approved by the Research & Development Committee 2/1/2010.

IRB Review of Data repositories Located at the Portland VA Medical Center, approved by the Research & Development Committee 2/1/2010.

10. FOLLOW-UP RESPONSIBILITY: ACOS/R&D

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