RESEARCH INFORAMTION PROTECTION POLICY

SOP RES-005-RD

VA Portland Health Care System
Portland, OR 97219

Service Line(s):
Research and Development Service

Effective Date:
April 5, 2021

Signatory Authority:
Associate Chief of Staff, Research and Development Service

Recertification Date:
April 5, 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 assuring compliance with VHA regulations governing security and protection of the confidentiality of research information, which includes all research data, and the privacy of research subjects participating in human research. This SOP must be followed by research personnel who accessed, collected, recorded, generated and/or disclosed research information for the purposes of conducting an approved research protocol.

b. This SOP sets forth mandatory procedures and processes to ensure compliance all VA and VHA Directives and Handbooks listed in Section 5, References below.

2. PROCEDURES

a. Only personnel who have completed all credentialing, education and training requirements, have been appointed to a VA-paid or without compensation (WOC) position and have been approved for specific human research protocols by the IRB may access identifiable information/data. (See VAPORHCS policies Credentialing of Personnel in R&D Service and Education Requirements for the Conduct of Research, available at: https://www.va.gov/PortlandResearch/piservices/rd_forms.asp#policies).

b. All individuals working in VAPORHCS R&D Service must appropriately protect and secure all research information.

(1) All VA Sensitive Information/Data (VASI/D) must be stored in a locked file cabinet and/or a locked office or, if electronic, on a secure VA server, with access to the files restricted (e.g. via folder management and/or password protection) to authorized study personnel only.

(2) Participant contact information, including name, address, SSN and phone number, must be maintained in a separate file at the VAPORHCS and may be linked

with the remainder of the participant data only when it is necessary to conduct the research.

c. Accessing, recording, and disclosure of identifiable data for research purposes may occur only within the parameters of a research protocol submission approved by the appropriate subcommittees, e.g., the IRB, and the R&D Committee. Approved studies must include an IRB-approved Informed Consent Form and Privacy Officer-approved HIPAA Authorization or an IRB-approved waiver for these forms and/or processes. Protection of research data is additionally assured by completion and approval of the required research protocol submission materials. All submissions for research approval to the IRB must also be reviewed and approved with regard to information security and privacy by the VAPORHCS Privacy Officer (PO) and Information System Security Officer (ISSO) to ensure that the related requirements are met.

d. Data repositories must be established, maintained and used in compliance with the VAPORHCS policy, "IRB Review of Research Repositories" (available at https://www.va.gov/portlandresearch/hrpp/index.asp?tab=3#policies2).

e. Research preparation involving identifiable data may occur only after submission and approval of a Research Preparation Application (available at https://www.va.gov/portlandResearch/piservices/rd_forms.asp), which governs the access to and use/disclosure of identifiable information for this purpose.

f. Breaches of data security and protection must be reported in compliance with VHA Directive 1058.01.

g. Data Use Agreements (DUA), as applicable, must be approved and signed before research or applicable research preparation may begin and continue. Templates available at https://www.va.gov/portlandResearch/piservices/rd_forms.asp

h. A DUA is required when disseminating information from within a repository.

3. ASSIGNMENT OF RESPONSIBILITIES

a. **The Associate Chief of Staff / Research & Development (ACOS/R&D)** is responsible for developing, managing, and following policies and procedures that ensure compliance with all applicable state and federal regulations pertaining to research information protection. Policy development and management may be delegated to the Administrative Officer/R&D and the Research Assurance Officer. The ACOS/R&D is also responsible for assuring that all VAPORHCS investigators and R&D staff are aware of, and comply with, the regulations and local policies.

b. **The R&D Committee (R&DC)** is responsible for reviewing and approving this policy and providing initial approval of all research per the R&DC Policies & Procedures (available at: https://www.a.gov/portlandResearch/Committees/index.asp#policies).

(1) The R&DC must review all Research Information Security Incidents (RISPIs - e.g., loss of PHI) relating to studies not under the purview of one of the R&D subcommittees (e.g. IRB), as per VHA Directive 1058.01.

c. **R&D Subcommittees [e.g. Institutional Review Board (IRB), Exemption Subcommittee, Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS)]** are responsible for adhering to all rules and regulations governing research information protection.

(1) Each subcommittee must review all RISPIs (e.g., loss of PHI) relating to studies under their purview, as per VHA Directive 1058.01.

d. **The Privacy Officer (PO) and Information System Security Officer (ISSO)** are responsible for the following:

(1) Reviewing all proposed human research protocols, as referenced in the IRB P&P, to ensure that requirements pertaining to privacy and information security are met.

(2) Reviewing and approving all Health Insurance Portability and Accountability Act (HIPAA) Authorizations (PO only).

(3) Fulfilling other duties in relation to RISPIs, as per VHA Directive 1058.01.

e. **Principal Investigators** are responsible for protection of all research information/data for their studies, as per this policy, as well as:

(1) Adhering to all rules and regulations governing research information protection.

(2) Reporting RISPIs immediately (preferably within 1 hour) of their awareness to their direct Supervisor and PO, ISSO and/or Records Management Official, as applicable as per VHA Directive 1058.01.

(3) Assuring all research team members are appropriately appointed, credentialed, trained and aware of the relevant regulations and local policies and procedures.

f. **Research Employees and other Medical Center Staff working on approved research projects** are responsible for adhering to all rules and regulations governing research information protection and reporting RISPIs immediately (preferably within 1 hour) of their awareness to their direct Supervisor and PO, ISSO and/or Records Management Official, as applicable as per VHA Directive 1058.01.

g. **Non-Research employees with access to research areas** are responsible for adhering to all rules and regulations governing research information protection and reporting RISPIs immediately (preferably within 1 hour) of their awareness to their direct Supervisor and PO, ISSO and/or Records Management Official, as applicable as per VHA Directive 1058.01.

4. DEFINITIONS

a. **Coded information/data.** Identifying information (such as name or social security number) that has been replaced with a number, letter, symbol, or combination thereof that prevents a person's ability to readily ascertain the identity of the individual to whom the private information or specimens pertain (i.e., the code). A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

b. **De-identified information/data.** Health information that does not identify an individual and there is no reasonable basis to believe that the information can be used to identify an individual, directly or with a key to a code. In order to be considered de-identified, the following 18 elements must be removed: name; address; names of relatives; names of employers; birth date; telephone number; fax number; e-mail addresses; social security number; medical record number; health plan beneficiary number; account number; certificate/license number; any vehicle or device serial number; web URL; Internet Protocol (IP) Address; finger or voice prints; photographic images (e.g. full facial photographs); and any other unique identifying number, characteristic, or code. Information may also be determined by a qualified biostatistician to be statistically de-identified. De-identified data is not VA-sensitive data (see e. VA-Sensitive Information below).

c. **Identifiable information/data.** Any information/data that can be connected directly to an individual. This includes

d. **Individually-Identifiable Information (III).** Any information about an individual that is maintained and retrieved by VHA using the individual's name or other unique identifier, and either directly identifies the record's subject, or may be used with other information to identify the individual. Individually-Identifiable information is a subset of personally-identifiable information (PII). Individually-Identifiable Health Information is included in this definition whether or not the information is retrieved by name.

e. **Individually-Identifiable Health Information (IIHI).** A subset of health information, including demographic information collected from an individual that is created or received by a health care provider, health plan, or health care clearinghouse. This information relates to the past, present, or future condition of an individual and the provision or payment of health care; and it identifies the individual, or a reasonable basis exists to believe the information can be used to identify the individual. ***NOTE:*** *VHA uses the term Individually-Identifiable Health Information to define information covered by the Privacy Act and the Title 38 confidentiality statutes, in addition to HIPAA. Individually-Identifiable Health Information does not have to be retrieved by name or other unique identifier to be covered by this definition.*

f. **Limited Data Set**. Protected health information from which certain specified direct identifiers of the individuals and their relatives, household members, and employers have been removed. These identifiers include name, address (other than town or city, state, or zip code), phone number, fax number, e-mail address, Social Security Number (SSN), medical record number, health plan number, account number, certificate and/or

license numbers, vehicle identification, device identifiers, web universal resource locators (URL), IP address numbers, biometric identifiers, and full-face photographic images. A limited data set is not de-identified information or data. A limited data set can only contain dates (e.g. date of visit/encounter, date of birth/death, admission/discharge date) and certain geographic information (city, state, zip code).

g. **Personally Identifiable Information (PII).** Any information that can be used to distinguish or trace an individual's identity, such as their name, SSN, biometric records, etc., alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc. Information does not have to be retrieved by any specific individual or unique identifier (i.e., covered by the Privacy Act) to be personally identifiable information. ***NOTE:*** *The term "Personally Identifiable Information" is synonymous and interchangeable with "Sensitive Personal Information."*

h. **Protected Health Information (PHI).** The HIPAA Privacy Rule defines PHI as IIHI transmitted or maintained in any form or medium by a covered entity, such as VHA. ***NOTE:*** *VHA uses the term PHI to define information that is covered by HIPAA but, unlike IIHI, may or may not be covered by the Privacy Act or Title 38 confidentiality statutes.*

i. **VA Sensitive Information/Data (VASI/D).** All department information/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 specific 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.

5. REFERENCES

a. 38 CFR 16, Protection of Human Subjects http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=7d2283ab7c06ce1c6dc48c051e7cf022&ty=HTML&h=L&r=PART&n=38y1.0.1.1.18

b. 45 CFR 46, Protection of Human Subjects: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

c. VA IT Directive 06-2, Safeguarding Confidential and Privacy Act-Protected Data at Alternative Work Locations, dated June 6, 2006, https://www.research.va.gov/programs/nppo/policy.cfm

d. VA Directive 6500, VA Cybersecurity Program, dated February 24, 2021, https://www.va.gov/vapubs/Search_action.cfm

e. VA Directive 6502, VA Enterprise Privacy Program, dated May 5, 2008, https://www.va.gov/vapubs/Search_action.cfm

f. VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020, https://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

g. VHA Directive 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019 (amended March 3, 2020January 8, 2021, http://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

h. 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

i. VHA Directive 1605.02, Minimum Necessary Standard for Access, Use, Disclosure, and Requests for Protected Health Information, dated April 4, 2019, https://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

j. VHA Directive 1605.03(1), Privacy Compliance Assurance Program and Privacy/Freedom of Information Act (FOIA) Continuous Readiness Review and Remediation, dated September 19, 2019, (amended November 20, 2020), https://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

k. VA Handbook 6500, Risk Management for VA Information Systems VA Security Information Security Program, dated February 24, 2021, https://www.va.gov/vapubs/Search_action.cfm

l. VA Handbook 6502.1, Privacy Event Tracking, dated February 18, 2011, https://www.va.gov/vapubs/Search_action.cfm

m. VA Handbook 6508.1, Procedures for Privacy Threshold Analysis and Privacy Impact Assessment, dated July 30, 2015, https://www.va.gov/vapubs/Search_action.cfm

n. 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

o. VHA Handbook 1605.04, Notice of Privacy Practices, dated September 6, 2015, https://vaww.va.gov/vhapublications/publications.cfm?pub=2&order=asc&orderby=pub_Number

p. VHA Handbook 1907.01, Health Information Management and Health Records, dated March 19, 2015, 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 [Month Year – 5 years from effective date]. 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: 2021.04.08 12:42:08 -07'00'
David M. Cohen, MD
Associate Chief of Staff/R&D Service
Date Approved: 4/8/2021

Merritt H Raitt 388523
Digitally signed by Merritt H Raitt 388523
Date: 2021.04.08 15:03:59 -07'00'
Merritt Raitt, MD
R&D Committee Chairperson
Date Approved: 4/8/2021

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

DISTRIBUTION: SOPs are available at:
https://www.va.gov/portlandresearch/R&D_Forms.asp