EDUCATION REQUIREMENTS FOR THE CONDUCT OF RESEARCH

SOP RES-003-RD

VA Portland Health Care System
Portland, OR 97219

Service Line(s):
Research and Development Service

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

Effective Date:
April 5, 2021

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 to ensure the protection of all human research participants and animal research subjects and the safety of research personnel, and to promote ethical standards of human and animal research by identifying the educational requirements for conducting research at the VA Portland Health Care System (VAPORHCS). This SOP must be followed by research personnel who conduct, review, approve, oversee, support or manage research at VAPORHCS.

2. This SOP sets forth mandatory procedures and processes to ensure compliance with VHA Directive 1200.01(1), Veterans Health Administration Research and Development Program dated January 24, 2019 (amended January 8, 2021); VHA Directive 1200.02(1), Research Business Operations dated March 10, 2017 (amended September 6, 2017); and VHA Directive 1200.05(2), Requirements for the Protection of Human Subjects in Research dated January 7, 2019 (amended January 8, 2021).

3. PROCEDURES

a. All individuals working in VAPORHCS research are required to complete an education program consistent with Department of Veterans Affairs regulations. The Research & Development (R&D) Administration Office will monitor completion and renewal of educational requirements, except where otherwise noted.

b. All Research Personnel with VA-paid or Without Compensation (WOC) appointments, the Health Care System Director, the Chief of Staff, the Research Compliance Officer, voting and ex officio members of the Research and Development Committee (R&DC), and voting and ex officio members of the research subcommittees [i.e. Institutional Review Board (IRB), Exemption Subcommittee, Subcommittee on Research Safety (SRS), Institutional Animal Care and Use Committee (IACUC), Research Service Space Subcommittee (RSSS)] must complete the following, which are all required prior to appointment and yearly thereafter:

(1) Privacy and HIPAA Training

(2) Government Ethics Training (Exception: Non-hybrid Title 38 employees with a clinical occupation code and coded as either Part Time (Employee Status 2) or Intermittent (Employee Status 3) are considered Transient Clinical Staff. These employees are required to complete Mandatory Training for Transient Clinical Staff, which covers the two trainings listed above.)

(3) VA Privacy and Information Security Awareness and Rules of Behavior

c. Research Personnel Involved in VAPORHCS Human Research (including human research that has been certified Exempt from IRB review), who:

(1) will interact with participants, and/or

(2) will see identifiable data, and/or

(3) are members of the IRB, Exemption Subcommittee or the R&DC (voting or ex officio), and/or

(4) are VA representatives to external IRBs (e.g., affiliated academic institutions), and/or

(5) are members of the R&D Administration Office and their responsibilities include involvement with human research, must also complete:

(a) the initial Collaborative Institutional Training Initiative (CITI) Human Subjects Protection course prior to appointment and then the required CITI Human Subjects Protection refresher course once every three years thereafter; or

(b) the human subjects training course required by Oregon Health and Science University, including any VA-specific portions listed, prior to appointment and then the related renewal course(s) once every three years thereafter.

d. IRB and Exemption Subcommittee members who are a qualified designee of and IRB Co-Chair and conduct Limited IRB review and the duties of an Exemption Determination Official will also complete the following Collaborative Institutional Training Initiative (CITI) Human Subjects Protection modules prior to appointment:

(1) Limited IRB Review

(2) Updates to Exemption Categories

e. In addition, research personnel who conduct, review, approve, oversee, support or manage human research that will follow a Department of Defense (DOD) Addendum must meet any specific initial and continuing educational requirements or certification required by the DOD. R&D staff, delegated by the ACOS/R&D to submit the Federal

Wide Assurance (FWA), will notify IRB staff, IRB chairpersons and members, investigators and research staff of any additional educational requirements.

f. Research Personnel with access to VAPORHCS research areas (e.g., those working in labs or other research areas) must also complete General Safety Training. This training must be taken prior to appointment and yearly thereafter.

g. Research Personnel Working in Wet Labs must also complete Biosafety Training prior to appointment and yearly thereafter.

h. Research Personnel Working with Radiation must also complete Radiation Safety Training prior to appointment and yearly thereafter.

i. Research Personnel Involved in VAPORHCS Animal Research, who:

(1) participate in or supervise animal procedures conducted at the VAPORHCS, and/or

(2) work with animals purchased with VA funds, regardless of performance location, and/or

(3) work with animals during VA duty hours, regardless of location, must also complete the following CITI courses prior to appointment and once every three years thereafter:

(a) “Working with the IACUC,” and

(b) Appropriate species-specific courses (e.g., “Working with Mice in Research Settings,” Working with Rats in Research Settings”).

j. Staff of the Veterinary Medical Unit may receive other training appropriate for their responsibilities and consistent with the training commitments in both the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) Program Description and Public Health Service Assurance.

k. IACUC Members and IACUC Coordinators must also complete the CITI course, “Essentials for IACUC Members,” prior to such appointment and once every three years thereafter.

4. ASSIGNMENT OF RESPONSIBILITIES

a. **The Health Care System Director** is required to fulfill all educational requirements mandated by the VA Office of Research and Development and the Office for Human Research Protections.

b. **The Associate Chief of Staff/R&D** is responsible for developing and managing policies and procedures that ensure compliance with the educational requirements of the R&D Service.

c. **The Administrative Officer/R&D or the Deputy Associate Chief of Staff /R&D** is responsible for implementing the educational requirement policy through the R&D Administration Office. Responsibilities of this position may be delegated to another qualified staff person within the Research Office, including but not limited to:

(1) developing and presenting educational programs for investigators and research staff, and

(2) advising committee and subcommittee members, analysts and coordinators, ACOS/R&D, Deputy ACOS/R&D, R&D investigators and research staff about state, VA and other federal regulations as needed to assure compliance.

d. **The R&D Committee (R&DC)** is responsible for reviewing and approving this policy and assuring training requirements have been met by all research personnel before initially approving a research study that is not reviewed by any subcommittees.

e. **R&D Subcommittees** (e.g. IRB, Exemption Subcommittee, IACUC, SRS) are responsible for assuring that applicable training requirements have been met by all research personnel before initially approving a research study.

f. **The IRB Analysts** are responsible for providing IRB-specific training for IRB Chairs and members prior to IRB appointment and during their tenure on the IRB.

g. **The IACUC Coordinators** are responsible for providing IACUC-specific training for IACUC Chairs and members prior to IACUC appointment and during their tenure on the IACUC.

h. **The SRS Coordinators** are responsible for providing SRS-specific training for SRS Chairs and members prior to SRS appointment and during their tenure on the SRS.

i. **The Research Compliance Officer** is responsible for auditing all research and reporting any training deficiencies found during an audit to the ACOS/R&D, appropriate subcommittees and R&DC.

j. **Principal Investigators** are responsible for:

(1) submitting documentation of successful completion of educational requirements, initially and as required thereafter, to the R&D Administration Office; and

(2) ensuring that all individuals involved in their studies have completed all required training.

k. **Research Employees and other Medical Center Staff** participating in approved research projects are responsible for submitting documentation of successful completion of educational requirements, initially and as required thereafter, to the R&D Administration Office.

5. DEFINITIONS

a. None.

6. REFERENCES

a. VAPORHCS of Research & Development, Required Research Training webpage https://www.va.gov/PortlandResearch/training/index.asp

b. VHA Directive 1200.01(1) Veterans Health Administration Research and Development Program, January 24, 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. VA Handbook 6500, Risk Management Framework for VA Information Systems, VA Information Security Risk: VA Information Security Program, dated February 24, 2021, https://www.va.gov/vapubs/Search_action.cfm

7. 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.

8. RECERTIFICATION

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

9. SIGNATORY AUTHORITY

DAVID M COHEN 386526
Digitally signed by DAVID M COHEN 386526
Date: 2021.04.08 12:40:44 -07'00'
David M. Cohen, MD
Associate Chief of Staff/R&D Service
Date Approved: 4/8/2021

Merritt H Raitt
388523
Merritt Raitt, MD
R&D Committee Chairperson
Date Approved: 4/8/2021

Digitally signed by Merritt H Raitt
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Date: 2021.04.08 15:03:11
-07'00'

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