

**RESEARCH CONDUCTED BY  
EMPLOYEES OF VHA PROGRAM OFFICES**

**1. PURPOSE.** This Veterans Health Administration (VHA) Handbook sets forth procedures for oversight of research conducted by employees of VHA Program Offices.

**2. SUMMARY OF MAJOR CHANGES.** This is a new VHA Handbook that:

a. Clarifies procedures for oversight of compliance with requirements for research conducted by employees of VHA Program Offices.

b. Assigns responsibility for oversight of research conducted by VHA Program Office employees to the Principal Deputy Under Secretary for Health, VHA Program Offices, and VHA research facilities.

**3. RELATED ISSUES.** VHA Directive 1058, VHA Directive 1200, VHA Handbook 1058.01, VHA Handbook 1058.2, VHA Handbook 1058.03, VHA Handbook 1058.04, VHA Handbook 1100.19, VHA Handbook 1200.01, VHA Handbook 1200.05, Handbook 1200.06, VHA Handbook 1200.07, VHA Handbook 1200.08, VHA Handbook 1200.12, and VHA Handbook 1605.1.

**4. RESPONSIBLE OFFICE.** The Office of Research Oversight (ORO) (10R) is responsible for the contents of this Handbook. Questions may be referred to (202) 266-4580.

**5. RESCISSIONS.** None.

**6. RECERTIFICATION.** This VHA Handbook is scheduled for recertification on or before the last working day of October 2016.

Robert A. Petzel, M.D.  
Under Secretary for Health

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## OVERSIGHT OF RESEARCH CONDUCTED BY EMPLOYEES OF VHA PROGRAM OFFICES

### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook sets forth procedures for oversight of research conducted by employees of VHA Program Offices. The requirements of this Handbook are applicable to all studies initiated on or after May 1, 2012.

### 2. BACKGROUND

This Handbook clarifies the procedures through which VHA Program Office employees comply with VA and other Federal requirements for the conduct of research.

### 3. SCOPE

a. **Program Office Activities.** The requirements of this Handbook apply to all research conducted by individuals acting as VHA Program Office employees, regardless of duty station. These requirements do not apply to research activities conducted in any capacity other than as an employee of a Program Office. *NOTE: VHA Network Office employees wishing to conduct research must secure oversight from an appropriate VHA research facility within their Veterans Integrated Service Network (VISN) and obtain written approval of the arrangement from the relevant Facility Director and Network Director.*

b. **Other Requirements.** In addition to the requirements of this Handbook, VHA Program Office employees must comply with all Department of Veterans Affairs (VA) and other Federal requirements applicable to research.

### 4. DEFINITIONS

The following definitions are intended for use only within this Handbook.

a. **Animal Research.** Animal research is research involving live (non-human) vertebrates. *NOTE: Animal research is further discussed in VHA Handbook 1200.07.*

b. **Basic Laboratory Research.** Basic laboratory research is research taking place in a laboratory equipped with the plumbing, ventilation, and equipment needed for hands-on biological, biomedical, or biochemical experimentation. *NOTE: Basic laboratory research is further discussed in VHA Handbooks 1200.06 and 1200.08.*

c. **Clinical Privileges.** Clinical privileges are the privileges required under VHA Handbook 1100.19 for all health care professionals permitted by law and the VA facility to practice independently.

d. **Debarment.** Debarment is an action taken by the Under Secretary for Health to exclude a person from participating in certain covered transactions, including exclusion from applying for,

or receiving approval to conduct, VA research. *NOTE: Debarment is further discussed in VHA Handbook 1058.04.*

e. **Human Research Protection Program (HRPP).** An HRPP is a comprehensive system to ensure the protection of human subjects participating in research. *NOTE: HRPPs are further discussed in VHA Handbook 1200.05.*

f. **Institutional Official (IO).** The IO is the individual legally authorized to serve as the Signatory Official committing a research entity to compliance with Federal requirements.

g. **Institutional Review Board (IRB).** An IRB is a board, committee, or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of research involving human subjects. *NOTE: IRBs are further discussed in VHA Handbook 1200.05.*

h. **Program Office.** A Program Office is any office within the VHA Office of the Under Secretary for Health. A Program Office includes all of its component offices and subdivisions, regardless of physical location. *NOTE: The organization chart for the VHA Office of the Under Secretary for Health may be found on the VHA Web site.*

i. **Program Office Employee.** A Program Office employee is any individual working under an appointment in a VHA Program Office, regardless of duty station, including (but not limited to) full and part-time employees, without compensation (WOC) employees, and employees under the Intergovernmental Personnel Act, Title 5 Code of Federal Regulations, Part 334 (5 CFR 334).

j. **Research.** Research is a systematic investigation designed to develop or contribute to generalizable knowledge. *NOTE: Research is further discussed in VHA Handbooks 1058.01 and 1200.01.*

k. **Research and Development Committee (R&DC).** The R&DC is the VA committee responsible for oversight of a VA entity's research program. *NOTE: R&DCs are further discussed in VHA Handbook 1200.01.*

l. **Research Misconduct.** Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. *NOTE: Research Misconduct is further discussed in VHA Handbook 1058.2.*

m. **Research Review Committee.** A research review committee is any committee or subcommittee designated by the IO of a VA research program to ensure compliance with pertinent requirements for the conduct of research (e.g., the R&DC, IRB, Institutional Animal Care and Use Committee, and Subcommittee on Research Safety). *NOTE: Certain research review committees may be operated by another entity as specified in applicable VHA Handbooks and designated in a Memorandum of Understanding (MOU) or other written agreement.*

n. **VA Facility.** A VA facility is any entity that is operated by VA, including but not limited to, VA hospitals, Medical Centers, and health care systems; space owned, leased, or rented by

VA; and space that is “shared” with a non-VA entity. A VA facility may include multiple campuses and satellite components. **NOTE:** *VA facilities are further discussed in VHA Handbooks 1058.01 and 1200.05.*

o. **VA Research.** VA research is research conducted by VA investigators (serving on compensated, WOC, or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g., equipment), or on VA property including space leased to or used by VA. The research may be funded by VA, by other sponsors, or be unfunded. **NOTE:** *VA research is further discussed in VHA Handbooks 1058.01 and 1200.01. Criteria for distinguishing VA research from non-research operations activities are discussed in VHA Handbook 1058.05.*

## 5. PROGRAM OFFICE DOCUMENTATION

a. **Documentation Requirement.** All research conducted by individuals acting as Program Office employees must be prospectively documented in writing by the employee’s supervisor. All individuals conducting research as Program Office employees must provide a copy of the supervisor’s documentation to the research review committees responsible for oversight of their research.

b. **Documentation Content.** The Program Office documentation must include:

(1) The title of the research project, which must match the title of the research project to be reviewed by the research review committee(s).

(2) A brief description of the research project, which must match the description of the research project to be reviewed by the research review committee(s).

(3) The expiration date, not to exceed 36 months. Documentation may be renewed as necessary for continuation of ongoing research.

(4) The signature of the employee’s Program Office supervisor.

**NOTE:** *A sample format for Program Office research documentation is provided on Office of Research Oversight’s (ORO) Web site at [www.va.gov/oro/](http://www.va.gov/oro/).*

## 6. BASIC LABORATORY RESEARCH AND ANIMAL RESEARCH

a. **Research in a VA Laboratory.** Individuals acting as Program Office employees may be approved to conduct basic laboratory research or animal research in a laboratory operated by a VA research facility (or routinely utilized by a VA facility under a MOU, lease, or other written agreement).

(1) In addition to the documentation described in paragraph 5, the Program Office employee must obtain:

(a) An appropriate appointment and research scope of practice from the VA facility operating (or routinely utilizing) the laboratory; and

(b) Review, approval, and continuing oversight from the facility's relevant research review committees prior to initiating the research.

(2) In addition to any other required notifications, the IO of the VA facility must notify the employee's Program Office Director (or Chief Officer) and the ORO within 5 business days after any determination of serious or continuing noncompliance in the employee's research.

b. **Research in Non-VA Laboratories.** Under special circumstances, individuals acting as Program Office employees may be approved to conduct basic laboratory research or animal research in a laboratory not operated (or routinely utilized) by a VA facility.

(1) In addition to the documentation described in paragraph 5, the arrangement must be carried out under a written agreement signed by the employee's Program Office Director (or Chief Officer) and the IO of the entity operating the laboratory.

(2) The agreement must ensure:

(a) Appropriate review, approval, and continuing oversight of the research in accordance with applicable Federal requirements; and

(b) Notification of the employee's Program Office Director (or Chief Officer) and ORO within 5 business days after any determination of serious or continuing noncompliance in the employee's research.

(3) A copy of the agreement must be provided to the ORO Chief Officer within 5 business days after execution.

## 7. HUMAN RESEARCH

a. **Human Research Protection Program (HRPP).** In addition to the documentation described in paragraph 5, research involving human subjects, human biological specimens, or de-identified information about living individuals that is conducted by individuals acting as Program Office employees must be performed under the oversight of a VA HRPP, except as described in subparagraph 7f.

b. **VHA Central Office HRPP.** The Principal Deputy Under Secretary for Health serves as the IO for the VHA Central Office HRPP in addition to:

(1) Serving as Signatory Official for the HRPP's Federalwide Assurance (FWA).

(2) Arranging for administrative support and training opportunities as the HRPP may require.

(3) Arranging for documented scientific review of all proposed research.

(4) Arranging for documented review of all proposed research by an appropriate Privacy Officer (PO) and Information Security Officer (ISO) in accordance with applicable VHA requirements.

(5) Designating one or more IRBs for oversight of research under the HRPP.

(6) Appointing the Chairperson and members of any IRB(s) operated by the HRPP.

(7) Appointing an HRPP Coordinator to perform relevant duties typically performed by an Associate Chief of Staff for Research (ACOS/R) under VHA Handbook 1200.01, including notifying investigators when research may be initiated.

(8) Appointing the Chairperson and members of a Program Office Research Committee to perform relevant duties typically performed by a R&DC under VHA Handbook 1200.01, including conducting an annual evaluation of the HRPP.

(a) Members of the Program Office Research Committee must be compensated full-time or permanent part-time VA employees with relevant administrative, research, or patient care experience.

(b) The Program Office Research Committee must include at least one voting member from the Office of Research and Development, the National Center for Ethics in Health Care, the Office of Patient Care Services, the Office of Quality and Performance Management, the Office of Public Health, the Office of Nursing, and the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations.

(9) Appointing an HRPP Research Compliance Officer (RCO) and ensures timely completion of required RCO audits.

c. **Non-Clinical Research.** Individuals acting as Program Office employees in the conduct of human research studies (as described in subpar. 7a) that do not require clinical privileges may secure oversight of their research either from the VHA Central Office HRPP or from another VA HRPP.

(1) Program Office employees who hold an appointment (and applicable research scope of practice) at a VA research facility may routinely receive oversight of their human research by the HRPP of that facility.

(2) Program Office employees who do not hold a research appointment at a VA research facility may obtain oversight of individual human research studies from the HRPP of another VA investigator involved in the study. Such oversight must be acknowledged by the HRPP and documented in writing, either separately or by specific reference in the approved study protocol.

d. **Clinical Research at VA Facilities.** Program Office employees conducting clinical research at a VA facility must:

(1) Secure the required appointment, privileges, and scope of practice from the VA facility in which the activities are to be conducted; and

(2) Conduct the research under the oversight of that facility's HRPP.

e. **Notification of Noncompliance.** In addition to any other required notifications, the IO of any VA HRPP exercising oversight of a Program Office employee's research must notify the employee's Program Office Director (or Chief Officer) within 5 business days after any determination of serious or continuing noncompliance in the employee's research.

f. **Research at a Non-VA Federal Facility.** Under special circumstances, individuals acting as Program Office employees may be approved to conduct human research at a non-VA Federal facility.

(1) In lieu of the VA HRPP oversight described in subparagraph 7a, the Program Office employee conducting such research must do so under a written agreement signed by the employee's Program Office Director (or Chief Officer) and the IO of the entity operating the facility. The agreement must ensure:

(a) Appropriate review, approval, and continuing oversight of the research in accordance with applicable Federal requirements;

(b) Notification of the employee's Program Office Director (or Chief Officer) and ORO within 5 business days after any determination of serious or continuing noncompliance in the employee's research; and

(2) A copy of the agreement must be provided to the ORO Chief Officer and the Principal Deputy Under Secretary for Health within 5 business days of execution.

## **8. RESEARCH MISCONDUCT AND DEBARMENT OR SUSPENSION**

a. **Proceedings.** VHA Handbook 1058.2 (on research misconduct) and VHA Handbook 1058.04 (on debarment and suspension for research impropriety) are applicable to research conducted by Program Office employees as follows:

(1) Where the research was performed under oversight from the VHA Central Office HRPP:

(a) The Program Office HRPP Coordinator carries out the responsibilities assigned to the Research Integrity Officer (RIO).

(b) The Chairperson of the Program Office Research Committee carries out the responsibilities assigned to the VA Facility Director.

(c) The Principal Deputy Under Secretary for Health carries out the responsibilities assigned to the VISN Director.

(2) Where the research was performed under oversight from a VA facility's HRPP, proceedings and responsibilities are carried out as described in the respective Handbooks.

(3) Where the research was performed under subparagraph 6b or subparagraph 7f (i.e., in a non-VA facility):

(a) Proceedings are carried out according to the policies of the facility in which the research was conducted.

(b) The Chairperson of the Program Office Research Committee carries out the responsibilities assigned to the VA Facility Director.

(c) The Principal Deputy Under Secretary for Health carries out the responsibilities assigned to the VISN Director.

b. **Notification.** As applicable, the RIO, Facility Director, and Network Director (or Program Office HRPP Coordinator, Program Office Research Committee Chairperson, and Principal Deputy Under Secretary for Health) must notify the relevant Program Office Director (or Chief Officer) within 5 business days after being notified about research misconduct and debarment or suspension proceedings, findings, or adjudications involving a Program Office employee.

## 9. REFERENCES

a. Title 5 CFR Part 334, Temporary Assignments Under the Intergovernmental Personnel Act.

b. VHA Directive 1058, The Office of Research Oversight.

c. VHA Directive 1200, VHA Research and Development.

d. VHA Handbook 1058.01, Research Compliance Reporting Requirements.

f. VHA Handbook 1058.2, Research Misconduct.

g. VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research.

h. VHA Handbook 1058.04, Debarments and Suspensions based on Research Impropriety in VA Research.

i. VHA Handbook 1058.05, VHA Operations Activities That May Constitute Research.

j. VHA Handbook 1100.19, Credentialing and Privileging.

k. VHA Handbook 1200.01, Research and Development Committee.

- l. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.
- m. VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories.
- n. VHA Handbook 1200.07, Use of Animals in Research.
- o. VHA Handbook 1200.08, Safety of Personnel Engaged in Research.
- p. VHA Handbook 1200.12, Use of Data and Research Repositories in VHA Research.
- q. VHA Handbook 1605.1, Privacy and Release of Information.