

**RESPONSIBLE CONDUCT OF RESEARCH AT THE
PORTLAND VA MEDICAL CENTER**

1. PURPOSE: To establish policy and procedures for conducting safe and ethical research at the Portland VA Medical Center (PVAMC) that promotes compliance with federal and VA regulations. This Medical Center Memorandum (MCM) also establishes the Human Research Protection Program (HRPP), a systematic and comprehensive approach by the PVAMC to assure human subjects protection in all research.

2. POLICY:

A. The PVAMC is engaged in research when the following two items are met:

1) The project is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” and thus meets the definition of research provided by the Common Rule (38 CFR 16 and 45 CFR 46.102). The definition is refined with the following understanding that:

a) A systematic investigation is an activity that is planned in advance and that uses data collection and analysis to answer a question.

b) Generalizable knowledge is information that expands the knowledge base of a scientific discipline or other scholarly field of study.

2) The work is conducted at the PVAMC by PVAMC employees (to include, but not limited to, full-time, part-time, consulting and attending, fee basis, trainees (i.e., residents, fellows, etc.), contract and without compensation appointments) on PVAMC time and/or using PVAMC equipment and/or within PVAMC space.

All projects that meet these two items must receive notification from the Associate Chief of Staff for Research Service (ACOS/R) that a project may begin prior to initiation. The ACOS/R will, prior to signing such notification, assure that all appropriate committee approvals are in place, which may include approval from the Research & Development (R&D) Committee and any appropriate subcommittees: Institutional Review Board (IRB) for human studies, Institutional Animal Care & Use Committee (IACUC) for animal studies, and Subcommittee on Research Safety (SRS) for studies involving biohazards/radiation.

B. The PVAMC is engaged in human research when an investigator involves human subjects as defined in the Common Rule in research: “a living individual from whom an investigator (whether professional or student) conducting research obtains:

1) Data through intervention or interaction (communication or interpersonal contact) with the individual, or

2) Identifiable private information.”

The HRPP abides by the ethical principles governing research involving human subjects, as provided in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. The PVAMC distributes information about volunteering in human research to all

potential research participants. More complete information is available in the IRB Policies and Procedures (P&P) and other Human Research Protection Program (HRPP) policies.

C. All individuals involved in human, animal, or basic science research at the PVAMC share responsibility for ethical conduct of the research. This responsibility requires cooperation, collaboration, and trust among all institutional representatives, investigators and their staff, the subjects who enroll in the research, members of the IRB, IACUC, SRS, and R&D Committee, and R&D Service staff.

3. **RESPONSIBILITIES:**

A. **The Medical Center Director is** the Federal-wide Assurance (FWA) Signatory Official and Institutional Official, and is responsible for fulfilling all educational requirements mandated by VA Office of Research Oversight (ORO) and the Office for Human Research Protections (OHRP) and ensuring compliance with all federal and VA regulations governing research. S/he is accountable for the HRPP and the protection of human research subjects within the facility. The Director appoints the chairs and members of the R&D Committee and all subcommittees and reviews and approves all R&D Committee meeting minutes. The Director delegates the authority to administer the R&D program to the ACOS/R or his/her designees and ensures the Research Program, including committee and subcommittee support, is adequately staffed and that resources are available to maintain full compliance with all applicable regulations and standards. Such authority also includes ensuring that all members of the R&D Committee, its subcommittees, and all investigators are appropriately knowledgeable to oversee and conduct research in accordance with all ethical standards and applicable regulations. The Director ensures all Research personnel are included in the Facility Occupational Safety and Health program. The Director is also responsible for all elements of research compliance described in VHA Handbook 1058.01, including appointing and supervising one or more research compliance officers.

B. **The Chief of Staff (COS)** is responsible for consulting with the IRB Chair when a human research study is suspended or approval lapses to determine if subjects currently involved in the study may continue participating in the research interventions or interactions.

C. **The Human Resources Management Service** is responsible for assisting the research program with issues related to personnel, including new personnel actions, appointment of without compensation (WOC) employees; initiating the appropriate background investigations; and communicating the results of background checks to the Administrative Officer for R&D Service (AO/R) in a timely manner.

D. **The Police Service** is responsible for assisting with security of research laboratories; providing emergency response; conducting an annual security vulnerability assessment; acting as a resource to the R&D Service in the creation and monitoring of security policies; and monitoring security compliance by walking through the secured area once per day during normal working hours.

E. **The Employee Health Service** is responsible for completing initial screening (physicals when applicable, blood draws, etc) of all research personnel and for completing annual screening of research personnel engaged in animal research.

F. **The Privacy Officer (PO) and Information Security Officer (ISO)** are responsible for ensuring proposed human research complies with all applicable requirements for privacy, confidentiality, and information security.

G. **The ACOS/R** is responsible for:

- 1) Developing, managing and evaluating policies and procedures that ensure compliance with all state and federal regulations governing research. This includes monitoring changes in state, VA and other federal regulations and policies that relate to human research protection and overseeing all aspects of the HRPP program.
- 2) Acting as liaison between the VHA Office of Research and Development and the institution's R&D Committee and advising the director and VISN 20 leadership on key matters regarding research.
- 3) Implementing the institution's research and HRPP policies.
- 4) Submitting, implementing, and maintaining an approved FWA through the Medical Center Director and the Office of Research Oversight (ORO) to the Office of Human Research Protections (OHRP) and registering its IRBs with the OHRP.
- 5) Administering the facility's R&D Programs, including the R&D Committee and applicable subcommittees.
- 6) Managing the finances of the facility's R&D Program.
- 7) Assisting investigators in their efforts to carry out the VA's research mission. This responsibility includes, but is not limited to, the following:
 - a) Assuring all principal investigators (PIs) are VA-paid, Without Compensation (WOC), or Intergovernmental Personnel Agreement (IPA) employees.
 - b) Assuring all PIs are aware of their responsibilities for the ethical conduct of research and adherence to all applicable federal, state and local regulations as well as PVAMC policies.
 - c) Assuring all PIs are aware of the policies and procedures governing human, animal, and laboratory research accessible on the R&D website (see References in this MCM).
- 8) Developing and implementing needed improvements and ensuring follow-up of actions as appropriate for the purpose of managing risk in the research program.
- 9) Developing and ensuring completion of human, animal, and bio-safety training requirements for research investigators, members of the R&D Committee and subcommittees, and R&D staff.

- 10) Reviewing or designating a reviewer for all sponsor agreements to assure ethical standards and practices in research are upheld.
- 11) Designating the responsibility to the Deputy ACOS/R and/or the Administrative Officer for R&D to annually assess performance of all R&D staff and provide feedback on their performance.
- 12) Developing and overseeing an outreach program to all active and potential research participants at PVAMC.
- 13) Delegating duties and responsibilities to the Deputy ACOS/R.
- 14) Fulfilling all other responsibilities and adhering to the policies and procedures outlined in the appropriate institutional, HRPP, and R&D Committee's and Subcommittees' policies and procedures.

H. **The Deputy ACOSR** reports to the ACOS/R and is responsible for fulfilling all responsibilities of the ACOS/R in his/her absence or as delegated by the ACOS/R and for adhering to the policies and procedures outlined in the appropriate institutional, HRPP, and R&D Service committee's and subcommittees' policies and procedures.

I. **The AO/R** reports to the ACOS/R and Deputy ACOS/R. S/he is responsible for supervision of R&D Administration Staff, tracking training of all research employees, fulfilling all other responsibilities assigned by the ACOS/R or Deputy ACOS/R, and adhering to the policies and procedures outlined in the appropriate institutional, HRPP, and R&D Committee's and subcommittees' policies and procedures.

J. **The Research & Development Committee** serves in an advisory capacity to the Medical Center Director through the COS on the professional and administrative aspects of the research program. Responsibilities of the committee may be found in the Standard Operating Procedures for the Research & Development Committee (see References in this MCM).

K. **The Research Assurance Officer (RAO)** reports to the AO/R and is responsible for the following:

- 1) Critically evaluating adherence of the institution, the IRB, and investigators to applicable federal regulations, state laws, local HRPP policies and accreditation standards, which govern human research.
- 2) Writing and maintaining local research policies and standard operating procedures (SOPs) for use in the Research Service to assure functioning in accordance with all federal and applicable state regulations.
- 3) Working with the R&D staff, including those who coordinate functions of the R&D Committee and all subcommittees, to ensure day-to-day operations are consistent with local policy.
- 4) Working with IRB analysts to evaluate the performance of each IRB member and chair annually, reviewing evaluations with the chair of the R&D

Committee and the ACOS/R, providing written feedback as needed to individual IRB members or chairs and submitting a report to the R&D Committee. Such evaluation and feedback shall also be provided as needed if performance problems are observed by the RAO or reported to the RAO by someone else.

- 5) Critically evaluating the impact of the institution's systemic changes on the conduct of human research and providing information as to whether these changes have led to improvements.
- 6) Suggesting systemic improvements in the institution's human research efforts that will either increase human research subject safety or improve compliance with applicable federal regulations, state laws and accreditation standards governing the conduct of human research.
- 7) Directing and facilitating the process of applying for and maintaining accreditation of the HRPP.
- 8) Advising and teaching PIs and their research teams concerning the ethical conduct of human research, good clinical practice, local policies and procedures, and federal and applicable state regulations.
- 9) Reporting events as required by VA Handbook 1058.01.
- 10) Fulfilling all other assigned responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP, R&D Committee's and subcommittees' policies and procedures.

4. PROCEDURES:

A. The SOP for the R&D Committee (see References in this MCM) is a reference for R&D Committee members, subcommittee members, investigators and R&D Service staff. This SOP details the policies and procedures specifying the functions of the R&D Committee and the regulations and policies governing the R&D Committee in overseeing the functions of its subcommittees. The R&D Committee abides by the HRPP Policies & Procedures and all other PVAMC Research Policies & Procedures.

B. The R&D Committee has charged the PVAMC Institutional Animal Care and Use Committee (IACUC) with ensuring compliance with animal research regulations and oversees the IACUC. The IACUC SOP (see References in this MCM) is a reference for the chair and all IACUC members, investigators, and administrative personnel working with animal research. The IACUC abides by the procedures and principles of the VHA Handbook 1200.7, Use of Animals in Research, (see References in this MCM) in the review and conduct of research involving animal research subjects.

C. The R&D Committee has charged the PVAMC Institutional Review Boards (IRB) with oversight of all research activities meeting the definition of human research. The PVAMC IRBs shall perform all functions required under 38 CFR 16 (Common Rule) for reviewing and approving human research conducted under the auspices of the institution's FWA. This includes, but is not limited to, research supported by the VA, on VA time or conducted at the PVAMC and research involving VA patients or their data. These responsibilities include maintaining the assurances of compliance set forth in the FWA obtained from the OHRP. IRB review and approval of VA human research shall be

conducted in accordance with all applicable regulations and in compliance with all PVAMC HRPP. The PVAMC IRB Standard Operating Procedures is a reference for the chair and all IRB members, coordinators, investigators and other individuals associated with the HRPP. This SOP specifies local policies and procedures in compliance with the regulations and accreditation standards governing human research and the requirements for submitting research proposals for review by a PVAMC IRB. The IRBs and all human research must adhere to VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research (see Reference A in this MCM).

D. The R&D Committee has charged the Subcommittee on Research Safety (SRS) with ensuring compliance with all applicable regulations, policies, and guidelines pertinent to biological, chemical, physical, and radiation hazards, and with oversight of all research activities involving safety hazards. The SRS SOP is a reference for the chair, SRS members, all investigators, and all involved in research at the PVAMC. The SRS adheres to the policies in VA Handbook 1200.8, Safety of Personnel Engaged in Research (see References in this MCM).

E. The R&D Committee has charged the Subcommittee on Research Space with reviewing requests and reports involving research space in addition to assigning research space. The term “research space” refers to all types of space where research is conducted including dry lab space (for programs more dependent on generation, collection and analysis of clinical data), wet lab space (for biomedical experimentation) and any combination or customization of wet or dry lab space to meet the special needs of PVAMC investigators. The Research Service Space Policy details the procedures followed by the chair and the Subcommittee on Research Space.

F. The R&D Committee may not approve research that has not been approved by all appropriate subcommittee(s) of record, nor may the Medical Center Director approve research that has not been approved by the R&D Committee. The Medical Center Director, R&D Committee or higher authority, i.e., the VHA Office of Research and Development (ORD) may strengthen requirements and/or conditions, add other modifications to a protocol approved by all appropriate subcommittees, or disapprove any research.

G. Policies governing PVAMC research are initiated by the ACOS/R, reviewed and approved/disapproved by the applicable subcommittees and the R&D Committee and implemented as appropriate by the subcommittees, R&D Service staff, investigators, and employees of the PVAMC.

H. Principal Investigators must follow applicable procedures for all research conducted at the PVAMC as described in policies and procedures and using forms found on the R&D website (see References in this MCM).

1) For research projects to be conducted by VA investigators on VA time at the PVAMC and/or elsewhere, e.g., OHSU, and/or using VA resources, and/or administered by the Portland VA Research Foundation (PVARF), a PVAMC Proposed Project Questionnaire and other applicable materials based on the type of research with the research proposal and abstract must be submitted to the R&D Administration Office. The submission must be received in a timely manner to allow adequate time for processing.

- 2) Complete all required education for research.
- 3) Maintain credentials and, if applicable, privileges at the PVAMC appropriate for performing all procedures proposed in all research protocols involving human subjects submitted by the principal investigator. If the principal investigator lacks the requisite credentials and/or privileges, a collaborating VA clinician who is appropriately credentialed and, if applicable, privileged must be listed on the application. The collaborating clinician assumes responsibility for the specific procedures in question.
- 4) Cooperate fully with triennial reviews of research studies as well as annual reviews of all informed consent documents conducted by the Research Compliance Officer.
- 5) Fulfill all other responsibilities and adhere to the requirements outlined in the appropriate institutional, R&D Service, committee and subcommittee policies and procedures.

I. For human research at the PVAMC, principal investigators must adhere to the following procedures:

- 1) Obtain approval from the PVAMC IRB. As part of the review process, the principal investigator must comply with all requests for information to assess conflicts of interest.
- 2) Initiate the study only after approval by the IRB, any other applicable subcommittee, and notification of final R&D Committee approval from the ACOS/R.
- 3) Adhere to all assurances given to the IRB at the time of project approval.

J. For research involving animals at the PVAMC, the principal investigator must adhere to the following procedures:

- 1) Obtain approval from the PVAMC IACUC.
- 2) Initiate the study only after approval by the IACUC, any other applicable subcommittee, and notification of final R&D Committee approval from the ACOS/R.

K. For research involving biohazards and/or radioactive materials at the PVAMC, the principal investigator must adhere to the following procedures:

- 1) Obtain approval for all new grant applications from the PVAMC SRS.
- 2) Initiate the study only after approval by the SRS, any other applicable subcommittee, and notification of final R&D Committee approval from the ACOS/R.
- 3) Complete an annual self-inspection survey and pass an inspection conducted by members of the SRS.

- 4) If applicable, obtain an “Authorized Users License” issued by the Radiation Safety Subcommittee authorizing the use and purchase of isotopes.

5. REFERENCES:

- A. [VHA Handbook 1200.05](#) - Requirements for the Protection of Human Subjects in Research, dated May 2, 2012
- B. [VHA Handbook 1058.01](#) - Research Compliance Reporting Requirements, dated November 15, 2011
- C. [21CFR50 \(FDA - Protection of Human Subjects\)](#)
- D. [21CFR56 \(FDA - Institutional Review Boards\)](#)
- E. [21CFR312 \(FDA - Investigational New Drug Application\)](#)
- F. [21CFR812 \(FDA - Investigational Device Exemptions\)](#)
- G. VHA [Handbook 1200.7, Use of Animals in Research](#), dated 11/23/2011
- H. VHA Handbook 1200.08, [Safety of Personnel Engaged in Research](#), dated March 6, 2009.
- I. VHA Handbook 1200.19, [Presentation of Research Results](#), dated September 17, 2008.
- J. PVAMC R&D Website: <http://www.portland.va.gov/Research/index.asp>
- K. PVAMC [IRB Standard Operating Procedures](#)
- L. PVAMC [Institutional Animal Care & Use Committee \(IACUC\)](#)
- M. PVAMC [Space Policy](#)
- N. PVAMC R&D Committee [Policies and Procedures](#)
- O. PVAMC [HRPP policies](#)
- P. Department of Defense (DOD) regulations: [32CFR219 \(DOD - Protection of Human Subjects\)](#)
- Q. The Freedom of Information Act (FOIA), Title 5 United States Code (U.S.C.) 552: http://www.justice.gov/oip/foia_updates/Vol_XVII_4/page2.htm as implemented by [Veterans Affairs Handbook 6300.3](#), January 12, 1998.
- R. The Privacy Act, 5 U.S.C. 552a: <http://www.justice.gov/opcl/privstat.htm> as implemented by [VHA Handbook 1605.1](#) – Privacy and Release of Information, May 17, 2006.
- S. The VA Claims Confidentiality Statute, 38 U.S.C. 5701 implemented by [38 CFR Sections 1.500-1.527](#)
- T. Confidentiality of Drug Abuse, Alcoholism and Alcohol Abuse, Human Immunodeficiency Virus (HIV) Infection, and Sickle Cell Anemia Medical Records, 38 U.S.C. 7332, implemented by [38 CFR Section 1.460-1.496](#)
- U. The Health Insurance Portability and Accountability Act (HIPAA) (Public Law (Pub. L.) 104-191) implemented by 45 CFR Parts 160, 162, and 164, as amended through February 16, 2006.

6. PRIMARY CONCURRENCES:

Chief, Human Resources Management Service
Chief, Police Service
Associate Chief of Staff, Research
Clinical Director, Primary Care
Associate Deputy Chief of Staff
Chief, Employee Health

REVIEWED BY:

Clinical Director, DHSM
Administrative Director, DHSM
Chief, Surgery Service
Chief, Anesthesiology Service
Administrative Director, Operative Care
Nursing Director, Operative Care
Chief, Dermatology
Chief, Eye Care Services
Clinical Director, Rehab and LTC
Administrative Director, Rehab and LTC
Chief Physical Medicine and Rehabilitation
Administrative Director, Primary Care
Nursing Director, Primary Care
Administrative Director, Mental Health
Clinical Director, Mental Health
Director, Inpatient & Emergency Care
Chief, Emergency Medicine
Chief, Imaging Service
Director, Critical Care
Chief, Audiology & Speech Pathology
Chief, Neurology Service
Director, Chaplain and Social Work Service
Chief, Pharmacy Service
Chief, Nutrition & Food Services
Chief, Dental Service
Chief, Pathology & Laboratory Service
Chief, Prosthetics & Sensory Aids Service
Clinical Director, Compensation & Pension
Administrative Director, Compensation & Pension
Research Compliance Officer

7. **RESCISSION:** Medical Center Memorandum No. 151-01 dated March 31, 2010.
8. **FOLLOW-UP RESPONSIBILITY:** ACOS Research & Development Service (R&D)
9. **PVAMC REVIEWED & LAST APPROVED:** October 30, 2013

MICHAEL W. FISHER
Interim Medical Center Director

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