

## **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 and human subject rights. 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. All research conducted at the PVAMC by PVAMC employees (full-time, part-time, consulting and attending, contract and without compensation appointments) on PVAMC time and/or using PVAMC property must receive approval through the Research Service prior to initiation. This 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 VA defines research per the Common Rule (38 CFR 16 and 45 CFR 46.102) as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

C. All individuals involved in human, animal, or basic 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.

D. 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:

- Data through intervention or interaction (communication or interpersonal contact) with the individual, or
- Identifiable private information.”

More complete information is available in the IRB Standard Operating Procedures (SOP) and other Human Research Protection Program (HRPP) policies.

1) 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.

2) The HRPP is also governed by the Federal Policy for the Protection of Human Subjects (The Common Rule, Department of Health & Human Services (DHHS) regulations at Title 45 Code of Federal Regulations (CFR) Part 46), codified by the Department of Veterans Affairs at 38 CFR 16. In addition, the institution adheres to the Food & Drug Administration (FDA) regulations at 21 CFR 50, 56, 312, 361 and 812; Department of Defense (DOD) regulations at 32CFR219 (DOD - Protection of Human Subjects); The Freedom of Information Act (FOIA), Title 5 United States Code (U.S.C.) 552, implemented by 38 CFR

1.550-1.559; The Privacy Act, 5 U.S.C. 552a implemented by 38 CFR Section 1.575-1.584; The VA Claims Confidentiality Statute, 38 U.S.C. 5701, implemented by 38 CFR Section 1.500-1.527; 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; the Health Insurance Portability and Accountability Act (HIPAA) (Public Law (Pub. L.) 104-191) implemented by 45 CFR Parts 160, 162, and 164; Confidentiality of Healthcare Quality Assurance Review Records, 38 U.S.C. 5705 implemented by 38 CFR §17.500, §17.501, §17.502, §17.503, §17.504, and §17.505; all relevant academic affiliate policies; and VA rules and policies in all relevant VHA Handbooks including VHA Handbook 1200.05 - Requirements for the Protection of Human Subjects in Research, and others pertaining to human research as seen on the VHA Office of Research and Development (ORD) Program for Research Integrity Development & Education (PRIDE) website. (Internet links for all references in section 5 of this MCM.)

3) The PVAMC distributes information about volunteering in human research to all potential research participants.

### 3. RESPONSIBILITIES:

A. **The Medical Center Director**, the Federal-wide Assurance (FWA) Signatory Official, 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 Associate Chief of Staff/R&D or his/her designees. 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 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 Associate Chief of Staff for Research & Development (ACOS/R&D)** 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&D 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&D.

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.

D. **The Deputy ACOS / R&D** reports to the ACOS/R&D and is responsible for fulfilling all responsibilities of the ACOS/R&D in his/her absence or as delegated by the ACOS/R&D 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.

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

F. **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).

G. **The Research Assurance Officer (RAO)** reports to the AO/, R&D, 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&D, 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) 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 Research & Development Committee (see References in this MCM) is a reference for R&D Committee members, subcommittee members, investigators and R&D Service administrative 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. Neither the R&D Committee, nor the Medical Center Director may approve research that has not been approved by the R&D Committee and all of the appropriate subcommittee(s) of record. 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. The annual budget for the HRPP is submitted to the R&D Committee for review and approval.

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

I. Principal Investigators must follow applicable procedures for human, animal and/or basic 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), submit a PVAMC Proposed Project Questionnaire and other applicable materials based on the type of research with the research proposal and abstract to the R&D Service 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.

J. 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&D.
- 3) Adhere to all assurances given to the IRB at the time of project approval.
- 4) Fulfill all other responsibilities and adhere to the policies and procedures outlined in the appropriate institutional and HRPP policies and procedures.

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

- 1) Obtain approval from the PVAMC IACUC and other applicable subcommittees.
- 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&D.
- 3) Complete all applicable education requirements.
- 4) Fulfill all other responsibilities and adhere to the policies and procedures as outlined in the appropriate institutional and R&D Service committees' policies and procedures.

L. 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 and any other applicable subcommittees.
- 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&D.
- 3) Complete an annual self-inspection survey and pass an inspection conducted by a member of the SRS.
- 4) If applicable, obtain an "Authorized Users License" issued by the Radiation Safety Subcommittee and authorizing the use and purchase of isotopes,

- 5) Complete all applicable education requirements.
- 6) Fulfill all other responsibilities and adhere to the policies and procedures as outlined in the appropriate institutional and R&D Service committees' policies and procedures.

**5. REFERENCES:**

- A. [VHA Handbook 1200.05](#) - Requirements for the Protection of Human Subjects in Research, dated October 15, 2010.
- B. [VHA Handbook 1058.01](#) - Research Compliance Reporting Requirements, dated May 21, 2010.
- 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 May 27, 2005.
- H. VHA Handbook 1200.8, [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](http://www.justice.gov/oip/foia_updates/Vol_XVII_4/page2.htm) as implemented by [Veterans Affairs Handbook 6300.3](#)
- 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.

S. The VA Claims Confidentiality Statute, 38 U.S.C. 5701 implemented by 38 CFR Section 1.500-1.527: [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d3e0736d7ed7ef91de0b4d47a7f136c8&tpl=/ecfrbrowse/Title38/38cfr1main\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d3e0736d7ed7ef91de0b4d47a7f136c8&tpl=/ecfrbrowse/Title38/38cfr1main_02.tpl)

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](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d3e0736d7ed7ef91de0b4d47a7f136c8&tpl=/ecfrbrowse/Title38/38cfr1main_02.tpl) ([http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d3e0736d7ed7ef91de0b4d47a7f136c8&tpl=/ecfrbrowse/Title38/38cfr1main\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d3e0736d7ed7ef91de0b4d47a7f136c8&tpl=/ecfrbrowse/Title38/38cfr1main_02.tpl))

U. The Health Insurance Portability and Accountability Act (HIPAA) (Public Law (Pub. L.) 104-191) implemented by 45 CFR [Part 160](#), [Part 162](#), and [Part 164](#)

**6. CONCURRENCES:**

Associate Chief of Staff, R&D  
Deputy Associate Chief of Staff, R&D  
Administrative Officer, R&D  
Chair, R&D Committee  
Research Assurance Officer (RAO)  
Chief, Human Resources Management Service

**7. RESCISSION:** Medical Center Memorandum No. 151-01 dated December 4, 2009.

**8. FOLLOW-UP RESPONSIBILITY:** ACOS Research & Development Service (R&D)

**9. LAST APPROVED:** March 31, 2010

JOHN E. PATRICK  
Medical Center Director

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