

**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) and/or on PVAMC time and/or using PVAMC property must receive Research & Development Committee (R&D) approval prior to being conducted. This includes approval from all appropriate R&D Service subcommittees: either of the two Institutional Review Boards (IRBs) (human studies), Institutional Animal Care & Use Committee (IACUC) (animal studies), and Subcommittee on Research Safety (SRS) (biohazards/radiation studies).

b. Research is defined by the VA as “the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. The Common Rule ([38 CFR 16](#) and [45 CFR 46.102](#)) defines research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.”

c. The FDA regulations ([21 CFR 50.3](#)) define research as “any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i)” (i.e. any use of a drug other than the use of an approved drug in the course of medical practice [[21 CFR 312.3\(b\)](#)]), “or [520\(g\)](#),” (i.e. any activity that evaluates the safety or effectiveness of a device [[21 CFR 812.2\(a\)](#)]), “of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.”

d. In summary, an activity is FDA-regulated research (clinical investigation) when 1) it involves the use of a drug other than the use of an approved drug in the course of medical practice; and/or 2) it involves evaluating the safety or effectiveness of a device and/or 3) data will be submitted to or held for inspection by FDA.

e. The FDA regulations further state that “...the terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.” Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. Any prospective or retrospective collection of clinical data with the intent to contribute to generalizable knowledge constitutes research as

defined by VA regulations. Examples of such clinical data collection include data for research seminars, posters, abstracts, manuscripts, and pilot data.<sup>1</sup> Whether such research constitutes human research is determined by the definitions under 2.f.

f. The VA defines a human subject as “a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information ([38 CFR 16.102\(f\)](#)). The definition provided in the Common Rule includes investigators, technicians, and others assisting investigators, when they serve in a "subject" role by being observed, manipulated, or sampled. As required by [38 CFR 16.102\(f\)](#) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes.”

g. The FDA defines a human subject as “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.” ([21 CFR 50](#)) The FDA further defines a subject as “a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.” ([21 CFR 812.3](#))

h. Research involving human subjects means any activity that either:

- (1) Meets the VA definition of “research” and involves “human subjects” as defined by VA; or
- (2) Meets the FDA definition of “research” and involves “human subjects” as defined by FDA.

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

- Data through intervention or interaction with the individual, or
- Identifiable private information.

(1) *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about

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<sup>1</sup> Local medical center and affiliated institutional conferences for teaching, quality assurance or quality improvement activities, and patient care activities (for example, ward rounds, case conferences, departmental seminars, morbidity & mortality conferences, X-ray conferences, tumor boards) are usually not considered research by this definition. Case Reports (published reviews of  $\leq 3$  clinical records by one or more members of a care team) are not considered research, but do require submission of a Case Report Review application to an IRB coordinator. Clinical reviews (reviews of  $\geq 4$  clinical records whether or not care team members are involved) are considered human research and must have IRB and Research & Development Committee approval.

behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.” ([45 CFR 46](#) and [38 CFR 16](#))

j. The HRPP abides by the ethical principles governing research involving human subjects, which are provided in the Nuremberg Code, the Declaration of Helsinki and the Belmont Report.

(1) The Nuremberg Code addresses the necessity of requiring the voluntary consent of the human subject and that any individual “who initiates, directs or engages in the experiment” must bear personal responsibility for ensuring the quality of consent. The Declaration of Helsinki calls for prior approval and ongoing monitoring of research by independent ethical review committees. Finally, the Belmont Report identifies three basic ethical principles: respect for persons, beneficence and justice. Respect for persons requires treatment of individuals as autonomous agents and protection of persons with diminished autonomy. Beneficence requires minimization of risks and maximization of benefits. Justice requires equal distribution of burdens and benefits among individuals. All activities related to human subject research, regardless of funding source, are guided by these ethical principles. These ethical principles serve as the foundation for federal regulations, guidance, and the HRPP.

(2) The HRPP is additionally 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 [32 CFR 219](#); 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 and 164](#); Confidentiality of Healthcare Quality Assurance Review Records, 38 U.S.C. 5705 implemented by [38 CFR Section 17.500-17.511](#); and all relevant academic affiliate policies and VA rules and policies set forth in writing in VHA Handbooks [1200.5](#), [6300.3 through 6300.7](#) and [1605.1-1605.2](#).

k. The ethical conduct of research is a shared responsibility among all individuals involved in the HRPP. It requires cooperation, collaboration, and trust among all institutional

representatives, investigators and their staff, the subjects who enroll in the research, IRB members, R&D Committee members, and R&D Service staff.

1. The PVAMC has obtained and continues to maintain a Federalwide Assurance (FWA) and has registered its IRBs with the Office of Human Research Protections (OHRP).

### 3. RESPONSIBILITIES:

a. The **Medical Center Director** is the Federalwide Assurance Signatory Official. The Medical Center Director is responsible for fulfilling all educational requirements mandated by VA Office of Research Oversight (ORO) and OHRP and ensuring compliance with all federal and VA regulations governing research. S/he is accountable for the HRPP including 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 conduct research in accordance with all ethical standards and applicable regulations.

b. The **Chief of Staff** (COS) at PVAMC reports to the Medical Center Director and has overall responsibility for all clinical activities under the purview of the PVAMC.

c. The **Associate Chief of Staff for Research & Development** reports to the Director through the COS and is responsible for the following:

- (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 HRPP policy.
- (4) Submitting, implementing, and maintaining an approved FWA through the Medical Center Director and the Office of Research Oversight (ORO) and to the Office of Human Research Protections (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.
- (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 and members of the applicable subcommittees and 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 Administrative Officer for R&D to annually assess performance of all R&D staff and provide feedback on their performance.
- (12) Fulfilling all other responsibilities and adhering to the policies and procedures outlined in the appropriate institutional, HRPP, and R&D Service committee's and subcommittees' policies and procedures.

d. 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. This oversight includes the assessment of scientific quality of research and development projects and protection of human research subjects. The R&D Committee is responsible for the following:

- (1) Assuring the continuing high quality of the facility's R&D program.
- (2) Planning and developing broad objectives of the R&D program assuring support of the patient care mission of the facility.
- (3) Evaluating critically and deciding approval/disapproval of research with respect to the following:
  - (a) quality, design, desirability and feasibility of each new R&D proposal;
  - (b) continuing R&D projects;
  - (c) applications for funding;
  - (d) manuscripts to be submitted for publication; and
  - (e) other reporting activities to assure maintenance of high scientific standards, protection of human subjects, adequate safety measures and proper use of animal subjects.
- (4) Reviewing and declaring approval/disapproval of recommendations from its subcommittees:
  - (a) Institutional Review Board (IRB);
  - (b) Institutional Animal Care and Use Committee (IACUC);
  - (c) Subcommittee on Research Safety (SRS); and
  - (d) Subcommittee on Research Space.

The R&D Committee shall not approve any proposal that has been disapproved by any subcommittee, nor shall it alter any documents or recommendations made by any subcommittees.

- (5) Recommending the distribution of R&D funds, space, personnel, equipment, supplies, use of animal facilities and other common resources on the basis of such evaluations and after consideration of other needs. This includes an annual review of the budget assigned to the HRPP.
- (6) Reviewing on an annual basis the subcommittees' chairs and members and their qualifications and experiences and providing feedback as needed. These subcommittees include the IRB, IACUC, SRS and Subcommittee on Research Space.
- (7) Reviewing, evaluating, and as needed, recommending appropriate corrective actions regarding the reports and results of compliance assessment and quality improvement activities (QA/QI) related to research.

- (8) Reviewing and declaring approval/disapproval of new and revised HRPP policies and procedures.
- (9) Evaluating investigator compliance with HRPP and IRB requirements.
- (10) Fulfilling all other responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP, and R&D Service committee's policies and procedures.

e. The **R&D Committee subcommittees' chairs and members** are responsible for fulfilling all responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP and R&D Committee's and subcommittees' policies and procedures.

f. The **Principal Investigators** (VA employees) planning to conduct research at the PVAMC are responsible for the following:

(1) Submitting the following forms (available from R&D Service website: <http://www.visn20.med.va.gov/portland/research/index.htm>), as applicable, to the Administrative Officer of R&D Service in a timely manner prior to submitting a research proposal to a funding agency:

- (a) Proposed Project Questionnaire (PPQ);
- (b) Data Security Checklist: Storage and Security of VA Research Information;
- (c) Administrative Review forms;
- (d) Project Proposal and Abstract;
- (e) Institutional Review Board forms;
- (f) Institutional Animal Care and Use Committee forms; and
- (g) Subcommittee on Research Safety forms.

(2) Submitting annual and continuing reviews as well as any amendments for each research project to the R&D Service administrative office according to stated deadlines for entry into the Research & Development Information System (RDIS) database. All required reports will be submitted by the due date(s) specified by the R&D Service administrative office to comply with Federal, VACO and local requirements. All materials must be submitted to appropriate sub-committees.

(3) Assuring completion of educational requirements by themselves and their staff, monitoring compliance with all safety rules and regulations in their laboratory including requirements for annual safety training, and all human research protection policies. Compliance with all requirements of all applicable subcommittees is the responsibility of each employee.

(4) Submitting publications that result from approved research to the R&D Committee for approval prior to publication. The publication must include the PVAMC in the address of authors, and VA support must be mentioned in a footnote or acknowledgment.

(5) Fulfilling all other responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP, and R&D Service committee's and subcommittees' policies and procedures.

g. The **Research & Development Service Administrative Staff** assigned to the various committees and subcommittees are responsible for the following:

- (1) Reviewing research proposal submissions, advising principal investigators about federal, VACO, and local requirements for conducting research, placing research proposals on the appropriate subcommittee agenda, and coordinating the final approval by the R&D Committee.
- (2) Maintaining subcommittee meeting calendars, minutes, membership information, membership education, study documentation and records in accordance with regulatory requirements.
- (3) Assisting principal investigators who receive approval and funding for research projects with recruitment of research personnel, purchase of equipment and supplies, preparation of monthly budget reports, financial projections, training requirements, and assistance with day-to-day issues of individual research programs.
- (4) Tracking the progress of submitted research protocols.
- (5) Fulfilling all other responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP, and R&D Service committee's and subcommittees' policies and procedures.

h. The **Research Assurance and Compliance Coordinator** reports to the Associate Chief of Staff, R&D and is responsible for the following:

- (1) Critically evaluating institution's adherence to applicable federal regulations, state laws and accreditation standards, which govern human subjects research.
- (2) Critically evaluating the IRB's function and adherence to applicable federal regulations, state laws and accreditation standards governing human subjects research.
- (3) Critically evaluating investigators' performance of human subjects research and adherence to applicable federal regulations, state laws and accreditation standards, which govern human subjects research.
- (4) Evaluating performance of each IRB member and chair no later than 2 months before expiration of term and before re-appointment, providing written feedback to the IRB member or chair 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 RACC or reported to the RACC by someone else.
- (5) Critically evaluating the impact of the institution's systematic changes on the conduct of human subjects research and providing information as to whether these changes have led to improvements.
- (6) Suggesting systematic improvements in the institution's human subjects 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) Participating, as appropriate, in the training, education and development of individuals responsible for the oversight or conduct of human research.
- (8) Reviewing investigator compliance with HRPP and IRB requirements.
- (9) Fulfilling all other responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP, and R&D Service committee's and subcommittees' policies and procedures.

#### 4. PROCEDURES:

- a. The PVAMC **R&D Committee** Standard Operating Procedures (SOP) is a reference for R&D Committee members, subcommittee members, investigators and R&D Service administrative staff. The R&D Committee 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 reviewing research project proposals and overseeing the functions of its subcommittees. The R&D Committee also abides by the HRPP 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 abides by the procedures and principles of the IACUC Committee Handbook 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 the oversight of all research activities involving the use of human subjects. The PVAMC IRBs shall perform all functions required under [38 CFR 16](#) (Common Rule) for reviewing and approving human subjects 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, except as outlined below, and research involving VA patients as research subjects (hereafter "VA research"). These responsibilities include maintaining the assurances of compliance set forth in the FWA obtained from the OHRP and only approving research involving human research subjects in accordance with all applicable federal requirements in the protection of human research subjects and operations of the IRB. IRB review and approval of VA Research shall be conducted in accordance with [38 CFR 16](#), [45 CFR 46](#) Subparts A through D, [21 CFR 50](#) and [56](#) (where applicable), and all relevant academic affiliate policies and VA rules and policies set forth in writing in handbooks and directives.
- d. The [PVAMC IRB Standard Operating Procedures \(SOP\)](#) is a reference for IRB members, coordinators, investigators and other individuals associated with the HRPP. This SOP details the policies and procedures specifying the regulations and policies governing human subjects' research and the requirements for submitting research proposals for review by the PVAMC IRBs.
- e. 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 adheres to the policies in VHA Handbook 1200.8.
- f. 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 by which the Subcommittee on Research Space abides.

g. If in the course of its review, the R&D Committee requires changes to a protocol, including those that relate to the determination of the protection of human subjects, the R&D Committee must refer those changes back to the appropriate subcommittee for its approval before the R&D Committee may give final approval.

h. Neither the R&D Committee, nor the director may approve a research project that has not been approved by all appropriate subcommittees.

i. The annual budget for the HRPP is submitted to the R&D Committee for review and approval.

j. Policies to protect human research subjects are initiated by the ACOS/R&D, reviewed and approved/disapproved by the R&D Committee and implemented as appropriate by the subcommittees, R&D Service administrative staff, investigators, and employees of the PVAMC.

k. Subcommittee meeting minutes shall be available to the R&D Committee no later than three weeks after the convened meeting.

**l. Principal Investigators must adhere to the following procedures for research conducted at the PVAMC:**

(1) For research projects to be conducted at the PVAMC, prepare a PVAMC Proposed Project Questionnaire and other applicable materials listed in 3.f.1 above and submit these items 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 the research proposal.

(2) For research projects that will be conducted at both the PVAMC and Oregon Health & Science University (OHSU), prepare a PVAMC Proposed Project Questionnaire, OHSU Proposed Project Questionnaire, and other applicable materials listed in 3.f.1 above. Submit these items with the research proposal and abstract to the R&D Service Office. VA signatures must be obtained prior to submitting the grant to OHSU Research Services. The submission must be received in a timely manner to allow adequate time for processing the research proposal.

(3) Research conducted in hospital wards leased by OHSU that does not involve patients currently considered to be PVAMC in-patients must be reviewed and approved according to all applicable policies at OHSU.

(4) For research projects to be administered and conducted only at OHSU (no PVAMC patients, work time, space, supplies, or funds will be utilized), no PVAMC paperwork is required.

(5) For research projects to be administered by the Portland VA Research Foundation and conducted at the PVAMC and/or OHSU, submit a PVAMC Proposed Project Questionnaire

and other applicable materials listed in 3.f.1 above and submit these items 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 the research proposal.

(6) Research conducted under the purview of the PVAMC must be conducted in compliance with all applicable institutional, HRPP, and regulatory requirements.

m. For **research involving human subjects** at the PVAMC, principal investigators must adhere to the following procedures:

- (1) Complete all required education in the protection of human research participants.
- (2) 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.
- (3) 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.
- (4) Initiate the study only **after** approval by **both** the IRB and the R&D Committee.
- (5) Adhere to all assurances given to the IRB at the time of project approval.
- (6) Forward to the R&D Service the original signed informed consent form (VA Form 10-1086) for each patient enrolled in the research project for scanning into the patient's electronic medical record. After scanning, an R&D administrative staff member will return the informed consent form to the principal investigator for inclusion in the protocol case history files. The PI will assure a copy of the informed consent is given to the patient, and that the patient initials the original signed consent form acknowledging receipt of said copy.
- (7) Promptly report any items listed in item G.1. of RR 602 "Ongoing Review" in the IRB Standard Operating Procedures (SOP).
- (8) Complete annual review forms for continuing approval of ongoing research. The R&D Committee on an annual basis will assure the scientific quality of each active research protocol.
- (9) Cite PVAMC IRB approval in the methods section of all manuscripts involving human studies at the PVAMC.
- (10) Fulfill all other responsibilities and adhere to the policies and procedures outlined in the appropriate institutional, HRPP policies and procedures, and the IRB SOP.

n. For **research involving animal subjects** at the PVAMC, the principal investigator must adhere to the following procedures:

- (1) Obtain approval from the PVAMC IACUC.
- (2) Complete continuing review forms for approval of ongoing research and indicating research results, changes in protocol, and completion and termination of the research.
- (3) Cite PVAMC IACUC approval in the methods section of all manuscripts involving animal studies at the PVAMC.
- (4) Complete all applicable education requirements.
- (5) 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.

- o. 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) Complete an annual self-inspection survey and pass an inspection conducted by a member of the SRS.
  - (3) Obtain an “Authorized Users License” issued by the Radiation Safety Subcommittee and authorizing the use and purchase of isotopes.
  - (4) Complete all applicable education requirements.
  - (5) 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:**

[VHA Handbook 1200.1](#), The Research and Development (R&D) Committee  
[VHA Handbook 1200.5](#), Requirements for the Protection of Human Subjects in Research, July 15, 2003  
[VHA Handbook 1200.7](#), Use of Animals in Research  
[VHA Handbook 1200.8](#), Safety of Personnel Engaged in Research, June 7, 2002  
[VHA Handbook 1200.19](#), Presentation of Research Results, June 19, 2001  
[VHA Handbook 1605.1](#), - Privacy and Release of Information  
[VHA Handbook 1605.2](#), - Minimum Necessary Standard for Protected Health Information  
[PVAMC IRB Standard Operating Procedures \(SOP\)](#)  
[PVAMC IACUC website](#)  
[PVAMC Research Service Space Policy](#)  
[PVAMC R&D Committee Standard Operating Procedures](#)  
[Nuremberg Code, 1949](#)  
[Declaration of Helsinki, June 10, 2002](#)  
[Belmont Report, April 18, 1979](#)  
[21 CFR 50](#) Protection of Human Subjects  
[21 CFR 56](#) *Institutional Review Boards*  
[38 CFR 16](#) *Protection of Human Subjects*  
[45 CFR 46](#) *Common Rule*

**6. CONCURRENCES:**

Research Assurance and Compliance Coordinator (RACC)  
R&D Committee (R&D)  
Chief, Human Resources  
Chief of Staff (P3CCE)

**7. RESCISSIONS:** Medical Center Memorandum No. 151-01 dated December 21, 2006

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

**9. REVIEW DATE:** June 11, 2011

**VA MEDICAL CENTER, PORTLAND, OREGON**

**Medical Center  
Memorandum No. 151-01**

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