

**PORTLAND VETERANS AFFAIRS
MEDICAL CENTER**

RESEARCH & DEVELOPMENT COMMITTEE

Standard Operating Procedures

*Approved by the Research & Development Committee and Effective:
September 8, 2008*

—TABLE OF CONTENTS—

I. INTRODUCTION-----1

II. RESEARCH & DEVELOPMENT COMMITTEE ADMINISTRATION-----1

A. The Authority of the R&D Committee

B. Purpose of the R&D Committee

C. R&D Committee Subcommittees

III. R&D COMMITTEE MEMBERSHIP-----3

A. Voting Membership Composition

B. Membership Requirements

C. Ex-Officio Non-Voting Membership

D. Alternate R&D Committee Members

E. Ad Hoc Reviewers

F. Training of R&D Committee Chair and Members

IV. RESPONSIBILITIES OF THE R&D COMMITTEE-----5

A. Responsibilities of the R&D Committee

B. Reviews Required by the R&D Committee

V. PRE-SUBMISSION REVIEW PROCEDURES -----8

VI. CONDUCTING R&D MEETINGS -----8

A. Convened R&D Committee Meetings

B. Actions Which May be Taken by the Convened R&D Committee

C. Use of Primary Reviewers with Convened R&D Committee Research Project Reviews

D. Research Exempt from Institutional Review Board Review

VII. RECORD RETENTION & DOCUMENTATION-----10

A. R&D Committee Records

B. Written Standard Operating Procedures

C. R&D Committee Membership Roster

D. R&D Committee Correspondence

E. Research Project Application Files

F. Research Tracking System

G. Agenda for Convened R&D Committee Meetings

H. Documentation of Convened R&D Committee Meeting – Minutes

I. Documentation of Attendance at R&D Committee Meetings

J. Access to Records

K. Record Retention

VIII. NON-COMPLIANCE-----13

A. Complaints and Allegations of Non-Compliance Pertaining to Human Research

B. Suspension or Termination of R&D Committee Approval of Research

IX. CONFLICT OF INTEREST IN RESEARCH -----13

A. Conflict of Interest in Research

APPENDICES

A. R&D Committee Membership Roster

B. R&D Committee Alternate Membership Roster

C. Portland VAMC Pre-Submission and Concurrence Review Checklist

IX. REFERENCES

- A. VHA Handbook 1200.1, Research & Development Committee Handbook**
- B. VHA Handbook 1200.5, Requirements for the Protection of Human Subjects in Research**
- C. MCM. No. 151-01, Responsible Conduct of Research**
- D. HRPP, Policy & Procedure No. 3.: Complaints and Allegations of Non-Compliance Pertaining to Human Research**
- E. HRPP, Policy & Procedure No. 4: Education for the Protection of Human Research Participants**
- F. Conflict of Interest in Research Policy**
- G. IRB Standard Operating Procedures**
- H. IACUC Handbook**
 - I. Research Service Space Policy**
- J. Safety of Personnel Engaged in Research, VHA Handbook 1200.8**
- K. VHA Directive 2007-044, Use of a Cooperative Research and Development Agreement (CRADA)**

I. INTRODUCTION

The Portland VA Medical Center (PVAMC) Research & Development Committee (R&D) Standard Operating Procedures (SOP) is a reference for R&D Committee members, subcommittee members, investigators and Research 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 reviewing research project proposals and overseeing the functions of its subcommittees. The R&D Committee also abides by the Human Research Protection Program policies and procedures.

This document will be reviewed and modified as needed to reflect updated and applicable regulations, policies, and institutional procedures.

II. RESEARCH & DEVELOPMENT COMMITTEE ADMINISTRATION

A. The Authority of the R&D Committee (VHA Handbook 1200.1)

The R&D Committee is responsible through the Chief of Staff to the Portland VA Medical Center Director for maintaining high standards throughout the PVAMC's Research & Development program and for ensuring the scientific and ethical quality of all research, the protection of human subjects in research, the safety of personnel engaged in research, the welfare of laboratory animals, security of VA data, and the security of VHA research laboratories. The Medical Center Director is the institutional official responsible for all aspects of the research program. The Medical Center Director delegates the authority to administer the R&D program to the Associate Chief of Staff for Research & Development (ACOS/R&D), who reports to the Chief of Staff.

The R&D Committee acts as the governing body of the Research Service at the PVAMC. It serves as a parent committee to all of its subcommittees and must review and approve subcommittee actions, minutes, and periodic reports. All study protocols, which have been reviewed and approved by a PVAMC subcommittee, must also be reviewed and approved by the R&D Committee, regardless of funding status and source, prior to study initiation. No research may be undertaken without R&D Committee and appropriate subcommittee(s) review and approval.

Neither the R&D Committee, nor the Medical Center Director can approve research that has not been approved by all of the appropriate R&D Committee subcommittee(s) of record. The R&D Committee and higher authority may strengthen requirements and/or conditions, or add other modifications to secure R&D Committee approval or approval by a higher authority.

B. Purpose of the R&D Committee

The PVAMC R&D Committee's primary purpose is to maintain high standards throughout the R&D program.

The R&D 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, protection of human research subjects, safety of research laboratories and personnel engaged in research and welfare of animal subjects in research.

C. R&D Committee Subcommittees

The R&D Committee is the governing body for all research conducted at the PVAMC. The R&D Committee is responsible for maintaining high standards throughout the research program, through the review of actions of its subcommittees and for the scientific quality and appropriateness of all research, which may involve animal and human subjects. The subcommittees established by the R&D Committee include: the institutional review board (IRB), the institutional animal care and use committee (IACUC), the subcommittee on research safety (SRS) and the Subcommittee on Research Space.

The members of the IACUC, IRB and Safety subcommittees are nominated by the ACOS/R&D, approved and voted on by the R&D Committee and appointed by the Medical Center Director. Members of the Subcommittee on Research Space are approved as per the Research Service Space Policy. Each subcommittee must have at least one member from the parent committee. Each subcommittee keeps minutes of its meetings and reports to the R&D Committee, which accepts or rejects its recommendations, except that the R&D Committee cannot alter an adverse report or recommendation, e.g., disapproval for ethical or legal reasons by the Institutional Review Board (IRB/Subcommittee on Human Studies), Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS), or Subcommittee on Research Space. Subcommittee meeting minutes are kept on file in the Research Service office.

1. 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 of the functions required under 38 CFR 16 (Common Rule) for reviewing and approving human subjects research conducted under the auspices of the Institution's Federalwide Assurance (FWA). This includes, but is not limited to, research supported by the VA 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 Office of Human Research Protections (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 VHA Handbook 1200.5.

The R&D Committee oversees the IRB in these responsibilities.

The Department of Veterans Affairs (VA) and other Federal regulations require specific protections for human subjects. The Associate Chief of Staff/Research & Development is responsible for 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 Human Research Protection Program (HRPP) established for human research protections.

The PVAMC IRB Standard Operating Procedures (SOP) is a reference for IRB members, coordinators, investigators and other individuals associated with the HRPP. The 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 and R&D Committee.

2. The R&D Committee has charged the PVAMC **Institutional Animal Care and Use Committee (IACUC)** with ensuring compliance with animal research regulations. The R&D Committee oversees the IACUC in this responsibility. The IACUC Committee Handbook contains the procedures and principles by which the IACUC abides in the review and conduct of research involving animal research subjects.
3. The R&D Committee has charged the PVAMC **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.

4. The R&D Committee has charged the PVAMC **Subcommittee on Research Space** with the review of 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.

III. R&D COMMITTEE MEMBERSHIP

The membership of the R&D Committee, supplemented as needed by advisors or consultants, reflects a broad and balanced representation of all divisions within the PVAMC Medical Center. The Portland VA strives to maintain balance and expertise on the R&D Committee by approving members from mental health, neurology, surgery or anesthesiology, internal medicine, basic science, health services research, rehabilitative research and animal research. This balance maintains the expertise required to perform the scientific review of all research performed at the PVAMC and under PVAMC auspices.

The R&D Committee members are nominated by the Associate Chief of Staff/Research & Development, current R&D Committee members, subcommittee members and/or the facility’s staff. Nominations are voted on by the R&D Committee and appointed by the PVAMC Director.

A. Voting Membership Composition

1. At least one member of the committee should have expertise in bio-statistics and research design.
2. A member of the committee should have expertise in animal research techniques and biomedical animal study settings.
3. 3At least two members from the facility’s staff should have major patient care or management responsibilities.
4. At least two members should be VA investigators who are actively engaged in major R&D programs or who can provide R&D expertise.
5. At least one member should be an individual who holds an academic appointment at the PVAMC’s affiliated institution, Oregon Health & Science University (OHSU) and who is either a full-time Federal employee or a part-time permanent Federal employee.

Voting members may fill more than one criterion for membership requirements, for example, a member may have both major patient care or management responsibilities and be actively engaged in major R&D programs. The R&D Committee aims to include a member of each subcommittee on its membership. Membership also strives to represent diverse backgrounds with consideration given to race, gender, and ethnicity. The current composition of the R&D Committee in terms of members by name, degrees held, and representative capacity is located in Appendix A. In addition, the membership is summarized in the R&D Committee meeting minutes.

B. Membership Requirements (all but ex-officio members):

1. All voting members must be compensated full-time or part-time Federal government employees.
2. Voting members serve terms of 3 years, and may be reappointed without any lapse in time if it is deemed in the Committee’s best interest. The terms shall be staggered to provide partial change in membership annually.
3. The committee members, exclusive of ex-officio members, shall elect a chairperson on an annual basis. The Chairperson must be approved and officially appointed, in writing, by the medical center Director for a term of one year, and may be reappointed without any lapse in time. The chairperson may be someone who has just completed a 3 year term on the R&D Committee. The chairperson, if re-elected, may serve 2 consecutive 1 year terms. The Chairperson must not simultaneously chair a subcommittee of the R&D Committee.

C. **Ex-Officio Non-voting Membership**

Ex-Officio non-voting members include the:

1. Medical Center Director;
2. Chief of Staff (COS);
3. Associate Chief of Staff, Research & Development (ACOS/R&D);
4. Administrative Officer, Research & Development (AO/R&D);
5. Veterinary Medical Officer;
6. Representative of the Research Pharmacy;
7. Research Assurance and Compliance Coordinator;
8. Information Security Officer
9. Privacy Officer

The ACOS/R&D functions as Executive Secretary of the committee. Other ex-officio members may be appointed to the R&D Committee if their appointments assist the R&D Committee in fulfilling its responsibilities. If the ex-officio members are not full or permanent part-time compensated VA or Federal employees, they may only provide individual advice to the R&D Committee, or exchange facts and information.

VHA Directive 2007-040 states that VHA facility ISO and Privacy Officer must be appointed as non-voting members of either the facility's Internal Review Board(s) (IRB) or Research and Development (R&D) Committee of record. In order to comply, the Portland VA Medical Center (PVAMC) Director will appoint the Information Security Officer (ISO) and Privacy Officer (PO) as non-voting *ex-officio* members of the R&D Committee.

D. **Alternate R&D Committee Members**

Alternates for the R&D Committee members may be nominated in the same manner as regular members, approved by the R&D Committee and appointed by the Medical Center Director. The alternate member should have a similar or related work specialty or responsibility as the member s/he represents in their absence. The alternate member's term expires with the term of the individual that s/he is representing. The alternate member may serve on the R&D Committee with less than 1 year between terms, i.e. a R&D Committee member that is rotating off the committee may serve as an alternate for a new member voted to serve on the committee, since his/her service may be intermittent. The alternate member is only allowed to vote in the absence of the member s/he represents. An alternate Chairperson may be designated in the same manner as other alternate R&D Committee members.

E. **Ad Hoc Reviewers**

The R&D Committee may, at its discretion, obtain services of ad hoc reviewers when additional expertise is required. Ad hoc reviewers cannot have a conflict of interest (as defined in the PVAMC Conflict of Interest in Research Policy) with the study they are asked to review. Ad hoc reviewers do not vote with the committee. Such consultants may be asked to submit written evaluations of the programs or, when necessary, to present their recommendations to the committee in person. R&D funds may be used to pay for the services of consultants who are not employed by the Federal Government.

F. **Training of R&D Committee Chair and Members**

It is the responsibility of the ACOS/R&D and the Research Service to provide members with an initial orientation to their committee activities and appropriate continuing education related to the R&D Committee. Upon appointment to the R&D Committee, new members receive a copy of the most current R&D Committee SOP prior to the first meeting with the R&D Committee. All members receive updated versions of the R&D Committee SOP as they are issued. The ACOS/R&D may provide further guidance and training as needed.

Per the Office of Research & Development Stand Down requirements, members and alternates of the R&D Committee must complete the education in the protection of human research participants annually. These

requirements are outlined in the Human Research Protection Program, Policy & Procedure No.4, "Education for the Protection of Human Research Participants."

IV. RESPONSIBILITIES OF THE R&D COMMITTEE

The PVAMC R&D Committee's primary responsibility is to maintain high standards throughout the R&D program.

The R&D 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, protection of human research subjects, safety of research laboratories and personnel engaged in research and welfare of animal subjects in research.

A. Responsibilities of the Research & Development Committee (MCM No. 151-01)

The R&D Committee is responsible for:

1. Assuring the continuing high quality of the facility's R&D program.
2. Planning and developing broad objectives of the R&D program so that it supports the patient care mission of the facility.
3. Evaluating critically and deciding approval/disapproval of research with respect to the:
 - (a) Quality, design, desirability and feasibility of each new R&D proposal, regardless of funding;
 - (b) Continuing R&D projects;
 - (c) Non-protocol applications;
 - (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 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 will not approve any proposal that has been disapproved by any subcommittee, nor will 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' Chair and members and the members' qualifications, experiences, and performance. 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, annually, 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.
11. Security of research laboratories where hazardous agents are stored or utilized and all Biosafety Level 3 (BSL-3) research laboratories.
12. Security of VA data, VA protected information, and VA sensitive information.

B. Reviews Required by the R&D Committee**1. Initial Reviews**

In conducting an initial review, the R&D Committee must evaluate the scientific quality, design, desirability and feasibility of each new Research & Development proposal. The R&D Committee evaluates the scientific quality, the relevance to the VA's mission and the facility's research program, and the ability of the investigator to perform and complete the research. In addition, the review must include information on the use, storage, and security of VA data and VA sensitive information including VA protected information. The R&D Committee must also verify that the form of any applicable research agreement (Cooperative Research and Development Agreement or CRADA, grant, contract, or other) is appropriate for the research being proposed. The review should include review of the budget, requirements for space, personnel, equipment and supplies, the role of the investigator at the PVAMC, the investigator's qualifications, and any other information relevant by the R&D Committee. The review of some of these items may be delegated to the Administrative Officer/Research & Development by the R&D Committee.

Prior to the initiation of a research project, all appropriate subcommittees and the R&D Committee must approve it. Only research projects that have been approved or contingently approved by the appropriate subcommittees are forwarded to the R&D Committee for review. This includes evaluating the scientific quality and appropriateness of all research involving human subjects. For projects that involve the use of veterans' data or another person's data (either identified or de-identified), the R&D Committee or its designee must assess that there are mechanisms in place to ensure:

- (a) security of data and all files
- (b) confidentiality of data, including data derived from research subjects
- (c) release of data in accordance with VHA regulations and policies
- (d) control of the data so that reuse of the data is within an approved research protocol and in compliance with VHA procedures

Members of the R&D Committee shall be assigned research projects for review. The review consists of the research project protocol and abstract. Each reviewer will provide a brief summary of the research to the committee during the meeting. Any and all ethical, scientific or other concerns will be verbalized at this time.

2. Continuing Research & Development Projects

The R&D Committee will conduct continuing review of all research projects at least annually.

3. Non-Protocol Applications

These applications may include special initiatives (equipment requests) and research staff which include the following:

- (a) New non-clinical Ph.D. applicants for merit review eligibility;
- (b) Non-clinical Ph.D. applicants for the Career Scientist program;
- (c) Endorsement of new clinicians for the Career Development Program.

4. Manuscripts to be submitted for publication

All publications by VA investigators require approval by the R&D Committee. Reviewers must verify that the VA is listed in the address and/or acknowledgment sections. An annual quality assurance review of publications may be conducted, or the review can be conducted on a monthly basis.

5. Data Security

The R&D Committee takes seriously the protection of VA data, VA protected information, and VA sensitive information. Definitions for these terms are outlined in VHA handbook 1200.1. The R&D Committee delegates authority to the Associate Chief of Staff/R&D and the Administrative

Officer/R&D the responsibility to assess the data security checklist which is required for each protocol, and to assure that the checklists are assessed annually.

6. Other review activities

To assure maintenance of high scientific standards, protection of human subjects, adequate safety measures and proper use of animal subjects, other items may also be reviewed by the R&D Committee. Subcommittees forward policies, reports and research concerns to the R&D Committee for review. The R&D Committee will evaluate and may decide to endorse, approve or disapprove research projects, policies and procedures in order to maintain PVAMC scientific standards. Reports from subcommittees or other Research Service staff may include aspects of:

- (a) New and Continuing Institutional, Subcommittee and/or Investigator Compliance/Non-Compliance Assessments;
- (b) Performance Gaps;
- (c) Continuous Quality Improvement Assessments of the Institution, Subcommittees and/or Investigators;
- (d) Enforcement Issues; and
- (e) Evaluating conflicts of interest in proposed research projects according to the "Conflict of Interest in Research Policy."
- (f) The annual budget for the HRPP is submitted to the R&D Committee for review and approval.
- (g) Information pertaining to all requests for Without Compensation (WOC) appoints for research ensuring that all have been appropriately justified and the appointments are in compliance with all applicable research, Human Resource Management, and other VA policies.
- (h) Annual quality assurance review of research employees involved in human subject research to ensure the employees are working within their scope of practice and their privileges allowed by the PVAMC's By-laws and granted to them by the PVAMC.
- (i) Annual quality assurance review of Cooperative Research and Development Agreements and other agreements in support of the research program or specific research projects, and the assessment of the impact of these reports on the research program, when applicable.
- (j) Annual review of the Research Safety and Security Program, including planned training, compliance, or security issues
- (k) Review of the Animal Care and Use Program including inspection reports, IACUC composition, IACUC arrangements, budgets, space, support staff, training, quality improvement activities, compliance issues, and goals for the next year. (These items are reviewed at least annually)
- (l) Review on at least an annual basis of the Human Research Protection Program including IRB composition, credentialing and training status report, budget, space, support staff, quality improvement activities, performance, compliance issues and goals for the next year.
- (m) VHA Directive 2007-040 states the facilities are encouraged to engage the ISO and PO prior to submission of a protocol for review by the IRB. Therefore, the PVAMC ISO, PO, and the Administrative Officer (AO) for R&D will be tasked with the review of privacy and data security for all human subjects research conducted at the Portland VAMC. The ISO, PO, and AO will meet before each IRB meeting. They will receive any and all relevant pages of the Initial/Continuing Review Questionnaires (IRQ/CRQ) as well as any pages from the actual protocol referenced in the IRQ/CRQ, and the completed Data Security Checklist for Principal Investigators form and will review data security and privacy as described in the protocol. Any questions or concerns will be documented and forwarded to the Principal Investigator and will also be presented by the AO at the next IRB meeting when the protocol is reviewed. If there are no concerns, concurrence will be given at the IRB meeting. The IRB will review the entire protocol, taking into account any and all concerns expressed by the ISO, PO and AO, and vote for approval, contingent approval or disapproval with documentation in the minutes of the discussion and vote. The protocol,

including data security and privacy, will then be reviewed and voted on at a convened R&D meeting.

7. **Other Standing Agenda Items**

- (a) Review of Subcommittee meeting minutes.
- (b) **ACOS/R&D Report** – The ACOS/R&D will update the R&D Committee on any current issues facing the Research Service. Committee members are expected to provide feedback and advice.
- (c) Report of pre-submission reviews and concurrence by the Administrative Officer/R&D
- (d) **Human Research Protection Program** –Any issues regarding the human research protection program are brought forward to the R&D Committee as a formal agenda item. Policy to protect human research subjects is 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.

V. **PRE-SUBMISSION REVIEW PROCEDURES**

VHA handbook 1200.1 requires that research protocols that are to be submitted to VA, other Federal agencies, or other entities for funding consideration undergo a preliminary review and receive concurrence from the R&D Committee prior to submission of the protocol under a “Just-in-Time” procedure. Subcommittee approvals are not necessary at the time the project is submitted to the funding agency.

The R&D Committee delegates authority to conduct a presubmission review and give concurrence for the submission of non-VA grants to the R&D Committee Chair or the Administrative Officer/Research & Development. When such a preliminary review is conducted and concurrence granted, the individual completing the review will complete the Portland VAMC Pre-Submission/Concurrence Review Checklist, which is included in Appendix C. The preliminary review may be conducted at any time and will be reported to the full R&D Committee at the next convened meeting. Approval to submit a VA Merit Review or VA Investigator Initiated Research proposal can only be given at a convened meeting of the R&D Committee. Concurrence of the R&D Committee does not represent approval to conduct the research. Review by applicable subcommittees and final review by the R&D Committee, with full approval from all applicable committees, must be granted before the work on the research may begin.

VI. **CONDUCTING R&D MEETINGS**

A. **Convened R&D Committee Meetings**

A majority of the R&D Committee members, excluding the ex-officio members, must be present to conduct a convened meeting. An R&D Committee meeting is not convened until a quorum (one half of the voting members plus one) is present. The R&D Committee will conduct initial and continuing reviews of all research and any other issues brought forth to the R&D Committee at convened meetings at which a quorum of the members are present. For research and any other issues to be approved, it must receive the approval of a majority of those members present at the meeting where a quorum is present.

The R&D Committee meets once per month. The R&D Committee meets on the first Monday of the month, except for months in which a Federal holiday is on the first Monday of the month. In these rare cases, the R&D Committee meeting will be held on the Monday proceeding the Federal holiday.

Additional meetings may be called by the Chair, as required, to act on compliance issues, handle the volume of submissions and/or meet VA submission deadlines.

B. **Actions Which May Be Taken by the Convened R&D Committee**

R&D Committee may take any of the following four actions for initial or continuing review of research, policies, reports, etc.:

1. **Approved:** Approved with no changes (or no additional changes). The research may proceed once the R&D Committee approval is obtained in writing. The final R&D Committee approval is not to be released to the Principal Investigator by the Research Service until all contingencies of the subcommittees are appropriately met with the exception of grants submitted for “Just in Time” review.
2. **Contingent Approved:** Approvable with minor changes to be reviewed by a designated R&D Committee member or, if the committee determines it is appropriate, review by the R&D Coordinator. Such minor changes must be clearly delineated by the R&D Committee so the investigator may simply concur with the R&D Committee’s stipulations. The research may proceed after the required changes are verified and the protocol approved by the designated reviewer or the R&D Coordinator if so determined by the committee.
3. **Tabled:** pending receipt of additional substantive information or substantive changes. The R&D Committee determines that it lacks sufficient information about the research to proceed with its review or that the changes are so numerous as to require re-review by the full board. The research may not proceed until the convened R&D Committee has approved a revised application incorporating all necessary information.
4. **Disapproved.** The R&D Committee has determined that the research cannot be conducted at the PVAMC facility or by its employees or agents.

Studies which have received either outright approval or contingent approval from any of the subcommittees may be forwarded to the R&D Committee for review. However, final approval of the R&D Committee may only occur after all applicable subcommittees have granted final approvals.

C. Use of Primary Reviewers with Convened R&D Committee Research Project Reviews

The R&D Coordinator will make a preliminary review of the research project abstract and assign one primary reviewer to review the protocol and abstract for the next R&D Committee meeting.

The entire research file is available to all R&D Committee members prior to and during the convened meeting. All R&D Committee members are afforded full opportunity to discuss each research proposal during the convened meeting.

R&D Committee reviewers must evaluate the scientific quality of the research project, the relevance to both VA’s mission and the PVAMC’s research program, and the ability of the investigator to perform and complete the research. In addition, review by the R&D Committee must include information on the use, storage and security of VA data and VA sensitive information including VA protected information, the budget, the form of the funding agreement (CRADA, grant, etc.), the requirements for space, personnel, equipment, and supplies, the role of the investigator at the facility, the investigator’s qualifications, and any other information deemed relevant by the R&D Committee. The review of some of these items may be delegated to the AO/R&D or the ACOS/R&D to complete the review for the R&D Committee. Primary reviewers for the R&D Committee should determine if there are any scientific or ethical concerns and verify that each abstract is properly formatted and addressed according to: objectives, plan, methods, and findings to date. Animal and basic science research projects’ abstracts must also contain a clinical relevance section.

At the convened R&D Committee meeting, during the initial reviews of research projects, the members: provide a brief summary of the research project, voice any ethical or scientific concerns that they may have regarding the research, request clarification and if needed, request changes.

At the time of continuing review for research projects, an R&D Committee primary reviewer will re-evaluate the research project. 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 can give final approval.

D. Research Exempt from Institutional Review Board Review

The IRB serves as the R&D Committee's designee in the review of requests for exempt status based on categories stipulated at 38CFR16.101. A research project that is exempt from IRB review must be reviewed by the R&D Committee, prior to initiation. The R&D Committee will review the research project and make a final determination of whether or not the study is exempt from IRB review and will consider approval. Once approved by the R&D Committee, the project must be included in the R&D Committee's annual review of research projects. Any individual involved in making the determination of exempt status of a proposed research project cannot be involved in the proposed research.

VII. RECORD DOCUMENTATION AND RETENTION

A. R&D Committee Records

The R&D Committee records include the following:

1. Written Standard Operating procedures;
2. Membership rosters;
3. R&D correspondence to the PI regarding research projects is kept within the appropriate research project file located in the Research Service office;
4. Documentation of convened R&D Committee meeting minutes;
5. Research project application files, including copies of all research proposals, amendments reviewed, accompanying materials, and continuing and final reports.

B. Written Standard Operating Procedures

R&D Committee members are provided with a copy of the standard operating procedures at the time they join the R&D, and each time the SOP is updated.

The ACOS/R&D, Administrative Officer/R&D, R&D Coordinator, and Research Assurance & Compliance Coordinator work together to write and maintain the SOP. The SOP is reviewed and modified as needed to ensure compliance with federal and institutional regulations and policies.

C. R&D Committee Membership Roster

The R&D Service maintains the current R&D Committee membership roster. The R&D Coordinator is responsible for maintaining an updated R&D Committee roster and R&D Committee alternate membership roster. The rosters include name, degrees held, and representative capacity (e.g. service and OHSU representative) of each member. The R&D Committee membership roster is included in Appendix A. The Alternate Membership Roster is included in Appendix B.

D. R&D Committee Correspondence

Accurate records are maintained of all communications to and from the R&D Committee. The R&D Committee Chair signs R&D Committee correspondence. Copies of all correspondence are filed in the appropriate research project file kept in the PVAMC Research Service office. Investigators shall be notified in writing of the determination of the R&D Committee, and any changes that are required by the R&D Committee. A signed hard copy of the correspondence will be mailed to the investigator for their files. Responses to the R&D Committee should come from the Investigator or a designated study coordinator, and may be communicated electronically or by hard copy.

In cases in which a project being performed at the PVAMC has multiple investigators, correspondence will be sent to the Principal Investigator (PI) primarily in charge of the study or designated Study Coordinator, who will be responsible for communicating the results to the PI. The PI is ultimately responsible for communicating to the other investigators and assuring that they comply with R&D Committee requirements. In cases where communication is electronic, upon resolution of the topic of the communication, a hard copy

will be generated and filed with the project file by the R&D Coordinator and/or staff.

E. Research Project Application Files

Each research project has a separate file. Protocols are assigned a unique number from the Manage your Institutional Review Board (MIRB) computer program and a unique grant number for tracking and administration purposes. R&D Committee records which are specific to a project are kept in the file for that project. To decrease redundancy and increase efficiency, some of the required subcommittee records, such as the records for the IRB and the SRS are also kept in the same project-specific files. IACUC records are maintained in the Research Office space maintained near the Animal Care facility, and are house separately from the other project files. In this manner, copies of written subcommittee correspondence to and from VA investigators are available in the VA research office space for each project.

F. Research Tracking System

The R&D Service uses a reliable computerized tracking system, the MIRB computer program, which is maintained by the R&D, IRB and SRS Coordinators. MIRB stores information regarding which documents have been received, when they were reviewed, and the results of that review. Additionally, MIRB tracks changes that are needed, when those changes were received and approved, and the date of continuing review. MIRB also tracks R&D Committee membership and generates meeting minutes and correspondence.

The R&D Service also uses the VA enterprise project management information system (ePROMISE) Database which tracks research projects which have been reviewed by the R&D Committee and which are pending funding, active, and/or final.

G. Agenda for Convened R&D Committee Meetings

An agenda is developed prior to each meeting of the R&D Committee and is distributed to members prior to the meeting.

The agenda includes the following:

1. Review and approval of R&D Committee minutes of previous meeting.
2. Review and approval of each subcommittee's meeting minutes. If draft minutes are submitted for review by the R&D Committee, formally approved minutes must be sent to the R&D Committee prior to the following R&D Committee meeting.
3. Old Business, if unfinished business exists.
4. New Business. New business may include: the ACOS/R&D report, report from AO/R&D regarding projects which have received pre-submission review and concurrence, HRPP business items, review of the annual budget, publications, Research Pharmacy Activity Report, subcommittee member qualifications, and policies and procedures from the subcommittees.
5. Initial Review of research projects with responsible reviewers identified.
6. Continuing Review of research projects with responsible reviewers identified.

H. R&D Committee Meeting Minutes

1. R&D Committee minutes are completed by the R&D Coordinator. Minutes shall include:
 - (a) Time and date of the convened meeting.
 - (b) Attendance and absence by name of all voting and non-voting members, including ex officio members. If an alternate is present, the minutes include this fact and state the name of the voting member that the alternate member is replacing.
 - (c) The presence of a quorum.
 - (d) Approval of prior meeting minutes.
 - (e) All items of business or information brought before the R&D Committee.
 - (f) Actions taken by the R&D Committee. The minutes shall include a summary of any discussion, any modifications required, all actions taken by the convened R&D Committee and the votes underlying those actions. The actions which may be taken are listed in VI.B. Actions which require a vote have the votes categorized as the

- number who voted “for,” “against,” “abstained,” “recused,” and “excused.”
- (g) The stipulations required for research projects contingently approved, tabled or disapproved. This shall include any required follow-up and which committee, subcommittee, or person is responsible for the follow-up.
 - (h) Summary of controversial issues and their resolutions.
 - (i) Minutes note persons who excused or recused themselves by name and in reference to a specific protocol.
 - (j) Date and time of the next meeting, as well as the meeting location if it is different than Bldg. 101, Room 433.
2. Minutes of the meeting are reviewed and signed by the Chairperson, executive secretary (ACOS/R&D), Chief of Staff, and the Medical Center Director.
 3. After the meeting, copies of the minutes, together with any comments the Director may care to make, will be distributed to all members of the R&D Committee in the agenda packet for the next meeting, and made available upon request to any investigator.
 4. Minutes shall be maintained by the R&D Committee Coordinator and the PVAMC Research Service office and made available to VA Central Office upon request.

I. Documentation of Attendance at R&D Committee Meetings

R&D Committee minutes shall list attendance as follows:

1. Names of members present, including the presiding officer (Chairperson).
2. Names of excused members.
Members are designated EXCUSED if the Chairman or R&D Committee Coordinator was notified in advance.
3. Names of absent members.
Members are designated ABSENT if the Chairperson or R&D Committee Coordinator was not notified in advance.
4. Names of alternates attending in lieu of specified (named) excused/absent members.

J. Access to Records

Research records are accessible to Research Service staff, R&D Committee Chairperson and members. Research investigators shall be provided reasonable access to files related to their research. Other authorized individuals, such as officials of Federal and state regulatory agencies, including the: Office of Research Oversight (ORO), the Office for Human Research Protections (OHRP), and the Food and Drug Administration (FDA), will have access to R&D Service records for inspection and copying upon determination of appropriateness and necessity at reasonable times and in a reasonable manner. Appropriate accreditation bodies shall be provided access to and may recommend additional procedures for maintaining security of R&D Service records.

A log of such individuals who do access the R&D Service records, besides the R&D Committee members, IRB members, Chair and Research Service staff, is kept by the Research Service staff.

The R&D Committee may have access to all of its subcommittees' records.

K. Record Retention

The records of research studies conducted at the PVAMC are kept for six years after the study is closed. The R&D Service maintains all records collected over the course of a study. The R&D Service also maintains documentation of all activities of the R&D Committee, including but not limited to, minutes of the R&D Committee and subcommittees, copies of written correspondence, and membership lists, according to the VHA record control policies. VHA Handbook 1200.1 states that the items specifically listed here must be maintained for a minimum of 5 years.

VIII. NON-COMPLIANCE

All investigators conducting research as employees or agents in the PVAMC are required to comply with institutional policies regarding research. All issues of non-compliance will be forwarded from the appropriate subcommittee and reviewed by the R&D Committee. The R&D Committee will vote on all recommendations for corrective action forwarded by the subcommittee to resolve the issue of non-compliance.

A. Complaints and Allegations of Non-Compliance Pertaining to Human Research

All issues of research-related complaints and allegation of non-compliance with HRPP and IRB policies and procedures brought to the R&D Committee from the IRB or Research Assurance & Compliance Coordinator are reviewed by the R&D Committee. The R&D Committee will determine and vote on recommendations for corrective action, including those forwarded by the IRB. The R&D Committee will document in their meeting minutes, the discussion, deliberation and final determinations for remedial action voted on by the R&D Committee.

For the complete policy regarding non-compliance in human research projects, please refer to the Human Research Protection Program: Policy and Procedure No. 3, "Complaints and Allegations of Non-Compliance Pertaining to Human Research."

B. Suspension or Termination of R&D Committee Approval of Research

The R&D Committee shall notify the Principal Investigator in writing of such suspensions or terminations and shall include a statement of the reasons for the R&D Committee's actions. In addition, a copy of the R&D Committee correspondence will be forwarded to the appropriate IRB for review and appropriate action, as applicable. The terms and conditions of the suspension must be explicit. The investigator shall be provided with an opportunity to respond in person or in writing.

Where the R&D Committee Chairperson determines that such action is necessary to ensure the rights and welfare of animal or human subjects, the Chairperson may require an immediate, temporary suspension of enrollment of new subjects or of continued participation of previously enrolled subjects, pending review of the situation by the convened R&D Committee.

IX. CONFLICT OF INTEREST IN RESEARCH

The PVAMC advocates full disclosure of all conflicts of interest in research. A conflict of interest is defined as any situation in which financial or personal obligations may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing, or reporting research. This may include both financial and non-financial conflicts of interest. The mere appearance of a conflict may be as serious and potentially damaging to the public trust as an actual conflict. Therefore, potential conflicts must be disclosed, evaluated, and managed with the same thoroughness as actual conflicts.

The R&D Committee will review all potential conflicts of interest identified by the Proposed Project Questionnaire (PPQ), the Continuing Review Questionnaire, or identified otherwise, at a convened R&D Committee meeting at which a quorum is present. The R&D Committee will create management plans to manage conflicts of interest.

If the potential conflict of interest to be reviewed involves any member of the R&D Committee, the conflicted member will step out of the room during the discussion of the research project. The conflicted committee member will be recused from the vote on the project and will not be included in the quorum for the vote. These actions will be documented in the meeting minutes.

When the chair or alternate chair is presiding over a meeting and must leave the room for discussion and vote on a research proposal for which s/he is investigator, resulting in neither the chair or alternate chair being present to conduct the proceedings, the primary reviewer for the study will preside over that portion of the meeting, leading discussion and calling for a motion and a vote.

The Conflict of Interest Administrator will notify the conflicted researcher, the Principal Investigator for the study, the IRB, and the ACOS/R&D of the decisions of the R&D Committee to minimize, manage, monitor and/or eliminate all potentially significant financial or non-financial conflicts of interest.

The R&D Committee will also review audit reports received from the Conflict of Interest Administrator of research projects that the R&D Committee determined to have conflicts of interest and will deliberate on any corrective action that is needed.

For complete information on conflicts of interest, including who must disclose potential conflicts, please refer to the PVAMC “Conflict of Interest in Research” Policy.