

**PORTLAND VETERANS AFFAIRS
MEDICAL CENTER**

RESEARCH & DEVELOPMENT COMMITTEE

Standard Operating Procedures

Approved by the Research & Development Committee and Effective: 08/02/2010

—TABLE OF CONTENTS—

- I. INTRODUCTION-----1**
- II. RESEARCH & DEVELOPMENT COMMITTEE ADMINISTRATION-----1**
 - A. The Authority of the R&D Committee**
 - B. R&D Committee Subcommittees**
- III. R&D COMMITTEE MEMBERSHIP-----3**
 - A. Voting Membership Composition**
 - B. Election of Chairperson**
 - 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. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR-----7**
- VI. RESPONSIBILITIES OF THE ACOS/R&D-----7**
- VII. CONDUCTING R&D MEETINGS -----8**
 - A. Convened R&D Committee Meetings**
- VIII. RECORD DOCUMENTATION & RETENTION -----8**
 - 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. R&D Committee Meeting Minutes**
 - I. Documentation of Attendance at R&D Committee Meetings**
 - J. Access to Records**
 - K. Record Retention**

IX. CONFLICT OF INTEREST IN RESEARCH -----11

REFERENCES

- VHA Handbook 1200.01, Research & Development Committee Handbook**
- VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research**
- VHA Handbook 1200.7, Use of Animals in Research**
- VHA Handbook 1200.8, Safety of Personnel Engaged in Research**
- MCM. No. 151-01, Responsible Conduct of Research**
- HRPP, Policy & Procedure No. 4: Education for the Protection of Human Research Participants**
- Conflict of Interest in Research Policy**
- IRB Standard Operating Procedures**
- IACUC SOP**
- SRS SOP**
- Research Service Space Policy**
- 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's oversight of the research program at the PVAMC, the functions of its subcommittees, and in some instances, review of research project proposals.

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 1200.01)

The R&D Committee is responsible through the Chief of Staff to the Portland VA Medical Center Director for advising and assisting in providing oversight, planning and execution of the PVAMC research program, and for maintaining high standards throughout the PVAMC's Research & Development program. Those standards include 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.

Neither the R&D Committee, nor the Medical Center Director may 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 a protocol approved by all appropriate subcommittees.

B. 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 R&D program, through review of actions of its subcommittees. 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 SRS are nominated by the ACOS/R&D, approved by the R&D Committee and appointed by the Medical Center Director. Members of the Subcommittee on Research Space are approved per the Research Service Space Policy. Each subcommittee must have at least one member from the R&D Committee. Each subcommittee keeps minutes of its meetings and reports to the R&D Committee.

Each subcommittee is responsible for initial and annual continuing review of studies under their purview.

The subcommittees of the R&D Committee are as follows:

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 functions required under 38 CFR 16 (Common Rule) for reviewing and approving human 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 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.

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 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, the ISO and PO will initial the IRQ/CRQ for concurrence, and the IRB will be notified that concurrence was given. 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 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.

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 Standard Operating Procedures (SOP) contains the procedures and principles by which the IACUC abides in the review and conduct of research involving animal. The IACUC adheres to the policies in VHA Handbook 1200.7.
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 Standard Operating Procedures (SOP) contains the principals and procedures by which the SRS abides in the review and conduct of research which will include biohazards or be conducted in a wet lab. The SRS adheres to the policies in VHA Handbooks 1200.08 and 1200.06.
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.

Each subcommittee must maintain adequate records. These records must include the following:

1. Copies of all research proposals and their amendments (and any accompanying materials) reviewed by the subcommittees.
2. All continuing or final reports.
3. Minutes of its meetings.
4. Copies of all written correspondence.
5. A membership list of all voting, non-voting, and ex-officio members including their appointed roles.
6. Written records documenting actions taken to carry out the subcommittee’s responsibilities.
7. Standard Operating Procedures
8. All communications to and from investigators, other committees, subcommittees, and other entities or individuals.

Subcommittee meeting minutes are filed in the Research Service office. Each subcommittee must make available to the R&D Committee a complete, unredacted set of minutes.

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 and reflects the types and amount of research conducted at the PVAMC. 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 adequately govern the research programs at the PVAMC.

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

The R&D Committee must have at least five (5) voting members, including whenever possible, at least one member with expertise in biostatistics and research design.

1. Voting members of the R&D Committee must meet the following criteria:
 - a) All voting members must be compensated full-time or permanent part-time Federal employees.
 - b) At least two members from the facility's staff must have major patient care or management responsibilities.
 - c) At least two members must be VA investigators actively engaged in major R&D programs or able to provide R&D expertise.
 - d) At least one member must also hold an academic appointment at the PVAMC's affiliated institution, Oregon Health & Science University (OHSU).
 - e) 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.

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. A member of each subcommittee shall serve as a voting member of the R&D Committee. Membership also must 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 on the Portland Research website at <http://www.visn20.med.va.gov/portland/Research/committees/r-and-d/index.htm#roster>. In addition, the membership is summarized in the R&D Committee meeting minutes.

B. Election of Chairperson

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 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. Information Security Officer
8. Privacy Officer

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.

The Research Compliance Officer (RCO) serves as a nonvoting consultant of the R&D Committee when needed. Each subcommittee will determine whether they wish the RCO to attend their meetings on a regular basis as a nonvoting consultant or only when requested by the subcommittee.

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 shall serve as an alternate for a specific voting member. 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 program or issue they are asked to review. Ad hoc reviewers do not vote with the committee. Such consultants may be asked to submit written reports 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 requirements posted on the website at <http://www.research.va.gov/training/default.cfm> and on the PVAMC website at <http://www.visn20.med.va.gov/portland/research/training/index.htm>, members and alternates of the R&D Committee must complete Information 201 Data Security training before appointment and must annually complete education in the protection of human research participants. These requirements are outlined in the PVAMC Policy & Procedure "Education for Conducting Research."

IV. RESPONSIBILITIES OF THE R&D COMMITTEE

The PVAMC R&D Committee's primary responsibility is to oversee all research activities at PVAMC and maintain high standards throughout the R&D program.

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 in support of the VA's mission.
3. Determining the extent to which the research program has met its objectives.
4. Reviewing all written agreements that establish a committee for a non-VA entity in lieu of a required committee or subcommittee.

5. Reviewing at a convened meeting a list of projects that have received final initial approval by all relevant subcommittees.
6. Annually reviewing and evaluating all subcommittees. A summary of these reviews and evaluations must be sent to the Medical Center Director annually. The review and evaluation of these subcommittees must be an ongoing function of the R&D Committee, and must be accomplished in part by reviewing the minutes of each subcommittee, by close communication with the subcommittees, and through quality assurance and quality improvement activities. Subcommittees to be reviewed follow:
 - (a) Institutional Review Boards (IRB) including HRPP, IRB membership, credentialing and training status reports, budget, space, support staff, quality improvement activities, compliance issues, and yearly goals;
 - (b) Institutional Animal Care and Use Committee (IACUC) including inspection reports, membership, arrangements, budgets, space, support staff, training, quality improvement activities, compliance issues, and yearly goals. This process will be facilitated with use of a self-assessment / checklist tool.
 - (c) Subcommittee on Research Safety (SRS) including planned training, compliance, security issues, etc. This process will be facilitated with use of a self-assessment / checklist tool.
 - (d) Subcommittee on Research Space based on the PVAMC [Space Policy](#).
7. Establishing policy to ensure that all research in which the facility engages has been reviewed and approved for the ethical use of human subjects, animals, and biohazards. This review must promote:
 - (a) Maintenance of high standards of protocol review and relevance to the mission of VA;
 - (b) Protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel;
 - (c) Welfare and appropriate use of animals in research;
 - (d) Safety of personnel engaged in research;
 - (e) Security of research laboratories where hazardous agents are stored or utilized and all Biosafety Level 3 laboratories; and
 - (f) Security of VA data and VA sensitive information. The R&D Committee delegates 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.
8. Fulfilling such functions as may be specified by the Medical Center Director and VHA procedures. The functions may include review and approval of individual research projects, when necessary. However, the R&D Committee may not approve human subjects' research if it has not been approved by the IRB.

B. Reviews Required by the R&D Committee

The Research & Development Committee focuses on oversight of the PVAMC research program, rather than individual protocols. Review of individual protocols, including scientific review, is conducted by the appropriate subcommittee(s). However, investigators may not initiate a research project until they have been notified by the ACOS/R&D that the project has been approved by all relevant committees, subcommittees or other entities, per section VI.1 of this SOP.

For protocols not meeting criteria for assignment to any subcommittee, the R&D Committee is the review and approving committee of record for initial and continuing review. Human research protocols determined to be exempt from IRB approval will be forwarded by an IRB coordinator to the R&D C for review after an IRB chair or designated reviewer has approved the Certification of Exemption. The R&D C will review exempt protocols at least once yearly. Exception: If a protocol amendment/revision of a previously determined exempt protocol is reviewed by an IRB chair or designee and the protocol is determined to no longer meet exemption criteria, the IRB will assume

the annual and ongoing review of the study. An IRB coordinator will notify the R&D C coordinator if this occurs.

After initial or continuing review of protocols not meeting criteria for assignment to any subcommittee, if the project receives final approval, the investigator will be provided with an ACOS notification allowing them to initiate the study. In cases of contingent approval, or a tabled decision, the R&D coordinator will notify the PI within three weeks. Once the reviewer has approved the PI's response to contingencies, ACOS notification allowing the study to be initiated will be sent.

If a research protocol requires review by a non-research entity at the PVAMC, such as the Radiation Safety Committee, this review may be conducted at any time, but the research may not be initiated until the non-research entity and all applicable R&D Committee subcommittees have approved the project, and the investigator has been notified in writing by the ACOS/R&D.

1. Standing Agenda Items

- (a) Review and approval of R&D Committee minutes of previous meeting.
- (b) Review of Subcommittee meeting minutes. Final minutes must be sent to the R&D Committee for review and approval when they are available. This may include review of minutes of the VA Central IRB, on an ad hoc basis, when a project to be conducted at the PVAMC has been reviewed and approved by the VA Central IRB. Prior to review of any subcommittee minutes, the R&D Chair will ask the sitting subcommittee member if there are any issues to address or discuss. Should any finding or recommendation of a subcommittee be questioned, the issue will be discussed and recorded in the R&D Committee minutes.
- (c) **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.
- (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. Findings of audits by the Research Compliance Officer may be presented here. 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.
- (e) Old Business, if unfinished business exists.
- (f) New Business. New business may include: review of the annual budget, Research Pharmacy Activity Report, subcommittee member qualifications, and policies and procedures from the subcommittees.
- (g) Review of a list of all projects that have received final initial approval by all relevant subcommittees.

2. Other Agenda Items (as needed)

The R&D Committee may also review, as needed, applications for special initiatives (equipment requests) and for reviews required by other VA handbooks, which may 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.
- (d) Endorsement of specific projects or awards offered by the Office of Research & Development.
- (e) Full review of any projects not eligible for review by any subcommittee.

V. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR

The Medical Center Director, acting in the capacity of the Institutional Official, is responsible for meeting the requirements outlined in VHA Handbook 1200.01. These responsibilities include:

1. Serving as the institutional official responsible for all aspects of the research program.
2. Ensuring that research in which the facility is engaged is approved by the appropriate R&D Committee subcommittee.
3. Ensuring adequate resources and administrative support, including personnel, space, equipment, and training for the R&D Committee and its subcommittees to fulfill their responsibilities.
4. Ensuring appropriate education and training for members of the R&D Committee, the research administration staff, and other staff involved in research.
5. Ensuring that investigators meet all necessary requirements listed in MCM 151.01.
6. Appointing the members of the R&D Committee.

VI. RESPONSIBILITIES OF THE ACOS/R&D

The Associate Chief of Staff for Research & Development (ACOS/R&D) is responsible for:

1. Notifying the investigator when a research project may be initiated. This notification occurs only after the research project has been approved by all applicable R&D Committee subcommittees, and given final approval at a convened meeting of the R&D Committee. Notifying the investigator of approval after continuing review and final approval by the subcommittees or the R&D Committee.
2. Functioning as the Executive Secretary of the R&D Committee.
3. Conducting regular quality assurance reviews of publications assessing the acknowledgement of VA support and affiliation. This shall happen at least annually.
4. Ensuring that information pertaining to all requests to WOC appointments for research have been appropriately justified and the appointments are in compliance with all applicable research, Human Resource Management, and other VA policies.
5. Conducting regular quality assurance reviews of research employees involved in human subjects research to ensure the employees are working within their scopes of practice and their privileges allowed by the facility's by-laws and granted to them by the facility. This shall happen at least annually.
6. Conducting regular quality assurance reviews of Cooperative Research and Development Agreements (CRADAs) and other agreements in support of the research program or specific research projects and an assessment of the impact of these agreements on the research program, when applicable. This shall happen at least annually.
7. Ensuring that all minutes of the R&D Committee and its subcommittees are sent to the medical center Director and Chief of Staff for review and appropriate action. The Director and Chief of Staff may receive such minutes in the binders provided to all voting and *ex officio* members for each meeting.

VII. 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. Although it is recommended that members be physically present, if physical presence is not possible, a member may be considered present if they participate through teleconference or videoconference. In cases where video- or teleconference is used, the member must have received all pertinent material prior to the meeting, must be able to participate actively and equally in all discussions, and their participation in that manner will be so noted in the minutes. The R&D Committee will review any other issues brought forth to the R&D Committee at convened meetings at which a quorum of the members are present. In order for a policy to be approved, it must receive the approval of a majority of those members present at the meeting where a quorum is present. If a voting member steps out of the room causing a quorum to be lost during a

meeting, no business may be conducted by the R&D Committee until the member returns.

The R&D Committee meets on the first Monday of each 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 (for example, to act on compliance issues or meet VA submission deadlines). Any additional meetings must meet the quorum requirements (either in person or via video- or teleconference).

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

VIII. RECORD DOCUMENTATION AND RETENTION

A. R&D Committee Records

The R&D Committee records include the following:

1. R&D Committee meeting minutes;
2. Written Standard Operating procedures;
3. Membership rosters;
4. R&D correspondence to the PI regarding research projects (when necessary) is kept within the appropriate research project file located in the Research Service office;
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 others, as needed, 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 located on the PVAMC Research Service website at <http://www.visn20.med.va.gov/portland/research/committees/r-and-d/index.htm#roster>

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 as appropriate. R&D Committee correspondence includes written correspondence addressed to the medical center Director on behalf of the R&D Committee, the Chief of Staff, investigators and committees or subcommittees.

If necessary based on the nature of a study, copies of 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.

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 housed separately from the other project files. However, copies of IACUC approvals may be kept in the same project files as those used by the IRB and SRS. 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)

G. 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. Actions which require a vote have the votes categorized as the number who voted "for," "against," "abstained," "recused," and "excused." Any individuals who are recused from a vote will be noted by name, and notation will be made on whether or not the person was present during the discussion. When a member is recused, they must not be present for the vote and may not be counted toward a quorum.
 - (g) Summary of controversial issues and their resolutions.
 - (h) Names of persons who excused or recused themselves and reference to a specific issue.
 - (i) 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.

H. 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.

I. 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.

J. Record Retention

The records of research studies conducted at the PVAMC are kept according to the VHA records control schedule (RCS) 10-1. In cases where the sponsor or the Food and Drug Administration (FDA) require longer retention, the records will be retained for the longest of the required timelines. 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 for the R&D Committee and all subcommittees, according to the VHA record control policies.

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 conflict. These actions will be documented in the meeting minutes.

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.