Substantive changes in this revision:
1. The abbreviation ‘SOP’ was replaced with ‘P&P’ throughout the document
2. Clarification of procedures for reviewing the Subcommittee
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I. PURPOSE
The VA Portland Health Care System (VAPORHCS) Research & Development (R&D) Committee Policies & Procedures (P&P) is a reference for R&D Committee members, subcommittee members, investigators and the Research Administration Office. This P&P 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 VAPORHCS, 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 (HRPP) policies and procedures.

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

II. BACKGROUND
The research mission of the VAPORHCS R&D Committee is to ensure that research is conducted according to the highest ethical standards with accountability to all involved stakeholders. Responsibility for oversight and maintaining high standards is assigned to the R&D Committee.

III. ABBREVIATIONS
ACOS  Associate Chief of Staff
AE    Adverse Event
AO    Administrative Officer
CFR   Code of Federal Regulations
COS   Chief of Staff
CRF   Case Report Form
CRQ   Continuing Review Questionnaire
CRADO Chief Research and Development Officer
DHHS  Department of Health & Human Services
DOD   Department of Defense
DPAHC Durable Powers of Attorney for Health Care
DSMB  Data and Safety Monitoring Board
FDA   Food and Drug Administration
FWA   Federalwide Assurance
HIPAA Health Insurance Portability & Accountability Act
HRPP  Human Research Protection Program
IBC   Institutional Biosafety Committee
ICF   Informed Consent Form
IDE   Investigational Device Exemption
IND   Investigational New Drug
IRB   Institutional Review Board
IV. SHARED RESPONSIBILITIES OF THE INSTITUTION IN RESEARCH OVERSIGHT

The Health Care System Director is the institutional official responsible for all aspects of the research program. The Health Care System Director delegates the authority to administer the R&D program to the Associate Chief of Staff for R&D (ACOS/R&D), who reports to the Chief of Staff.

A. AUTHORITY OF THE R&D COMMITTEE (VHA HANDBOOK 1200.01)

The R&D Committee is responsible, through the Chief of Staff to the VAPORHCS Health Care System Director, for:

1. Advising and assisting the Health Care System Director in providing oversight, planning and execution of the VAPORHCS research program; and

2. Assisting the Health Care System Director in maintaining high standards throughout the VAPORHCS’s R&D 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;
• the security of VA data; and
• the security of VHA research laboratories.

The R&D Committee acts as the governing body of the R&D program at the VAPORHCS. It serves as the parent committee to all of its subcommittees and must review and approve subcommittee actions, minutes, and periodic reports.

The R&D Committee may not approve research that has not been approved by all of the appropriate subcommittee(s) of record. The Health Care System Director may not approve research that has not been approved by the R&D Committee. The Health Care System Director, R&D Committee or higher authority, i.e., the VHA Office of Research and Development (ORD) may strengthen requirements and/or conditions, add other modifications to a protocol approved by all appropriate subcommittees, or disapprove any research.

B. RESPONSIBILITIES OF THE HEALTH CARE SYSTEM DIRECTOR
The Health Care System Director is responsible for meeting the requirements outlined in the VHA Handbooks, including 1200.01 and 1058.01. 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 R&D Committee and appropriate subcommittee(s).

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 members to the R&D Committee and subcommittees.

7. Reporting events to ORO and other entities, as required by VHA Handbook 1058.01 and other applicable federal regulations.

8. Ensuring timely implementation of remedial actions in response to identified noncompliance or as otherwise found warranted by ORO, as required by VHA Handbook 1058.01.

C. RESPONSIBILITIES OF THE ACOS/R&D
The ACOS/R&D is responsible for:

1. Notifying the investigator when a research project can be initiated. This notification occurs only after the research project has been approved by
the R&D Committee and all applicable subcommittees. A voting member of the R&D Committee will verify in a memo to the ACOS/R&D that the necessary study approvals are in place. The ACOS/R&D will notify the investigator that the study may be initiated.

2. Notifying the investigator of approval after continuing review by the appropriate subcommittee(s) or the R&D Committee.

3. Functioning as the Executive Secretary of the R&D Committee.

4. Ensuring that information pertaining to all requests for Without Compensation (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, at least annually, 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.

7. Ensuring that all minutes of the R&D Committee and its subcommittees are sent to the Health Care System Director and Chief of Staff for review and appropriate action. The Health Care System Director and Chief of Staff may receive such minutes in the electronic packet of meeting materials provided to all voting and ex officio members for each meeting.

D. RESPONSIBILITIES OF THE INVESTIGATOR

The investigator is responsible for:

1. Confirming with the applicable service chief that they have been awarded the appropriate credentials and privileges to conduct research at the VAPORHCS prior to initiating any research.

2. Complying with all applicable personnel and other VA requirements whether the investigator is compensated, WOC, or Intergovernmental Personnel Act Agreement (IPA).

3. Obtaining approval of all appropriate non-research entities, R&D Committee and subcommittees, and written notification from the ACOS/R&D, prior to initiating a research project.

4. Developing a research plan that is
   • scientifically valid;
minimizes risk to human subjects (when applicable);
ensures animals are used appropriately in research (when applicable);
minimizes risk to research personnel; and
contains a sufficient description of the research including all procedures and the plan for statistical analysis, to allow the R&D Committee and subcommittees to fully review the research project.

4. Developing and implementing plans for data use, storage, and security that are consistent with VA Directive 6500, Information Security Program, and its implementing Handbooks and other legal requirements.

5. Preparing and submitting information, at least annually or as required, on their research program(s) and on each project to the appropriate R&D Committee or subcommittee for continuing review.

6. Ensuring that all research records are retained by the VA at the conclusion of the project unless directed otherwise.

7. Following the investigator responsibilities and procedures outlined in the Presentation and Publication of Research Results Policy and Procedure. This entails submitting manuscripts, abstracts for meetings, presentations, or other types of media to the Portland Publication mailbox, PVAMC.Publications@va.gov, both at the time they are submitted for review or consideration, and again when the investigator has been notified of acceptance.

E. RESPONSIBILITIES OF THE R&D COMMITTEE
The VAPORHCS R&D Committee’s primary responsibility is to oversee all research activities at VAPORHCS and maintain high standards throughout the R&D program. The responsibilities of the R&D Committee are outlined in MCM No. 151-01, and VHA Handbook 1200.01. The R&D Committee is responsible for:

- Assuring the continuing high quality of the facility’s R&D program.
- Planning and developing broad objectives of the R&D program in support of the VA’s mission.
- Determining the extent to which the research program has met its objectives.
- Reviewing all written agreements that establish a committee for a non-VA entity in lieu of a required committee or subcommittee.
- Distinguishing VA from non-VA research and approve only “VA research” activities.
- Reviewing at a convened meeting a composite list of projects that have received final initial approval by all relevant subcommittees.
• For protocols not meeting criteria for assignment to any local subcommittee, and for projects that are reviewed by the VA Central IRB or the Affiliate IRB, the R&D Committee is the review and approving committee of record. R&D Committee review procedures are described in section VI.B.1 below.

• Notifying the ACOS/R&D of all subcommittee initial and continuing review approvals.

• Annually reviewing and evaluating all subcommittees. A summary of these reviews and evaluations must be sent to the Health Care System 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 are:

• Institutional Review Boards (IRB). This includes reviews of HRPP, IRB membership, credentialing and training status reports, budget, space, support staff, quality improvement activities, compliance issues, and yearly goals. This process will be facilitated with use of a self-assessment / checklist tool. Note: All IRBs listed on the VAPORHCS FWA will be reviewed, including the VA Central IRB and the Affiliate IRB. Review by the VA Central IRB and the Affiliate IRB occurs through a MOU agreement between each off-site entity and the VAPORHCS.

• Institutional Animal Care and Use Committee (IACUC). This includes reviews of inspection reports, membership, 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.

• Subcommittee on Research Safety (SRS). This includes planned training, compliance, security issues, etc. This process will be facilitated with use of a self-assessment / checklist tool. Note: In addition to receiving review by the VAPORHCS SRS, the NIH-registered Institutional Biosafety Committee (IBC) at Oregon Health & Science University (OHSU) performs the required review and oversight of VAPORHCS studies that involve the use of recombinant DNA molecules. Review occurs through a MOU agreement between OHSU and VAPORHCS. The IBC will be included in the annual review of the subcommittees.

• Research Service Space Subcommittee (RSSS) based on the VAPORHCS RSSS Policy.
• Establishing policy to ensure that all research in which the facility engages has been reviewed and approved for the ethical use of human subjects, and/or animals, and/or biohazards. This review must promote:
  • Maintenance of high standards of protocol review and relevance to the mission of VA;
  • Protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel (when applicable);
  • Welfare and appropriate use of animals in research (when applicable);
  • Safety of personnel engaged in research;
  • Security of research laboratories where hazardous agents are stored or utilized and all Biosafety Level 3 laboratories; and
  • Security of VA data and VA sensitive information. The R&D Committee delegates to the ACOS/R&D, Deputy ACOS/R&D, and the AO/R&D the responsibility to develop, manage, and follow policies and procedures that ensure compliance with all applicable state and Federal regulations pertaining to research information protection, and to assure that all VAPORHCS investigators and R&D staff are aware of and comply with the regulations and local policies.

• Fulfilling such functions as may be specified by the Health Care System Director and VHA procedures. The functions may include review and approval of individual research projects, when necessary.

• Voting to recommend nominations to the Health Care System Director for membership appointment to the R&D Committee and subcommittees.

V. R&D COMMITTEE MEMBERSHIP

A. COMPOSITION OF THE R&D COMMITTEE
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 VAPORHCS and reflects the types and amount of research conducted at the VAPORHCS. The VAPORHCS 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 VAPORHCS.

In addition to the diversity of membership based on consideration of race, gender and cultural background, the R&D Committee must have at least:
1. five (5) voting members. All voting members must be compensated full-time or permanent part-time Federal employees.

2. two (2) members from the facility’s staff with major patient care or management responsibilities.

3. two (2) members who are VA investigators actively engaged in major R&D programs or able to provide R&D expertise.

4. one (1) member who also holds an academic appointment at the VAPORHCS’s affiliated institution, OHSU.

Whenever possible, the R&D Committee will have at least one member with expertise in biostatistics and research design.

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. A membership roster that lists 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. In addition, the membership is summarized in the R&D Committee meeting minutes and agendas.

B. CHAIRPERSON

1. Appointment – The R&D Committee shall elect a Chairperson (referred to as “Chair” throughout the P&P) on an annual basis. The Chair must be approved and officially appointed, in writing, by the Health Care System Director. The Chair must hold a paid appointment. The Chair may not simultaneously chair a subcommittee of the R&D Committee.

2. Voting Status – The Chair is a full voting member of the R&D Committee, and is counted in the quorum of the committee.

3. Length of Service – The Chair holds a one-year term and may be re-appointed indefinitely, without any lapse in time.

4. Responsibilities-

   • Conduct R&D Committee meetings;
   • Call special meetings when necessary;
   • Review and sign R&D Committee minutes that summarize the actions and reasons for the actions of each presented item reviewed by the R&D Committee;
   • Sign final Initial Review approval letters, unless the Alternate Chair is presiding, for protocols or actions reviewed by the R&D Committee; and
   • Sign R&D Notification memos to the ACOS/R&D for studies receiving Initial or Continuing Review by subcommittee(s).
C. VOTING MEMBERS

1. **Appointment** - The R&D Committee votes to recommend the R&D Committee member for formal appointment by the Health Care System Director. The member must hold a paid VA appointment.

2. **Voting Status** - The R&D Committee members are full voting members of the R&D Committee, and are counted in the quorum of the committee.

3. **Length of Service** – The R&D Committee members serve three-year terms and may be re-appointed indefinitely. The membership terms for approximately one-third of members expire on December 31 of each year. At the December R&D Committee meeting, new members will be nominated for appointment or current members nominated to be re-appointed.

4. **Responsibilities** –
   - Review and vote on R&D Committee minutes that summarize the actions and reasons for the actions of each presented item reviewed by the R&D Committee.
   - Conduct initial reviews and continuing reviews for projects that are not reviewed by a subcommittee at the VAPORHCS. Determine if projects being reviewed are categorized under the VA definition of “research.”
   - Notifying the ACOS/R&D when subcommittee initial or continuing review approvals have been generated and are ready to be distributed to the investigator. The R&D Committee member will review the signed approval letters prior to signing the R&D notification memo.

Regular attendance at R&D Committee meetings is expected, and a member may be removed from the R&D Committee by the Health Care System Director on the basis of repeated unexcused absences or non-attention to the functions and responsibilities of the R&D Committee.

D. ALTERNATE MEMBERS

1. **Appointment** - The R&D Committee votes to recommend the alternate R&D Committee members for formal appointments by the Health Care System Director. The Alternate members must hold paid VA appointments.

2. **Voting Status** - The Alternate members are full voting members of the R&D Committee, and are counted in the quorum of the committee. Alternate members shall serve as an alternate for a specific voting member. The alternate member is only allowed to vote in the absence of the member s/he represents.
3. **Length of Service** - The Alternate members serve three-year terms and may be re-appointed indefinitely. The alternate member’s term expires with the term of the individual that s/he is representing.

4. **Responsibilities** – Performs responsibilities of the regular voting member in his/her absence. The alternate member is expected to have a similar or related work specialty or responsibility as the member s/he represents in their absence.

**E. ALTERNATE CHAIR**

1. **Appointment** - The R&D Committee reviews the nomination, and votes to recommend the individual for formal appointment by the Health Care System Director. The Alternate Chair must hold a paid appointment.

2. **Voting Status** - The Alternate Chair is a full voting member of the R&D Committee, and is counted in the quorum of the committee.

3. **Length of Service** - The Alternate Chair serves a one-year term and may be re-appointed indefinitely. The Alternate Chair’s term expires with the term of the Chair that he/she is representing.

4. **Responsibilities** – Performs responsibilities of the Chair in his/her absence. The Alternate Chair serves as a regular voting member when the R&D Chair is presiding over the meeting.

**F. EX-OFFICIO NON-VOTING MEMBERS**

Ex-Officio members, appointed due to their position at the VAPORHCS, may not vote nor contribute to a quorum. These members must adhere to the same conflict of interest policies and procedures as voting R&D Committee members.

Ex-Officio non-voting members include the:

1. Health Care System Director;
2. Chief of Staff (COS);
3. ACOS/R&D;
4. Deputy ACOS/R&D;
5. AO/R&D;
6. Veterinary Medical Officer (VMO);
7. Representative of the Research Pharmacy;
8. Information Security Officers
9. Privacy Officers

The facility ISO and Privacy Officer are appointed as non-voting members of either the facility’s IRB(S) or R&D Committee of record. In order to comply, the VAPORHCS Health Care System Director will appoint, in writing, the Information Security Officer.
(ISO) and Privacy Officer (PO) as ex-officio non-voting members of the R&D 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.

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

G. 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 VAPORHCS Conflict of Interest in Research Policy) with the program or issue they are asked to review. Ad hoc reviewers do not vote. 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.

H. TRAINING OF R&D COMMITTEE CHAIR AND MEMBERS
It is the responsibility of the ACOS/R&D and the Research Administration Office 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 P&P prior to the first meeting. All members receive updated versions of the R&D Committee P&P as they are issued. The ACOS/R&D may provide further guidance and training as needed.

Per the Office of Research & Development (ORD) requirements, members and alternates of the R&D Committee must complete education in the protection of human research participants. These requirements are outlined in the VAPORHCS Research Program Policy & Procedures, “Education Requirements for the Conduct of Research.”

I. CONFLICT OF INTEREST OF R&D COMMITTEE MEMBERS
As indicated in the VAPORHCS “Conflict of Interest in Research Policy”, all R&D Committee members must aim to avoid real or perceived conflicts of interest and follow the conflict of interest policy. The R&D Committee chair and members may find themselves in any of the following potential conflicts of interest:

1. The R&D Committee chair or member is listed as an investigator on the research.
2. An investigator must report to or is under the supervision of an R&D Committee chair or member.

3. The R&D Committee chair or member competes for research grants or contracts in the same or similar field as an investigator whose research is scheduled for review.

4. The R&D Committee chair or member is a family member of an investigator whose research is scheduled for review.

In cases where a conflict of interest exists, the member must step out of the room during the review of the study. Conflicts of Interest of R&D Committee members will be noted in the minutes, and the individual is identified as “recused” during the vote.

VI. R&D COMMITTEE MEETINGS AND PROCEDURES

A. CONVENED MEETINGS

A quorum 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. The following are exceptions for which meetings are scheduled not on the first Monday of each month:

1. Months in which a Federal holiday is on the first Monday of the month. In these cases, the R&D Committee meeting will be held on the Monday proceeding or following the Federal holiday.

2. In lieu of the October meeting being held on the first Monday of the month, a second meeting will be held during the month of September. The purpose of this scheduling exception is to accommodate the review of various projects before the start of the new fiscal year.
Additional meetings may be called by the Chair, as required (for example, to act on compliance issues or to 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.

B. REVIEWS REQUIRED BY THE R&D COMMITTEE
The R&D Committee focuses on oversight of the VAPORHCS research program, as well as individual protocols that don’t fall under the purview of any subcommittee. 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.B.1 of this P&P.

The R&D Committee conducts reviews of the following items:

1. Initial/Continuing Review of Studies
   The R&D Committee is the review and approving committee of record for initial and continuing reviews of protocols not meeting criteria for assignment to any local subcommittee. This includes the following types of studies:
   - IRB Exempt Projects - Human research protocols determined to be exempt from IRB approval, if they are not assigned for review to any other subcommittee, will be reviewed initially and annually by the R&D Committee. IRB exempt projects will be forwarded by an IRB analyst to the R&D Committee for review after an IRB Co-Chair, a qualified designee or the Lead IRB Analyst has approved the Certification of Exemption. The R&D Committee will review exempt protocols at least once yearly.

   Protocol amendment/revisions to IRB exempt projects will be submitted to the IRB Co-Chair, a qualified designee or the Lead IRB Analyst for confirmation that the proposed change will not affect the previously-approved exempt status. If it is determined the project remains exempt, the protocol amendment/revision will be forwarded to the R&D Committee.

   Exception: If a protocol amendment/revision of a previously determined exempt protocol is reviewed by an IRB Co-Chair, qualified designee or the Lead IRB Analyst and the protocol is determined to no longer meet exemption criteria, the IRB will conduct an Initial Review of the project and assume responsibility for the future ongoing review of the study. The Lead IRB Analyst will notify the R&D Committee coordinator if this occurs.
Minor administrative revisions of IRB Exempt projects, such as changes to research personnel, do not require R&D Committee approval. A proposed change in research personnel will be verified by the R&D Committee coordinator to assure that any new staff members have been credentialed through Research Administration Office and their education requirements have been met. The personnel change will be presented as a Notification event at the following R&D Committee meeting. This event does not require a committee review or vote; it will be included on the meeting agenda to be acknowledged by the committee. The R&D Committee coordinator will send correspondence to the PI confirming the minor revision(s).

• “Science-Only” Projects - Projects involving research activities that do not qualify for review by a subcommittee (termed “science-only”) are reviewed by the R&D Committee. This includes studies that were previously reviewed by one or more subcommittee(s) but no longer include research activities necessitating the review of such subcommittee(s). If study activities continue but the subcommittee study closure(s) have been approved, the subcommittee coordinator will forward the study on to the R&D Committee for future annual review(s).

• VA Central IRB-reviewed Studies - Studies that are reviewed by the VA Central IRB will undergo initial and annual continuing reviews locally by the R&D Committee. Initial Review will occur when the final approval letter and documents have been generated by the VA Central IRB for either a new Principal Investigator/Study Chair (PI/SC) application, or a Local Site Investigator application. Once the minutes from the VA Central IRB meeting containing the review of the project are posted to the VA Central IRB SharePoint site, they will be reviewed at the next R&D Committee. Local approval by the R&D Committee is granted for a period of 12 months. The local continuing review will occur before the expiration of the current approval period, but does not necessarily occur in conjunction with the continuing review conducted by the VA Central IRB. Minutes from the VA Central IRB meetings are presented to the R&D Committee on a monthly basis for review and approval.

• Studies reviewed by the Affiliate IRB (IRB #3) - Studies that are reviewed by the Affiliate IRB (also referred to as IRB #3) will undergo initial and annual continuing reviews by the R&D Committee. Initial Review will occur when the final approval letter and documents have been generated by the Affiliate IRB and provided to the R&D Committee coordinator. The minutes from the Affiliate IRB meeting for the project reviewed will also be reviewed by the R&D Committee. The local continuing review will
occur before the expiration of the current approval period, but does not necessarily occur in conjunction with the continuing review conducted by the Affiliate IRB.

The R&D Committee coordinator will verify the appointment status, the scope of practice statement, and the training status of all study personnel prior to initial and continuing review by the R&D Committee. For the initial review of a study, a Scope of Work form (IRQ Appendix L) will be required for each study staff. On the continuing review form, the investigator will provide the names and roles of personnel. The investigator will be prompted to submit a revised Scope of Work form for any individual whose role in the study has changed.

After initial or continuing review approval of protocols not meeting criteria for assignment to any subcommittee, the investigator will be provided with the signed R&D Committee approval letter and ACOS notification allowing them to initiate or continue the study.

In cases of a tabled decision by the R&D Committee, the R&D Committee coordinator will notify the PI within ten days. The PI’s response to the R&D Committee’s contingencies/stipulations will be reviewed as a Previously Tabled event at the next convened R&D Committee.

If a research protocol requires review by a non-research entity at the VAPORHCS, 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.

2. Reports of System Deficiencies
The R&D Committee is responsible for reviewing reports of system deficiencies. A systemic deficiency is defined as a fundamental, underlying problem that jeopardizes the effectiveness of the facility’s research protection system(s).

VA personnel, including WOC and IPA appointees, must ensure written notification of the VA facility’s R&D Committee within 5 business days after becoming aware of any apparent systemic deficiency that has a reasonable likelihood of substantially compromising the facility’s research protection programs, including persistent failure by any subcommittee of the R&D Committee to adhere to the requirements governing VA research.

For any reports of systemic deficiency, the R&D Committee:
- Must review the report at its earliest practicable convened meeting, not to exceed 30 business days after the date of notification.
• May hold unscheduled meetings in response to emergent issues in accordance with VHA Handbook 1200.01.
• Must determine whether the report involves an actual systemic deficiency that could substantially compromise the VA facility’s research protection programs, and if so:
  o The R&D Committee must determine what remedial actions, if any, are warranted to ensure effective research protections;
  o The R&D Committee must notify the VA facility Director and the ACOS/R&D within 5 business days after the determination; and
  o The VA facility Director must report the determination and the resultant remedial actions to ORO within 5 business days after receiving the notification.

3. Reports of Research Information Security Incidents

VA personnel, including WOC and IPA appointees, must ensure notification of the ACOS/R&D, Information Security Officer (ISO), Privacy Officer (PO), and relevant investigators immediately (i.e., within one hour) upon becoming aware of any information security incidents related to VA research, including:

- any inappropriate access, loss, or theft of PHI;
- noncompliant storage, transmission, removal, or destruction of PHI; or
- theft, loss, or noncompliant destruction of equipment containing PHI.

These personnel must also ensure written notification of the ACOS/R&D within 5 business days of becoming aware of any such research information security incidents.

The R&D Committee is responsible for reviewing reports of research information security incidents that are not relevant to the IRB, IACUC or SRS. Such reports must be reviewed by the R&D Committee at its earliest practicable convened meeting, not to exceed 30 business days from the date of notification of the incident.

As part of their review of such reports, the R&D Committee must determine:

- Whether or not the incident constitutes a serious problem (see definition in VHA Handbook 1058.01); and
- In conjunction with the ISO and/or PO as applicable, whether and what remedial actions are warranted by the facility or the relevant investigator(s).

If the R&D Committee determines that the incident constitutes a serious problem:

- The committee must notify the VA facility Director and the ACOS/R&D within 5 business days after the determination.
• The VA facility Director must report the determination to ORO within 5 business days after receiving the committee’s notification.

If the R&D Committee makes additional determinations under its authority, any reporting requirements pertinent to such determinations must also be satisfied.

4. Standing Agenda Items
   • Review and approval of R&D Committee minutes of previous meeting.
   • Review of Subcommittee meeting minutes.
     i. Final versions of the subcommittee meeting minutes will be presented to the R&D Committee for review. 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.
     ii. Minutes of the VA Central IRB are presented to the R&D Committee after they have been distributed to the field
     iii. Minutes of the Affiliate IRB are presented to the R&D Committee after they have been generated by the IRB staff.
   • 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.
   • Initial Review Approval List – following subcommittee approval of protocols, the subcommittee coordinators will forward the approval memos to the R&D Committee coordinator. After all relevant subcommittees have given approval, the R&DC will review each subcommittee approval memo followed by a review of the composite list of projects that have received final initial review approval at the next available R&D Committee meeting. The R&D Committee will vote for approval of the aggregate composite list. The signed approval letters from each relevant subcommittee will also be attached to the R&D Notification document when it is routed to a R&D Committee member for signature.
   • Old Business, if unfinished business exists.
• New Business items, including review of the annual budgets, subcommittee member qualifications and nominations, goals and objectives of the Research program, policies and procedures from the subcommittees, updates on grant submissions, Research Compliance Officer (RCO) audit reports, Veterinary Medical Unit (VMU) post-approval monitoring reports, and reports to other agencies (Office of Human Research Protections (OHRP) and Office of Research Oversight (ORO)), and the annual review and evaluation of each subcommittee.

5. Other Agenda Items (as needed)
The R&D Committee may also review, as needed, applications for special initiatives (equipment requests) and may also conduct reviews required by other VA handbooks, which may include the following:

• New non-clinical Ph.D. applicants for Merit Review eligibility;
• Non-clinical Ph.D. applicants for the Career Scientist program;
• Endorsement of new clinicians for the Career Development Program; and
• Endorsement of specific projects or awards offered by the Office of Research & Development.

VII. RECORD DOCUMENTATION AND RETENTION

A. R&D RECORD RETENTION
The records of research studies conducted at the VAPORHCS 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 Research Administration Office maintains all records collected over the course of a study. The Research Administration Office 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.

B. R&D COMMITTEE RECORDS
The R&D Committee records include the following:

1. Meeting Minutes
R&D Committee minutes are completed by the R&D Committee coordinator. Minutes shall include:

• Time and date of the convened meeting.
• Attendance and absence by name of all voting and non-voting members, including ex officio members. R&D Committee minutes shall list attendance as follows:
  
  i. Names of members present, including the presiding officer (Chairperson).
  
  ii. Names of excused members. Members are designated EXCUSED if the Chairman or R&D Committee coordinator was notified in advance.
  
  iii. Names of absent members. Members are designated ABSENT if the Chairperson or R&D Committee coordinator was not notified in advance.
  
  iv. Names of alternates attending in lieu of specified (named) excused members.
  
  v. Names of guests.

• The presence of a quorum.

• Approval of prior meeting minutes.

• All items of business or information brought before the R&D Committee.

• 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.”

• Summary of controversial issues and their resolutions.

• Names of persons who were excused at the time of the vote, and names of persons who recused themselves from voting, with reference to a specific issue.

• Date and time of the next meeting, as well as the meeting location if it is different than Bldg. 101, Room 433.

Minutes of the meeting are reviewed and signed by the R&D Committee chair, the Executive Secretary (ACOS/R&D), Chief of Staff, and the Health Care System Director.

After the meeting, copies of the minutes, together with any comments the Health Care System Director may wish 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.
Minutes shall be maintained by the R&D Committee coordinator and the VAPORHCS Research Administration Office and made available to VA Central Office upon request.

2. Written Standard Operating procedures
R&D Committee members are provided with a copy of the P&P at the time they join the R&D, and each time the P&P is updated. The ACOS/R&D, Deputy ACOS/R&D, AO/R&D, R&D Committee coordinator, and others, as needed, work together to write and maintain the P&P. The SOP is reviewed and modified as needed to ensure compliance with federal and institutional regulations and policies.

3. Membership rosters
The R&D Committee coordinator maintains the current R&D Committee roster, which includes R&D Committee memberships, alternate memberships, and Ex-Officio non-voting memberships. The R&D Committee membership roster is located on the VAPORHCS Research Service website, and is saved in a folder on the restricted-access, Research Service common folder.

- The R&D Committee roster will include the following information:
  i. Names
  ii. Degrees
  iii. Voting and alternate status and representative capacity
  iv. Academic appointment at OHSU
  v. Subcommittee membership
  vi. Federal employment status (full-time or part-time)
  vii. Term expiration

4. R&D Committee Correspondence to the PI
R&D correspondence to the PI regarding research projects, when necessary, is kept within the appropriate research project file located on the secure Research network folder.

5. Research Project Files
The research project application files include copies of all research proposals, amendments reviewed, accompanying materials, and continuing and final reports. Each research project has a separate file. The project files are electronic. Protocols are assigned a unique number from the Manage your Institutional Review Board (MIRB) computer program for tracking and administration purposes. R&D Committee records which are specific to a project are kept in the file for that project. All required
subcommittee records, including any IRB, IACUC, and SRS records, are maintained in the project-specific files.

C. ACCESS TO RECORDS
Research records are accessible to Research Administration Office staff, the R&D Committee chair and members, and the RCO personnel. 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 Research Administration Office 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 Research Administration Office records.

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

D. RESEARCH TRACKING SYSTEM
The Research Administration Office uses a reliable computerized tracking system, the MIRB computer program, which is maintained by the R&D, IRB, IACUC 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 committee membership and generates meeting minutes and correspondence.

The R&D Service also uses the VA enterprise project management information system (ePROMISe) to track study initiation of all active studies, and to update the abstracts submitted with continuing review of studies reviewed by the R&D Committee. Studies are initialized in ePROMISe once the R&D Committee has conducted the initial review, or approved the initial review(s) conducted by the subcommittee(s).

E. R&D COMMITTEE CORRESPONDENCE
Accurate records are maintained of all communications to and from the R&D Committee, including correspondence with investigators, subcommittees, consultants if applicable, and VA Central Office. All correspondence written on behalf of the R&D Committee is signed by the R&D Committee Chair. Correspondence related to the review and/or approval of continuing reviews, amendments, or notifications is signed by the R&D Committee coordinator. At the time of any disapproval (initial, continuing, amendment, etc.), correspondence is signed by the R&D Committee chair. Copies of all correspondence are filed in the appropriate investigator research project file.

1. Initial Review: Investigators will be notified within 10 business days of final, tabled, or disapproval of initial review or modifications. Once final
approval has been generated by the R&D Committee, the signed committee approval will be given to the ACOS/R&D. The ACOS will send the final R&D Committee approval to the PI/study contact notifying them that the project has approval to begin.

2. Continuing Review: Investigators will be notified within three weeks of final, tabled, or disapproval of continuing review or modifications. Once final approval has been generated by the R&D Committee, the signed committee approval will be given to the ACOS/R&D. The ACOS/R&D will send the final R&D Committee approval to the PI/study contact notifying them that the project may continue.

If the continuing review is not held, or is held but tabled or disapproved, prior to the approval expiration date, the study will be suspended. A notification letter to the Investigator from the R&D Committee chair will be generated promptly by the R&D Committee coordinator, once they have determined the continuing review has not been submitted, reviewed and approved, or stipulations of a tabled continuing review have not been addressed and re-submitted to the R&D Committee for review.

Once suspended, the continuing review and re-approval must occur prior to re-initiation of the research. If study approval has lapsed two months or less, the items requested at the time of continuing review may be reviewed by the R&D Committee for consideration of continued approval. If the study approval has lapsed for more than two months, the R&D Committee will administratively terminate the study. A termination letter to the Investigator from the R&D Committee chair will be generated promptly by the R&D Committee coordinator. In the event that the Investigator wishes to re-open the study, the R&D Committee may require the PI to submit new materials for an initial review.

Copies of correspondence are filed in the appropriate research project file. 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. Responses to the R&D Committee should come from the Investigator or a designated study coordinator electronically.

When original signatures are required on documents, either a paper copy of the signature sheet must be maintained or an electronic signature may be used. Electronic signatures must meet all of the requirements of the VA, the Department of Health and Human Services (HHS), Office of Human Research Protection, the Food and Drug Administration (FDA), and any other relevant requirements.

VIII. SUBCOMMITTEES OF THE R&D COMMITTEE
The R&D Committee is the governing body for all research conducted at the VAPORHCS. 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:

1. Institutional Review Boards (IRBs). This includes all IRBs covered under the auspices of the VAPORHCS FWA: the local VAPORHCS IRB, the VA Central IRB, and the Affiliate IRB;

2. Institutional Animal Care and Use Committee (IACUC);

3. Subcommittee on Research Safety (SRS), which also utilizes the OHSU IBC for review of recombinant DNA protocols; and


Candidates for membership of the IACUC, the local IRB, affiliate IRB (VA representatives only), and SRS are placed before the R&D Committee. The R&D Committee votes to recommend the member's appointment to the Health Care System Director. Members of the VA Central IRB are appointed per the policy of the VA Central IRB. Members of the RSSS are approved per the Research Service Space Subcommittee Policy. Each local 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 (except for the RSSS) is responsible for initial and annual continuing review of studies under their purview.

A. RESPONSIBILITIES OF SUBCOMMITTEES

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. Policies & Procedures or Standard Operating Procedures; and

8. All communications to and from investigators, other committees, subcommittees, and other entities or individuals.

Subcommittee meeting minutes are filed in the Research Administration Office. Electronic records are kept on a restricted network drive maintained by the Research Administration Office as part of their official employment duties. Each subcommittee must make available to the R&D Committee a complete, unredacted set of minutes.
B. SUBCOMMITTEE DESCRIPTIONS

1. Institutional Review Boards (IRB)

The R&D Committee has charged the IRBs with the oversight of all research activities involving the use of human subjects. The VAPORHCS has three IRBs that are responsible for reviewing and approving human research conducted under the auspices of the Institution’s FWA: a VAPORHCS IRB, the VA Central IRB, and the Affiliate IRB. Policy & Procedures (for the VAPORHCS and the Affiliate IRBs) or Standard Operating Procedures (for VAPORHCS studies reviewed by the VA Central IRB) contain the procedures and principles by which the IRBs abide in the review and conduct of human subjects research.

All VAPORHCS IRBs shall perform all functions required under 38 CFR 16 (Common Rule). This includes, but is not limited to, research supported by the VA or conducted at the VAPORHCS 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 1200.05.

The R&D Committee oversees the IRB in the following responsibilities:

- **Human Research Protection Program (HRPP)**
  
The Department of Veterans Affairs (VA) and other Federal regulations require specific protections for human subjects. The ACOS/R&D 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.

- **Privacy Officer (PO) and Information Security Officer (ISO)**
  
The ISO and PO are responsible for ensuring proposed human research complies with all applicable requirements for privacy, confidentiality, and information security. The ISO and PO review all proposed study protocols and any other relevant materials submitted with the IRB application, continuing review, and/or any
amendments or modifications that involve a change in data use, disclosure or storage, in order to assure all studies are in compliance before research initiation and throughout the life of the study. The ISO and PO document their review in a checklist that is maintained in the study file.

- VAPORHCS IRB Policies & Procedures
  The VAPORHCS IRB Policies & Procedures is a reference for IRB members, coordinators, investigators and other individuals associated with the HRPP. The Policies & Procedures document details the regulations and policies governing human subjects’ research and the requirements for the submission and review of research proposals for review by the VAPORHCS IRBs.

2. Institutional Animal Care and Use Committee (IACUC)
   The R&D Committee has charged the VAPORHCS 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 animals. The IACUC adheres to the policies in VHA Handbook 1200.07.

3. Subcommittee on Research Safety (SRS)
   The R&D Committee has charged the VAPORHCS 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 that will include biohazards or will be conducted in a wet lab. The OHSU IBC provides the required reviews of studies utilizing recombinant DNA. The SRS adheres to the policies in VHA Handbooks 1200.08 and 1200.06.

4. Research Service Space Subcommittee (RSSS)
   The R&D Committee has charged the VAPORHCS RSSS 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 VAPORHCS investigators. The Research Service Space Subcommittee Policy details the procedures by which the RSSS abides.
IX. CONFLICT OF INTEREST IN RESEARCH

VA investigators and R&D Committee members must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal criminal code. The obligation to follow applicable ethics laws and regulations also applies to WOC employees and IPAs conducting VA research or participating on a R&D Committee.

The VAPORHCS 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 as 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.

The Conflict of Interest Administrator will notify the conflicted researcher, the Principal Investigator for the study, the Chair of the applicable subcommittee, 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 VAPORHCS “Conflict of Interest in Research” Policy.

X. REFERENCES

VHA Handbook 1200.01, Research & Development Committee Handbook
VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research
VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories
VHA Handbook 1200.07, Use of Animals in Research
VHA Handbook 1200.08, Safety of Personnel Engaged in Research
VHA Handbook 1058.01, Research Compliance Reporting Requirements
MCM. No. 151-01, Responsible Conduct of Research
HRPP, Policy & Procedure No. 4: Education for the Protection of Human Research Participants
RPPP, Education Requirements for the Conduct of Research
Research Program Presentation and Publication Policy
Conflict of Interest in Research Policy
IRB Standard Operating Procedures
IACUC SOP
SRS SOP
VAPORHCS SOP for Use of VHA Central Office IRB
Research Service Space Policy