VETERANS AFFAIRS
PORTLAND HEALTH CARE SYSTEM

RESEARCH & DEVELOPMENT COMMITTEE

Policies & Procedures

Revised 04/09/2019
Approved by the Research & Development Committee and Effective: 05/06/2019

Substantive changes in this revision:

1. GENERAL: This VAPORHCS R&D Committee P&P reflects the newly released VHA Directive 1200.01, published on 01/29/2019
2. Section I., addition of language regarding establishment of the R&D Committee and removed reference to the HRPP
3. Section II., addition of language regarding the VA mission and how research is overseen at facilities
4. Section II., addition of language regarding provision of necessary medical treatment to VA research subjects
5. Section III., “Information Security Officer (ISO)” has been replaced by “Information System Security Officer (ISSO)” throughout the document
6. Section IV., Policy section added
7. Section V., Shared Responsibilities of the Institution in Research Oversight section re-named and re-organized
8. Section V.A., addition of Veterans Integrated Service Network Director responsibilities

9. Section V.B., “VA Medical Facility Director” replaced the previous title of “Health Care System Director” throughout the document
10. Section V.B.1., specified research program aspects
11. Section V.B.2., addition of establishing the facility’s R&D Committee
12. Section V.B.3., addition of committee and subcommittee membership appointments
13. Section V.B.5., addition of suspension, termination of research
14. Section V.B., deletion of ensuring education and training
15. Section V.C.1, addition of support functions
16. Section V.C.2, deletion of R&D Committee notification memo
17. Section V.C.3., addition of research program resource needs assistance
18. Section V.C.4., deletion of WOC oversight
19. Section V.C.5., deletion of quality assurance reviews requirement
20. Section V.C.6., deletion of annual CRADA and agreement reviews
21. Section V.C.7., deletion of requirement to send committee and subcommittee minutes to the Director and COS for review and action
22. Section V.D., section was moved and re-organized
23. Section V.D.2., addition of requirement to review and approve all proposals, including the option to require modifications or to disapprove the research
24. Section V.D.3., addition of ensuring research operations
25. Section V.D.4., addition of ensuring all research is consistent with VA mission
26. Section V.D.5., addition of establishing subcommittees, removal of subcommittee descriptions
27. Section V.D.6., addition of ensuring ISSO and PO reviews prior to final approval
28. Section V.D.10., addition of review of protocols that are approved by the subcommittee(s), external IRBs, and the VACO Central IRB, and recommending approval to the ACOS/R&D
29. Section V.D.11., addition of meeting attendance requirement
30. Section V.D.12., addition of option to appoint a Chair Pro Tempore
31. Section V.D.13., addition of determining facility participation in a study and ensuring IRB agreements are in place when utilizing an external IRB
32. Section V.D.15., addition of R&D Conflict of Interest Committee
33. Section V.D.16., addition of ensuring Classified Research is not conducted at the VA
34. Section V.D.17., addition of approving non-Veteran participation in research
35. Section V.E., addition of R&D Conflict of Interest Committee
36. Section V.F., addition of ISSO role
37. Section V.G., addition of PO role
38. Section V.H., VA Investigator responsibilities re-arranged
39. Section V.H.1., addition of research plan development requirements
40. Section V.H.2., addition of approval requirements
41. Section V.H.3., addition of Conflict of Interest form submission requirements
42. Section V.H.6., addition of ensuring research proposal support VA mission
43. Section V.H.9., addition of ensuring research record retention
44. Section VI., R&D Committee Operations section completely re-organized

45. Section VII., R&D Committee Membership section completely re-organized and redundant information was deleted
46. Section VII.A., addition of VA appointment types of R&D Committee members
47. Section VII.B., addition of representation from HSR&D and RR&D centers
48. Section VII.C.4., term “Alternate Chair” replaced with “Vice Chair”
49. Section VII.C.7., “Ad hoc reviewer” was replaced with “Consultant”. Deleted information regarding payments to consultants
50. Section VIII. R&D Committee Subcomittees section was re-organized and information was deleted that can be found in VHA Handbooks and subcommittee P&Ps and SOPs
51. Section VIII.A., addition of language re: external committees
52. Section VIII.A.3., addition of requirement to review subcommittee minutes within 60 days of subcommittee finalization
53. Section IX. R&D Committee Review of Research section was re-named and re-organized
54. Section IX.A., addition of authority of R&D Committee to require modifications or disapprove research, and to suspend or terminate a research protocol
55. Section IX.B., R&D Committee Review of Research Overseen by a Subcommittee section added
56. Section IX.B.1. addition of R&D Committee review of protocols, and addition of contingent approval process
57. Section IX.B.2., addition of required documents for protocol review and approval
58. Section IX.B.3., addition of ability to disapprove a study
59. Section IX.B.4., addition of language clarifying the R&D Committee does not need to approve continuing reviews or amendments
60. Section IX.C., R&D Committee Review of Research Overseen by an External IRB section added
61. Section IX.C.1., addition of External IRB description
62. Section IX.C.2., addition of required documents for R&D Committee review of an External IRB’s initial review
63. Section IX.C.3., addition of determination requirements
64. Section IX.C.4., addition of R&D Committee actions
65. Section IX.C.5., addition of language describing approval and ACOS notification
66. Section IX.C.6., addition of language clarifying the R&D Committee does not need to approve continuing reviews or amendments
67. Section IX.D., R&D Committee Review of Research Overseen by the VACO Central IRB section added
68. Section IX.D.1., addition of language describing procedures for initial review
69. Section IX.D.2., addition of determination requirements
70. Section IX.D.3., addition of R&D Committee actions
71. Section IX.D.4., addition of language describing approval and ACOS notification
72. Section IX.D.5., addition of language clarifying the R&D Committee does not need to approve continuing reviews or amendments
73. Section IX.E., R&D Committee Review of Research as the Only Oversight Committee section added

74. Section IX.E.1., simplification of protocol types only reviewed by the R&D Committee
75. Section IX.E.1.c., removal of VACO Central Office IRB-reviewed studies
76. Section IX.E.2.a.ii., addition of initial review form
77. Section IX.E.2.a.iii., addition of designated review option
78. Section IX.E.2.c., addition of designated review option for amendments
79. Section IX.E.3., R&D Committee Correspondence section re-organized, including the addition of designated (contingent) approval process
80. Section IX.F., Designated Review process added and described
81. Section X., R&D Committee Records section re-titled and re-organized to eliminate redundancies
82. Section X.C., removed references to MIRB
83. Section XI., Collaborative Research section added
84. Section XII., addition of R&D Conflict of Interest Committee process
85. Section XIII., addition of Participation of Non-Veterans as Research Subjects section
86. Section XIV., references updated

I. PURPOSE

The VA Portland Health Care System (VAPORHCS) Research & Development (R&D) Committee Policies & Procedures (P&P) establishes the responsibilities and operations of the R&D Committee, as well as establishes the responsibilities of other research and facility staff relating to the operation of the R&D Committee. ***AUTHORITY****: Title 38 United States Code (U.S.C.) 7303.*

The R&D Committee 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, how the R&D Committee interacts with its subcommittees, and in some instances, review of research project proposals.

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

II. BACKGROUND

A. The research mission of the Department of Veterans Affairs (VA) is conducted primarily within individual VA medical facilities according to the highest ethical standards, with accountability to all involved stakeholders. The VAPORHCS R&D Committee is established to oversee the maintenance of high standards within the VA's research program and ensure that VA research is scientifically valid and complies with regulatory and ethical standards.

B. VA medical facilities must provide necessary medical treatment to research subjects injured as a result of participation in a research study approved by the R&D Committee and conducted under the supervision of one or more VA employees. VA research subjects are provided necessary medical treatment in VA medical facilities, including joint VA-Department of Defense (VA-DoD) Federal health care facilities (see 38 CFR 17.85).

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
IRQ	Initial Review Questionnaire
ISSO	Information System Security Officer
MIRB	Manage Your Institutional Review Board
OHRP	Office for Human Research Protections
OHSU	Oregon Health & Science University
ORD	Office of Research and Development, VA Central Office
ORO	Office of Research Oversight
P&P	Policies & Procedures
PHI	Protected Health Information
PI	Principal Investigator
PO	Privacy Officer
VAPORHCS	VA Portland Health Care System
R&D	Research & Development
RAO	Research Assurance Officer
RCO	Research Compliance Officer
RSO	Radiation Safety Officer
SAE	Serious Adverse Event
SOP	Standard Operating Procedures
UAE	Unanticipated Adverse Event/Experience
UPR	Unanticipated Problem Involving Risks to Subjects or Others

IV. POLICY

It is VHA policy that each VA medical facility conducting research must establish an R&D Committee. All VA research must be approved by the R&D Committee and cannot be initiated until the Associate Chief of Staff for Research & Development (ACOS/R&D) has notified the Principal Investigator (PI) in writing that all approvals are in place. Once approved, VA is responsible for all aspects of the VA research, including oversight by the R&D Committee, appropriate subcommittees, and when applicable, VHA Office of Research and Development (ORD) and VHA Office of Research Oversight (ORO).

V. SHARED RESPONSIBILITIES OF THE INSTITUTION IN RESEARCH OVERSIGHT

A. Veterans Integrated Service Network Director

Each Veterans Integrated Service Network (VISN) Director is responsible for ensuring that all research programs at VA medical facilities within the VISN comply with VHA Directive 1200.01.

B. VA Medical Facility Director

Each VA medical facility 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 (IO) responsible for all aspects of the research program, including but not limited to protection of human subjects, the care and use of animals in research, privacy and security of VA data, biosecurity, and biosafety.

2. Establishing the facility's R&D Committee.

3. Appointing members of the R&D Committee and its subcommittees in writing.

4. Ensuring that research in which the facility is engaged is approved by the R&D Committee and appropriate subcommittee(s).

5. Suspending or terminating research that has been approved by the R&D Committee when concerns are raised and substantiated about the conduct of the research (per VHA Handbook 1058.02 and VHA Handbook 1058.04).

6. Ensuring there are adequate resources and administrative support, including personnel, space, equipment, and training for the R&D Committee and its subcommittees to fulfill their responsibilities.

C. Associate Chief of Staff for Research & Development

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

1. Serving as the Executive Secretary of the R&D Committee and providing administrative support, including correspondence, scheduling meetings, and responding to questions about the Committee.

2. Notifying investigators, in writing, when a research project can be initiated, and the period for which the project is approved. This notification occurs only after the research project has been approved by all applicable R&D Committee subcommittees and the R&D Committee.

3. Assisting the medical facility Director in fulfilling responsibilities for the facility's research program by making recommendations regarding personnel, space and other resource needs of the research program.

D. Research & Development Committee

The VAPORHCS R&D Committee is responsible for:

1. Assisting the medical facility Director in fulfilling responsibilities for the facility's research program by making recommendations regarding personnel, space and other resource needs of the research program.

2. Reviewing research proposals and approving the research, requiring modifications to obtain approval, or disapproving the research.

3. Ensuring the effective operation of the facility research program through oversight of all R&D Committee subcommittees and facility's research portfolio.

4. Ensuring that all research in which the facility is engaged is consistent with the VA mission and complies with all applicable statutory and regulatory requirements.

5. Establishing appropriate subcommittees to review and oversee human subjects research, animal research, and safety and security reviews (see section VIII.).

6. Ensuring Information System Security Officer (ISSO) and Privacy Officer (PO) review is complete before a human subjects study (including IRB-exempt research) is given final approval.

7. Reviewing the operations of all research-related committees and subcommittees as an ongoing function. See section VI.F. for details of the review process.

7. Reviewing and voting on R&D Committee minutes that summarize the actions and reasons for the actions of each presented item reviewed by the R&D Committee.

8. Serving as the approving committee of record, including conducting initial reviews and continuing reviews, for projects that are not reviewed by any subcommittee, per the local SOPs, at the VAPORHCS.

9. Conduct reviews of protocols that are approved by the subcommittee(s), external IRBs, and the VA Central IRB, and recommending initial approval to the ACOS.

10. Regularly attend R&D Committee meetings. A member may be removed from the R&D Committee by the VA facility Director on the basis of repeated unexcused absences or non-attention to the functions and responsibilities of the R&D Committee.

11. Appointing a Chair Pro Tempore to serve when the Chair and Vice Chair are absent or have a conflict of interest that requires recusal.

12. Ensuring Information System Security Officer (ISSO) and Privacy Officer (PO) review is complete before a study is given final approval.

13. Determining whether the facility should participate in a study and ensuring that the appropriate Institutional Review Board (IRB) agreements are in place as required by VHA Directive 1200.05 and VHA Handbook 1058.03, prior to using the external IRB when a study is reviewed by an IRB of another Federal agency (for example, the National Cancer Institute Central IRB), or a non-VA IRB serving as the multi-site IRB for a study.

14. Establishing procedures to ensure that all research in which the facility is to be engaged has been reviewed and approved for high scientific quality, the protection of human subjects and their research staff, the welfare of animal subjects, the safety

of all involved in research, the security of research laboratories, and the security of VA data and sensitive information.

15. Establishing a local R&D Conflict of Interest Committee to ensure that potential financial conflicts of interest are reported, reviewed, and managed in accordance with government ethics rules and regulations and VA ethics policies.

16. Ensuring that Classified Research is not conducted as VA research. ***NOTE:*** *Classified research is research that is considered restricted or secret by the Federal government, sponsor, or any third party. For example, research for the Federal government that is considered sensitive or would affect national security.*

17. Approving the participation of non-Veterans as research subjects.

18. Fulfilling other functions as may be specified by the medical facility Director, ORD, and VHA leadership.

E. Research & Development Conflict of Interest Committee

The local R&D Conflict of Interest Committee is responsible for reviewing completed, signed and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement submitted by VA investigators.

F. Information System Security Officer

The Information System Security Officer (ISSO) is responsible for ensuring that the proposed research complies with information security requirements for VA sensitive information (see VA Handbook 6500).

G. Privacy Officer

The Privacy Officer (PO) is responsible for ensuring that the proposed research complies with VA Privacy requirements and the HIPAA Authorization contains all required elements (see VHA Directive 1605.01).

H. VA Investigators

Each VA investigator is responsible for:

1. Developing a research plan that is scientifically valid; minimizes risk to human and animal subjects used in research and 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 its subcommittees and other research-related committees to fully review the research project.

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

3. Submitting a completed, signed and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement for review by the R&D Conflict of Interest Committee prior to:

a. Initial review of a study protocol in which the employee is listed as Investigator;

b. Continuing review of a study protocol in which the employee is listed as Investigator;

c. The employee being added as an Investigator to a study protocol; and

d. When a change in relevant information requires that the investigator change an answer in section I of an earlier-filed OGE Form 450 Alternative – VA to "yes" or that changes the reason for a "yes" answer.

4. Submitting and implementing plans for data use, storage, and security to the PI and ISSO that are consistent with VHA Directive 1605.01, VA Directive 6500, implementing handbooks, and other legal requirements.

5. Preparing and submitting information, at least annually or as otherwise required, on all research projects to the appropriate R&D Committee subcommittee or the R&D Committee for continuing review.

6. Ensuring that research proposals support the mission of VHA and enhance the quality of health care for Veterans.

7. 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.

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

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

10. Following the investigator responsibilities and procedures outlined in the Presentation and Publication of Research Results Policy and Procedure.

11. Ensuring that all research personnel hold an official VA appointment from Human Resources Management Service (HRMS) as a compensated, full-time or part-time employee, a WOC, or under an IPA prior to conducting or being involved in any way in any VA research activities.

VI. R&D COMMITTEE OPERATIONS

A. Review Schedule. In order to meet the demands of the research program, 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, two meetings are scheduled for the month of August (one at the beginning and one at the end of the month, and a single meeting in September at the end of the month. The purpose of this scheduling exception is to accommodate the review of various projects before the start of the new fiscal year.

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 will have received all pertinent material prior to the meeting and will participate actively and equally in all discussions.

B. Additional meetings. Additional may be called by the Chair, in response to emergent issues. Any additional meetings must meet the quorum requirements (either in person or via video- or teleconference).

C. Official Business. All official business must be conducted at a convened R&D Committee meeting with a quorum present, except when a designated review procedure is used as allowed under this policy. In order for a protocol to be approved at a convened meeting, 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.

D. Minutes. Minutes for each meeting must be documented and disseminated to the facility leadership council. The minutes must include the following information:

1. A list of all voting members indicating the category of their membership and whether they are present, excused, or absent, and any other attendees. If an alternate is present in place of a voting member, the minutes must indicate this fact and name the voting member being replaced.

2. The presence of a quorum (a majority of members).

3. Actions taken by the R&D Committee, to include:
   a. The type of action.
   b. The vote on the action, including the number voting for, against, and abstaining. In addition, any recused member from the vote must be named, and whether the person was present during the discussion. ***NOTE:*** *If the member is recused, the member must not be present for the vote, and may not be counted toward the quorum.*

E. SOPs. SOPs or other written procedures will be maintained for all recurring processes. These processes include, but are not limited to, communication with the medical facility Director, the COS, investigators, and committees or subcommittees.

F. Committee and Subcommittee Reviews. The R&D Committee reviews all research-related committees and subcommittees at least annually in part by: reviewing the minutes of each subcommittee that reviews VA research protocols; by close communication with the subcommittees; and through Quality Assurance and Quality Improvement activities. When a VA facility uses an IRB other than its own internal IRB, such as, but not limited to, the VA Central Office (VACO) IRB, the IRB of another Federal agency such as the National Cancer Institute (NCI) Central IRB, or the academic affiliate institution's IRB such as the Oregon Health & Science University (OHSU) IRB, the role of the R&D Committee is to review and evaluate facility-specific aspects of these relationships, rather than the subcommittee itself, to ensure the obligations as detailed in the MOU are being met. For example, review of an external committee would include evaluation of the number of projects handled by the committee, communication between entities, changes in MOUs or other agreements, change in processes, and challenges. A summary of these reviews and evaluations will be sent to the medical facility Director annually.

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

H. Standing Agenda Items

1. Review and approval of R&D Committee minutes of previous meeting. In the event that the previous month's minutes are not completed in time for review by the next subsequent meeting, they will be presented at the following R&D Committee meeting.
2. Review of Subcommittee meeting minutes. Final versions of the subcommittee meeting minutes will be presented to the R&D Committee for review within 60 days of being approved by the subcommittee. As part of the review of a subcommittee's minutes, the R&D Committee Chair will ask a sitting subcommittee member (if present) 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.
3. Minutes of the VA Central (VACO) IRB are presented to the R&D Committee after they have been distributed to the field. Any/all item(s) in the minutes that concern(s) a study that takes place at the VAPORHCS will be discussed specifically, and supplemental documentation will be provided, if applicable.
4. Minutes of the academic affiliate institution's (OHSU) IRB are presented to the R&D Committee after they have been generated by the IRB staff.

5. ACOS/R&D Report – The ACOS/R&D will update the R&D Committee on any current issues relating to the Research Service. Committee members are expected to provide feedback and advice.
6. Old Business, if unfinished business exists that was discussed at a previous meeting.
7. New Business items, which may include 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.
8. Other Agenda Items, (as needed)**.** The R&D Committee may review applications for special initiatives (equipment requests) and also conduct reviews required by other VA handbooks/directives, 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 ORD.

VII. R&D COMMITTEE MEMBERSHIP

A. Appointment of Members.

The members of the R&D Committee are appointed by the VA medical facility Director. Nominations for membership may be submitted by current R&D Committee members, subcommittee members, and the facility's staff. All members of the R&D Committee must hold VA appointments (permanent, temporary, TERM, IPA, or WOC).

B. Composition and Number of Members

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 of research conducted at the VAPORHCS. The VAPORHCS strives to maintain balance and expertise on the R&D Committee by including members from mental health, neurology, surgery or anesthesiology, internal medicine, basic science, animal research, and the Health Services Research & Development (HSR&D) and Rehabilitation Research & Development (RR&D) Research Centers. 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, ethnicity, cultural background, and expertise, the R&D Committee must have at least:

1. five (5) voting members.
2. two (2) members from the VA medical facility's staff who have major patient care or management responsibilities.
3. two (2) members who are VA investigators actively engaged in major R&D programs who can provide R&D expertise.
4. one (1) member who also holds an academic appointment at the VAPORHCS's affiliated institution, OHSU.

Whenever practicable, the R&D Committee should 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 VAPORHCS Research website. In addition, the membership is summarized in the R&D Committee meeting minutes and agendas.

C. **Membership Categories**

1. Chairperson

The R&D Committee shall elect a Chairperson (referred to as "Chair" throughout the P&P) on an annual basis. The Chair holds a one-year term and may be re-appointed indefinitely, without any lapse in time. The Chair must be approved and officially appointed, in writing, by the medical facility Director. The Chair may not simultaneously chair a subcommittee of the R&D Committee. The Chair is a full voting member of the R&D Committee, and is counted in the quorum of the committee.

2. Voting Members

The R&D Committee votes to recommend the R&D Committee member for formal appointment by the medical facility Director. 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. The R&D Committee members are full voting members of the R&D Committee, and are counted in the quorum of the committee.

3. Alternate Members

The R&D Committee votes to recommend the alternate R&D Committee members for formal appointments by the medical facility Director. Alternate

members shall serve as an alternate for a specific voting member. The alternate member's qualifications must be comparable to those of the primary member(s) to be replaced. The alternate member is only allowed to vote in the absence of the member s/he represents. 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. When they attend in place of a member, they are serve as a full voting members, and are counted in the quorum of the committee.

4. Vice Chair

The R&D Committee votes to recommend the Vice Chair for formal appointment by the medical facility Director. The Vice Chair serves a one-year term and may be re-appointed indefinitely. The Vice Chair's term expires with the term of the Chair that he/she is representing. The Vice Chair is a full voting member of the R&D Committee, and is counted in the quorum of the committee.

5. 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:

a. Medical facility Director;

b. Chief of Staff (COS);

c. ACOS/R&D;

d. Deputy ACOS/R&D;

e. AO/R&D;

f. Veterinary Medical Officer (VMO);

g. Representative of the Research Pharmacy;

h. Information System Security Officers

i. Privacy Officers

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.

6. Research Compliance Officer (RCO)

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.

7. Consultants

The R&D Committee may, at its discretion, obtain services of consultants to assist in review of issues that go beyond the R&D Committee's expertise but are in the purview of the consultants. Consultants 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. Consultants do not vote or contribute to a quorum. Such consultants may be asked to submit written reports or, when necessary, to present their recommendations to the committee in person.

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

The R&D Committee Chair and members will receive 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."

E. **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” for the vote.

VIII. R&D COMMITTEE SUBCOMMITTEES

A. The R&D Committee may establish any subcommittee(s) deemed necessary for the efficient and effective management and oversight of the R&D Program. ***NOTE:*** *External committees established by MOUs or other agreements in lieu of required subcommittee(s) are not considered subcommittees and are governed by the agreement (e.g. the VA Central (VACO) IRB).*

1. At a minimum, subcommittees are appointed to oversee R&D activities related to human studies, animal studies, and research safety and security.
2. Findings and recommendations of the subcommittees are recorded and reported to the R&D Committee.
3. The R&D Committee must review subcommittee minutes within 60 days of the subcommittee’s finalization of the minutes.

B. The subcommittees established by the R&D Committee include:

1. Institutional Review Board (IRB). The R&D Committee has charged the VAPORHCS IRB with the oversight of research activities involving the use of human subjects. The VAPORHCS IRB Policy & Procedures contain the procedures and principles by which the IRB abides in the review and conduct of human subjects research. The IRB adheres to the policies in VHA Directive 1200.05.

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 and Security (SRSS).** The R&D Committee has charged the VAPORHCS SRSS 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 SRSS Standard Operating Procedures (SOP) contains the principals and procedures by which the SRSS 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 SRSS adheres to the policies in VHA Handbooks 1200.08.

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. R&D COMMITTEE REVIEW OF RESEARCH

A. Authority of the R&D Committee. The R&D Committee has the authority to review and approve research, require modifications to obtain approval, or disapprove research. It also has the authority to suspend or terminate a research protocol; suspend an investigator's or a research staff member's privilege to conduct research pending appropriate investigation and decision by the medical facility Director; and require the implementation of additional safeguards related to the safety of human subjects, the welfare of research animals, the protections of employees or the environment, or the security of VA Data and VA Sensitive Information. The R&D Committee focuses on oversight of the VAPORHCS research program, by reviewing the following categories of research:

B. R&D Committee Review of Research Overseen by a Subcommittee

1. The R&D Committee may approve a protocol contingent on the protocol being approved by one or more subcommittees. The R&D Committee must ensure the adequacy of each subcommittee's review procedures, including reviewing and approving all subcommittee's SOPs. Final approval may only be given after the R&D Committee receives documentation from all applicable subcommittees of their review and non-contingent approval. Final approval can be provided by a designated reviewer, if the study was previously reviewed by the R&D Committee and contingently approved pending final approval by applicable subcommittees, if there were no major changes made by the subcommittee(s). The designated reviewer must have sufficient documentation from the subcommittee(s) to make a determination about any changes requested. This final approval must be reported to the full R&D Committee at its next convened meeting and noted in the minutes.

2. When the R&D Committee relies on the initial review of the subcommittee, the R&D Committee must review the following documents:

a. A notice from the subcommittee that the research protocol has been approved;
b. A brief written summary of the research to be conducted;
c. The protocol that was reviewed by the subcommittee(s);
d. The subcommittee minutes section that describes the review of enrollment of non-Veterans (if applicable);

e. Approval by the PO and ISSO. ***NOTE:*** *The R&D Committee can approve contingent on ISSO and PO review.*

The R&D Committee may require specified changes or modifications that would require subcommittee re-review.

3. The R&D Committee may disapprove a study even if approved by all subcommittees. The disapproval may be based on such issues as inadequate qualifications of the investigator(s); insufficient relevance to the VA's mission; the presence of inadequate resources to conduct the study; the poor design of the study; concerns related to the protection of human subjects, the welfare of animals used in the research, safety to personnel, the environment, or others; unresolved conflicts of interest that may be detrimental to the research or the facility; or other serious concerns as defined by the R&D Committee. ***NOTE:*** *While the R&D Committee can disapprove research approved by one of its subcommittees, it is not permitted to approve research that has been disapproved by an appropriate subcommittee.*

4. The R&D Committee does not need to approve continuing reviews and amendments but should be provided sufficient documentation in the subcommittee minutes that are provided to the R&D Committee.

C. R&D Committee Review of Research Overseen by an External IRB

1. The R&D Committee may approve a protocol that is approved by an external IRB. This includes the academic affiliate institution (OHSU) IRB and the National Cancer Institute (NCI) Central IRB. The OHSU IRB and the NCI Central IRB are established and governed by an MOU. ***NOTE:*** *An external IRB is an IRB of another Federal agency or another non-VA institution's IRB. For purposes of this P&P, use of the VA Central IRB or another VA facility's internal IRB is no considered to be an external IRB.*

2. When the R&D Committee relies on the initial review of an external IRB, the R&D Committee must review the following documents at a convened meeting:

a. A notice from the external IRB that the research protocol has been approved;
b. A brief written summary of the research to be conducted;
c. The full protocol that was reviewed by the external IRB;
d. The external IRB minutes section or primary reviewers' checklist that describes the review of enrollment of non-Veterans (if applicable);
e. Approval by the PO and ISSO.

3. During a convened meeting, the R&D Committee must determine, and specifically document its determination, that the research:

a. Supports the VA mission and is relevant to the care of Veterans;
b. Is scientifically meritorious;
c. Ensures the security of VA Data, and the storage of data and specimens in accordance with all applicable requirements (see VHA Directive 1605.01 and VA Handbook 6500).

4. The R&D Committee must vote to approve, approve with contingencies, or not approve the research to be conducted at the facility unless the research can be approved by a designated review process.

5. When the written R&D Committee approval is obtained, the ACOS/R&D will notify the PI that the research project can be initiated, and the period for which the project is approved. This notification occurs only after the research project has been approved by all applicable R&D Committee subcommittees and the R&D Committee. ***Note:*** *The ACOS/R&D notification may be combined with the R&D Committee approval notice. If combined, the R&D Committee approval notice may be signed by the ACOS/R&D alone, or together with the R&D Committee Chair.*

6. The R&D Committee does not need to approve continuing reviews and amendments but should be provided sufficient documentation in the external IRB minutes that are provided to the R&D Committee.

D. R&D Committee Review of Research Overseen by the VA Central Office (VACO) Central IRB

1. The VACO Central IRB is established and governed by an MOU. The R&D Committee approves protocols that are approved by the VACO Central IRB as outlined in the VAPORHCS R&D Committee Use of VHA Central Office Institutional Review Board Research SOP. When the R&D Committee relies on the initial review of the VACO Central IRB, the R&D Committee must review the following documents at a convened meeting:

a. The VACO Central IRB documents that were approved, including:
   i. the PI/Study Chair (PI/SC) and/or Local Site Investigator (LSI) application;
   ii. full protocol;
   iii. any approved informed consent forms and HIPAA authorization forms;
   iv. the reviews by the VACO IRB PO and ISSO;
   v. an abstract, which provides a brief written summary of the research to be conducted;
   vi. the determination by the VACO IRB to allow the enrollment of non-Veterans (if applicable);
   vii. the determination by the VACO IRB that a research flag is required (if applicable);
   viii. the determination by the VACO IRB that pregnant women may be included as research participants (if applicable); and
   ix. the determination by the VACO IRB that local union notification is required (if applicable).

2. The R&D Committee must determine, and specifically document its determination, that the research:

a. Supports the VA mission and is relevant to the care of Veterans;
b. Is scientifically meritorious;

c. Ensures the security of VA Data, and the storage of data and specimens in accordance with all applicable requirements (see VHA Directive 1605.01 and VA Handbook 6500).

3. During a convened meeting, the R&D Committee must then vote to approve, approve with contingencies, or disapprove the research to be conducted at the facility unless the research can be approved by a designated review process.

4. When the written R&D Committee approval is obtained, the ACOS/R&D will notify the PI that the research project can be initiated, and the period for which the project is approved. This notification occurs only after the research project has been approved by all applicable R&D Committee subcommittees and the R&D Committee. ***Note:*** *The ACOS/R&D notification may be combined with the R&D Committee approval notice. If combined, the R&D Committee approval notice may be signed by the ACOS/R&D alone, or together with the R&D Committee Chair.*

5. The R&D Committee does not need to approve VACO Central IRB continuing reviews and amendments but should be provided sufficient documentation in the VACO Central IRB minutes that are provided to the R&D Committee.

E. R&D Committee Review of Research as the Only Oversight Committee

1. **Types of Protocols Reviewed.** The R&D Committee provides oversight to individual protocols that don't fall under the purview of any subcommittee or external IRB. This includes the following categories of protocols:

   a. 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.

   b. "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).

2. The R&D Committee conducts the following types of reviews:

a. Initial Reviews

i. The R&D Committee uses a primary reviewer system. The abstract, protocol, and all applicable documents are made available to the primary reviewer and all members to review.

ii. 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. On the initial review form, the PI will provide the names and roles of personnel. A Scope of Work form will be required to describe the study duties of each study staff.

iii. For protocols that require a modification to obtain approval, the R&D Committee must communicate their contingencies to the VA investigator. Minor changes may be reviewed and approved by the Chair or the primary or designated reviewer and given final designated approval of the protocol. This final approval must be reported to the full R&D Committee and noted in the minutes.

v. At approval, the R&D Committee must set the time frame for continuing review. The time frame may not exceed 365 days. For designated approval, the date of approval is the date of final approval by the designated reviewer once all changes have been made.

vi. For protocols approved or disapproved by the R&D Committee, a written notification from the R&D Committee Chair or Vice Chair is sent to the ACOS/R&D. The ACOS/R&D notifies the PI, in writing, when a research project can be initiated, and the approval period for the project.

b. Continuing Reviews

i. Information that must be received by the R&D Committee from the PI for continuing review includes:

1. Scientific progress of the research.
2. Budget requirements changes.
3. Changes in requirements for space, personnel, equipment, and supplies.
4. Summary and impact of any unanticipated problems.
5. Any issues of serious non-compliance with applicable policies, including privacy and security that have occurred since last approval.

ii. 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 continuing review by the R&D Committee. On the continuing review form, the PI will provide the names and roles of personnel. A Scope of Work form will be required to describe the study duties of each study staff.

The PI will be prompted to submit a revised Scope of Work form for any individual whose role in the study has changed.

iii. Once the R&D Committee approves the protocol's continuation, written notification from the R&D Committee Chair or Vice Chair is sent to the PI.

c. Amendments

Amendments to the approved research must be submitted to the R&D Committee for approval. Once the R&D Committee or designated reviewer has approved the amendment, written notification from the R&D Committee Chair, Vice Chair, or designated reviewer is sent to the PI.

d. Reports of Systemic Deficiencies

The R&D Committee is responsible for reviewing reports of systemic 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:
  - The R&D Committee must determine what remedial actions, if any, are warranted to ensure effective research protections;
  - The R&D Committee must notify the VA facility Director and the ACOS/R&D within 5 business days after the determination.

e. 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:

i. any inappropriate access, loss, or theft of PHI;

ii. noncompliant storage, transmission, removal, or destruction of PHI; or

iii. 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 SRSS. 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:

i. Whether or not the incident constitutes a serious problem (see definition in VHA Handbook 1058.01); and

ii. 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:

iii. The committee must notify the VA facility Director and the ACOS/R&D within 5 business days after the determination.

iv. 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.

3. R&D Committee Correspondence

Accurate records are maintained of all communications to and from the R&D Committee, including correspondence with investigators, subcommittees, consultants, and VA Central Office. All correspondence written on behalf of the R&D Committee is signed by the R&D Committee Chair, Vice Chair, or designated reviewer. At the time of any disapproval (initial, continuing, amendment, etc.), correspondence is signed by the R&D Committee Chair or Vice Chair. Copies of all correspondence are filed in the appropriate investigator research project file on the Research network.

a. Initial Review: Investigators will be notified within approximately 10 business days of final, tabled, or disapproval of initial review. Once final approval has been generated by the R&D Committee, the written committee approval will be given to the ACOS/R&D. The ACOS will send the final R&D Committee approval to the PI and notify them that the project has approval to begin.

b. Continuing Review: Investigators will be notified within three weeks of approval, contingent approval, tabled, or disapproval of continuing review. Once final approval has been generated by the R&D Committee, the signed committee approval will be sent to the PI 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 lapsed. A notification letter to the PI from the R&D Committee Chair or Vice 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 lapsed, 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 PI from the R&D Committee Chair or Vice Chair will be generated promptly by the R&D Committee coordinator. In the event that the PI wishes to re-open the study, the R&D Committee may require the PI to submit new materials for an initial review.

In cases of a tabled decision by the R&D Committee, the R&D Committee coordinator will notify the PI per the timeline outlined in each event. 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

When original signatures are required on documents, 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) (for applicable documents), and any other relevant requirements.

F. Designated Review

The following activities may be approved by the R&D Committee Chair or a voting member designated by the Chair:

1. Minor changes to a protocol required by the R&D Committee, following a full board review;

2. Final approval for protocols approved contingent on the full approval of a subcommittee if the subcommittee had not required major changes to the protocol since the R&D Committee conducted its review;

3. Final approval for protocols approved contingent upon completion of the PO and ISSO review.

4. Exempt human subject research protocols and protocols approved by expedited review by the IRB.

5. Amendments/revisions to IRB exempt projects. Prior to receiving designated review by the R&D Committee chair or appointed voting member, the amendment will first be submitted to the IRB Chair for confirmation, in writing, that the proposed change will not affect the previously-approved exempt status. If it is determined the project remains exempt, the protocol amendment/revision is then forwarded to the R&D Committee for designated review.

Exception: If a protocol amendment/revision of a previously determined exempt protocol is reviewed by an IRB Chair 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.

6. Single patient expanded access protocols approved by the IRB Chair or another appropriate IRB voting member;

7. Protocols that do not involve human subjects, biosafety level 3 (BSL-3) or higher containment, use of select agents or non-exempt quantities of select toxins, United States Department of Agriculture (USDA)-regulated animal species, or any animal research involving more than momentary pain or distress to animals.

X. R&D COMMITTEE RECORDS

A. Documentation Categories The adequate documentation of all the activities of the R&D Committee and subcommittees must be maintained, including, but not limited to, the following:

1. Copies reviews of all research proposals. This includes initial reviews, continuing reviews, amendments, and final reports reviewed by the R&D Committee and subcommittees, and any accompanying materials. These documents are saved within the electronic research project files, located on the secure Research network folder. Protocols are assigned a unique number 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 SRSS records, are maintained in the project-specific files.

2. Minutes of the R&D Committee and R&D Committee subcommittees. R&D Committee minutes are completed by the R&D Committee coordinator.

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.

Minutes shall be maintained by the R&D Committee coordinator and the VAPORHCS Research Administration Office and made available to VA Central Office and any investigator upon request. 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.

3. Copies of all written correspondence between the researchers and the R&D Committee and its subcommittees. All written correspondence between the researchers and the R&D Committee and its subcommittees regarding research projects is kept within the appropriate research project file located on the secure Research network folder.

4. Membership roster for the R&D Committee and all R&D Committee subcommittees. The R&D Committee and its subcommittees' coordinators maintain the current rosters, which include memberships, alternate memberships, and Ex-Officio non-voting memberships. The R&D Committee and subcommittees' membership rosters are located on the VAPORHCS Research Service website, and are saved in a folder on the restricted-access, Research Service network folder.

5. SOPs. Written records documenting actions taken to carry out the R&D Committee's and subcommittees' responsibilities for review of research, and for oversight of the research program are located on the VAPORHCS

Research Service website, and are saved in a folder on the restricted-access, Research Service network folder.

B. Record Retention. Written records documenting actions taken to carry out the committees' responsibilities for review of research, and for oversight of the research program are the property of VA and the policy for record retention is outlined in VHA Records Control Schedule (RCS) 10-1. ***NOTE:*** *Record retention may be longer depending upon other policies and regulations such as Food and Drug Administration (FDA) regulations or medical record retention policies.*

C. Research Tracking System

The Research Administration Office uses an electronic committee management system computerized tracking system, which is maintained by the R&D, IRB, IACUC and SRSS coordinators. The electronic committee management system stores information regarding which documents have been received, when they were reviewed, and the results of that review. Additionally, it tracks changes that are needed, when those changes were received and approved, and the date of continuing review; as well as 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).

XI. COLLABORATIVE RESEARCH

A. Definition. Collaborative research is a research collaboration involving investigators from VA and other institutions with VA investigators having a substantive role in the design, conduct, and/or analysis of the research.

B. Approval of Research. Each institution is responsible for safeguarding the rights and welfare of human subjects, ensuring the welfare of animals, complying with all applicable biosafety and biosecurity requirements and for providing oversight of the research activities conducted at that institution. The VA R&D Committee must ensure it only approves VA research activities in a collaborative study.

(1) Each collaborating institution engaged in the research must obtain approval from the applicable research review committee(s) such as the IRB or IACUC. Each institution must hold a Federalwide Assurance (FWA) if the research is non-exempt human subjects research or a Public Health Service Assurance when conducting research involving animals (see VHA Handbook 1058.03).

(2) For each individual research study, VA investigators must submit a protocol and other relevant or required documentation to their VA research review committees and subcommittees such as the IRB, the IACUC, the SRSS, and the R&D Committee.

C. Research Data. The protocol, protocol addendum, and/or subcommittee application must describe the data (identifiable or de-identified if from human subjects or sensitive or non-sensitive if animal or other research) to be disclosed to collaborators, the entity(ies) to which the data are to be disclosed, the method of how the data are to be transmitted, and the person who will own or have responsibility for the disclosed copies of the data. This includes data developed directly from the research including the analytic data and the aggregate data.

(1) Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Record Control Schedule 10-1.

(2) All disclosures and data transmission must meet privacy and security requirements per VHA Directive 1605.01 and VA Handbook 6500.

XII. 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 Conflict of Interest Committee will review all potential conflicts of interest identified by the OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement. If the R&D Conflict of Interest Committee determines there may be a

conflict, it will be referred to Legal for further review. If Legal determines a conflict exists, they will draft a management plan 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 were determined to have conflicts of interest. If an audit identifies problems with implementation or adherence to the management plan for a study, the R&D Committee will decide on corrective action to be taken.

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

XIII. PARTICIPATION OF NON-VETERANS AS RESEARCH SUBJECTS

A. Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment, but only when there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45, 17.92). The PI must justify including non-Veterans, and the R&D Committee must review the justification and provide specific approval for recruitment of non-Veterans. The R&D Committee will utilize the IRB’s review of the justification as part of their basis for determining that use of non-Veterans in a study is appropriate.

1. Outpatient Care for Research Purposes. Any person who is a bona fide volunteer may be furnished outpatient treatment when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (see CFR 38 17.92).

2. Hospital Care for Research Purposes. Any person who is a bona fide volunteer may be admitted to a VA hospital when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45).

B. Non-Veterans may be recruited for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they should be included in VA studies whenever appropriate, including research conducted jointly by VA and DoD or within DoD facilities.

C. All VA regulations and policies related to veterans as research subjects apply to non-Veterans entered into VA research.

D. Non-Veterans may not be entered into VA studies simply because a non-Veterans population is easily accessible to the PI.

E. Investigators must follow VHA Handbook 1605.04, Notice of Privacy Practices, to provide notice of privacy practices and acknowledgement for any non-Veteran enrolled into the approved protocol.

XIV. REFERENCES

Pub. L. 104-191, Health Insurance Portability and Accountability Act of 1996

5 U.S.C. 3371, Definitions

15 U.S.C. 3710a, Cooperative Research and Development Agreements

18 U.S.C. 11, Bribery, Graft, and Conflicts of Interest

38 U.S.C. 5727, Information Security, Definitions

38 U.S.C. 7303, Functions of Veterans Health Administration: Research Programs

5 CFR 2635, Standards of Ethical Conduct for Employees of the Executive Branch

38 CFR 16, Protection of Human Subjects

38 CFR 17, Medical

VA Directive 6500, Managing Information Security Risk: VA Information Security Program, dated September 20,2012

VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, dated March 10, 2015

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VAPORHCS RPPP, Credentialing of Personnel in Research and Development Service

VAPORHCS RPPP, Research Program Presentation and Publication Policy

VAPORHCS RPPP, Research Records Management

VAPORHCS RPPP, Research Information Protection Policy

VAPORHCS RPPP, Research Misconduct

Conflict of Interest in Research Policy

VAPORHCS IRB Policies & Procedures

VAPORHCS IACUC SOP

VAPORHCS SRSS SOP

VAPORHCS Use of VHA Central Office IRB Research SOP

Research Service Space Policy