RESEARCH & DEVELOPMENT COMMITTEE STANDARD OPERATING PROCEDURES

SOP RES-008-RD

VA Portland Health Care System
Portland, OR 97239

Service Line(s):
Research & Development Service

Signatory Authority:
Chief of Staff

Effective Date:
April 4, 2022

Associate Chief of Staff, Research and Development Service

Recertification Date:
March 31, 2027

Responsible Owner:
Research & Development Committee Coordinator

1. PURPOSE AND AUTHORITY

a. This SOP must be followed by research personnel who conduct, review, approve, oversee, support or manage research at the VA Portland Health Care System (VAPORHCS).

b. This SOP sets forth mandatory procedures and processes to ensure compliance with VHA Directive 1200.01(1), Veterans Health Administration Research and Development Program, dated January 24, 2019 (amended January 8, 2021). ***AUTHORITY****: Title 38 United States Code (U.S.C.) 7303.*

c. The Research & Development Committee (RDC) SOP is a reference for RDC members, subcommittee members, investigators and the Research Administration office. This SOP details the policies and procedures specifying the functions of the RDC and the regulations and policies governing the RDC's oversight of the research program at the VAPORHCS, how the RDC interacts with its subcommittees, and in some instances, review of project proposals.

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

2. RESPONSIBILITIES

a. **Associate Chief of Staff for Research and Development.** The Associate Chief of Staff for Research and Development (ACOS/R&D) 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.

b. **Research & Development Committee.** The RDC is responsible for:

(1) Ensuring that potential financial conflicts of interest are reported, reviewed, and managed in accordance with government ethics rules and regulations and VA ethics policies.

(2) Determining if a research flag should be added to the study participant's electronic health record for studies that are reviewed by an external IRB, if the external IRB did not make a determination.

(3) Reviewing Initial Reviews of all studies and conducting Initial and Continuing Reviews of all studies that are not overseen by another subcommittee.

(4) Attending at least 80% of all meetings

(5) Review of RDC and subcommittee meeting minutes. Final versions of the subcommittee meeting minutes will be presented to the RDC for review within 60 days of being approved by the subcommittee. As part of the review of a subcommittee's minutes, the RDC 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 RDC minutes.

(6) Review of all New and Old Business Items and other items as needed.

c. **VA Investigators.** Each VA 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, without compensation (WOC), or Intergovernmental Personnel Act Agreement (IPA).

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

(4) Following the investigator responsibilities and procedures outlined in the Presentation and Publication of Research Results SOP RES-004-RD.

(5) 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-approved research activities.

(6) Submitting a completed, signed and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement for review by a Financial Conflict of Interest (FCOI) Administrator 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.

(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.

(7) Assuring any Co-PI, Co-Investigator, Co-Local Site Investigator (LSI) on one’s study submits a completed, signed and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement for review by a Financial Conflict of Interest (FCOI) Administrator 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.

(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.

3. RESEARCH AND DEVELOPMENT COMMITTEE OPERATIONS

a. A quorum of the RDC members, excluding the ex-officio members, must be present to conduct a convened meeting. An RDC 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. **Review Schedule.** In order to meet the demands of the research program, the RDC 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, or immediate before or after, the first Monday of the month. In these cases, the RDC 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.

c. **Additional Meetings.** Additional meetings 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).

d. **Official Business.** All official business must be conducted at a convened RDC meeting with a quorum present, except when this SOP allows a designated review procedure. 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 RDC until the member returns.

e. **Standing Agenda Items.**

(1) Review and approval of RDC 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 RDC meeting.

(2) Review of Subcommittee meeting minutes. Final versions of the subcommittee meeting minutes will be presented to the RDC for review within 60 days of being approved by the subcommittee. As part of the review of a subcommittee's minutes, the RDC 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 RDC minutes.

(3) Minutes of the VA Central (VACO) IRB are presented to the RDC within 60 days after they have been distributed to the field. Any/all item(s) in the minutes that concern(s) a study and/or event 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 RDC after they have been generated by the IRB staff.

(5) ACOS/R&D Report – The ACOS/R&D will update the RDC 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 RDC may review applications for special initiatives (e.g., 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.

4. RESEARCH AND DEVELOPMENT COMMITTEE MEMBERSHIP

a. **Appointment of Members.** The members of the RDC are appointed by the VA medical facility Director and must reflect the types of research being conducted at the facility. Nominations for membership may be submitted by current RDC members, subcommittee members, and the facility's staff. All members of the RDC must hold VA appointments (permanent, temporary, TERM, IPA, or WOC). Nominations for committee service are proposed by R&D Service leadership (ACOS/R&D, Deputy ACOS/R&D, and Administrative Director (AD)), in conjunction with the RDC Chair. This nominating body will seek input from clinical leadership on station, where appropriate. Investigators may nominate themselves for committee service by alerting the ACOS/R&D and/or the RDC Chair. R&D leadership plus the RDC Chair will then propose the candidates to the full RDC for a confirmation vote. The number of candidates to be proposed will be the same as the number of anticipated vacancies (i.e., it is expected that each will be confirmed by the full-Committee vote). If a candidate is not confirmed by the RDC, a different candidate will be proposed by the ACOS/R&D at a subsequent meeting of the RDC. Names of candidates confirmed by the RDC are submitted to the medical facility Director for formal appointment to the Committee.

b. **Composition and Number of Members.** The membership of the RDC, 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 RDC by including members from mental health, neurology, surgery or anesthesiology, internal medicine, basic science, animal research, and health services and rehabilitation research. It strives to maintain representation from all of the major VA research service lines including Biomedical Laboratory R&D (BLR&D), Clinical Science R&D (CSR&D), Health Services R&D (HSR&D), and Rehabilitation R&D (RR&D). This balance maintains the expertise required to adequately govern the research program at the VAPORHCS.

In addition to the diversity of membership based on consideration of race, gender, ethnicity, cultural background, and expertise, the RDC must have at least one (1) member who also holds an academic appointment at the VAPORHCS's affiliated institution, Oregon Health & Science University (OHSU).

A member of each subcommittee shall serve as a voting member of the RDC. A membership roster that lists the current composition of the RDC 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 RDC meeting minutes.

c. **Membership Categories.**

(1) Chairperson. The RDC shall elect a Chairperson (referred to as "Chair" throughout the SOP) on an annual basis. The Chair holds a one-year term and may be re-appointed to a second term, 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 RDC. The committee also may appoint a Chair Pro Tempore to serve when the Chair and Vice Chair are both absent, and/or if both have conflicts of interest that require recusal. The Chair is a full voting member of the RDC and is counted in the quorum of the committee.

(2) Voting Members. Voting members are appointed by the medical facility Director in writing and serve terms of 3 years with a possibility for reappointment for an additional three-year term without any lapse in time if it is deemed in the RDC's best interest. After serving two consecutive terms (i.e., six years), a committee member is required to rotate off the committee for a period of at least one year before being deemed eligible for service again. There is no maximum number of terms or years that a committee member may serve. The terms of members must be staggered to provide continuity in membership. The RDC members are full voting members of the RDC and are counted in the quorum of the committee.

(3) Alternate Members. Alternate voting members must be appointed by the medical facility Director. The roster must identify the primary voting member(s) for whom each alternate voting member may substitute. 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. When they attend in place of a member, they serve as full voting members, and are counted in the quorum of the Committee. An alternate will be appointed for each Committee member by R&D leadership and the RDC Chair. There is no term limit for alternate members.

(4) Vice Chair. The RDC shall elect a Vice Chair, also referred to as an Alternate Chair, on an annual basis. The Vice Chair's initial appointment is set for the duration of the Chair that he/she is representing and may be re-appointed to a second term, without any lapse in time. The Vice Chair must be approved and officially appointed, in writing, by the medical facility Director. 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 RDC 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 RDC 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) Administrative Director (AD)/R&D;

(f) Veterinary Medical Officer (VMO);

(g) Representative of the Research Pharmacy;

(h) Information System Security Officer (ISSO)

(i) Privacy Officer (PO)

Other *ex-officio* members may be appointed to the RDC if their appointments assist the RDC in fulfilling its responsibilities.

(6) Research Compliance Officer (RCO). The Research Compliance Officer (RCO) may serve as a non-voting consultant, as needed, to the facility's RDC.

(7) Consultants. The RDC may, at its discretion, obtain services of consultants to assist in review of issues that go beyond the RDC's expertise but are in the purview of the consultants. Consultants cannot have a conflict of interest 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 RDC Chair and Members.** Upon appointment to the RDC, new members receive initial orientation to the committee and a copy of the most current RDC SOP prior to the first meeting. All members are provided updated versions of the RDC SOP as they are issued. The RDC Chair and members will receive appropriate continuing education related to the RDC. The ACOS/R&D may provide further guidance and training as needed.

Every 3 years the Chair and voting members of the RDC are required to complete two modules from ORD and Collaborative Institutional Training Initiative (CITI) on ethical principles of human research protection. See https://www.research.va.gov/pride/training/options.cfm for approved courses and VHA Handbook 1200.05(2) for additional information.

d. **Conflict of Interest of RDC Members.** All RDC members must aim to avoid real or perceived conflicts of interest. The RDC chair and members may find themselves in any of the following potential conflicts of interest:

(1) The RDC Chair or member is listed as an investigator on the research.

(2) An investigator must report to or is under the supervision of an RDC Chair or member.

(3) The RDC 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 RDC 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, or be removed from the virtual meeting, during the review and vote of the study. Potential Conflicts of Interest of RDC members will be noted in the minutes, and the individual is identified as “recused” for the vote.

5. RDC SUBCOMMITTEES

a. The RDC 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 RDC.

(3) The RDC must review subcommittee minutes within 60 days of the subcommittee’s finalization of the minutes.

b. The subcommittees established by the RDC include:

(1) **Institutional Review Board (IRB).** The RDC has charged the VAPORHCS IRB with the oversight of research activities involving the use of human subjects. The VAPORHCS IRB SOP contains 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).

(2) **Institutional Animal Care and Use Committee (IACUC).** The RDC has charged the VAPORHCS IACUC with ensuring compliance with animal research regulations. The IACUC 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 RDC has charged the VAPORHCS SRS with ensuring compliance with all applicable regulations, policies, and guidelines pertinent to biological, chemical, physical, and/or radiation hazards, and with oversight of all research activities involving safety hazards. The SRS 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 Institutional Biosafety Committee (IBC) provides the required reviews of studies utilizing recombinant DNA. The SRS adheres to the policies in VHA Handbooks 1200.08.

6. RDC REVIEW OF RESEARCH

a. **Authority of the RDC**. The RDC focuses on oversight of the VAPORHCS research program, by reviewing the following categories of research:

b. **RDC Review of Research Overseen by a Subcommittee**.

(1) When the RDC relies on the initial review of the subcommittee, the RDC 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, formatted according to local abstract requirements;

(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 ISSO, and PO if applicable. ***NOTE:*** *The RDC can approve contingent on ISSO and PO review.*

c. **RDC Review of Research Overseen by an External IRB**.

(1) The RDC may approve a protocol that is approved by an external IRB. This includes the academic affiliate institution (OHSU) IRB, the National Cancer Institute (NCI) Central IRB, and other external IRBs. The use of external IRBs is established and governed by MOUs.

(2) When the RDC relies on the initial review of an external IRB, the RDC 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, formatted according to local abstract requirements;

(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); ***Note:*** *this is only applicable to studies reviewed by the affiliate (OHSU) IRB; studies reviewed by commercial IRBs are governed by the Standard Operating Procedures (SOP).*

(3) The RDC will review reportable events that are not reviewed by the external IRB, but which meet VA requirements for reporting.

(4) During a convened meeting, the RDC must determine if a research flag should be added to subjects' electronic patient record.

d. **RDC Review of Research as the Only Oversight Committee.**

(1) **Types of Protocols Reviewed.** The RDC provides oversight to individual protocols that don't fall under the purview of any subcommittee or external IRB. This includes:

(a) "Science-Only" Projects. Projects involving research activities that do not qualify for review by a subcommittee (termed "science-only") are reviewed by the RDC, and include 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 to the RDC for future annual review(s).

(b) IRB Exempt Projects. Human research protocols determined to be exempt from IRB oversight will be reviewed initially by the RDC. IRB exempt projects will be forwarded by an IRB analyst to the RDC for review after an IRB Co-Chair, a qualified designee, or the Lead IRB Analyst has approved the Certification of Exemption. The RDC does not conduct annual continuing reviews of IRB Exempt Projects.

(2) **Types of Reviews Conducted by the RDC:**

(a) Initial Reviews

i. The RDC 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 RDC coordinator will verify the appointment status, the Scope of Work (SoW) statement, and the training status of all study personnel prior to initial and continuing review by the RDC. 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.

(b) Continuing Reviews

i. The RDC coordinator will verify the appointment status, the SoW statement, and the training status of all study personnel prior to continuing review by the RDC. 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.

(c) Amendments

i. Amendments to approved research must be submitted to the RDC for approval prior to the initiation of the change. Minor changes to the project, such as personnel additions, data storage location changes, or grammatical and/or typographical changes, may be approved administratively by the RDC Coordinator. This acknowledgment must be reported to the full RDC and noted in the minutes.

(d) Reports of System Deficiencies and Research Information Security and Privacy Incidents.

i. Reports of system deficiencies and research information security and privacy incidents for studies under the oversight of the RDC must be submitted to the RDC for approval. Corrective action will be voted on by the RDC.

7. CONFLICT OF INTEREST IN RESEARCH

VA investigators and RDC 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 the RDC and subcommittees.

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.

All potential conflicts of interest identified by the OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement will be reviewed. If the FCOI Administrator determines there may be a conflict, it will be referred to Office of General Counsel (OGC) for further review. If OGC determines a conflict exists, they will draft a plan to manage the conflicts.

The FCOI Administrator will work with OGC and the conflicted researcher to determine the best course of action. The FCOI Administrator will then present the final OGC determination to the RDC.

8. REFERENCES

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

b. VHA Directive 1200.01 (Amended), Research and Development Committee, dated January 8, 2021

c. VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research, dated November 12, 2014

d. VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011

e. VHA Handbook 1200.08, Safety of Personnel Engaged in Research, dated March 6, 2009

f. Presentation and Publication of Research Results, SOP RES-010-RD, dated April 5, 2021

g. VAPORHCS IRB Policy & Procedures, dated June 1, 2020

h. VAPORHCS IACUC SOP, dated February 3, 2021

i. VAPORHCS SRS SOP, dated November 2, 2021

9. REVIEW

This SOP must be reviewed, at minimum, at recertification, when there are changes to the governing document, and any regulatory requirement for more frequent review.

10. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of March, 2027. In the event of contradiction with national policy, the national policy supersedes and controls.

11. SIGNATORY AUTHORITY

DAVID M COHEN 386526
Digitally signed by DAVID M COHEN 386526
Date: 2022.04.05 10:44:51 -07'00'

David Cohen, M.D.
Associate Chief of Staff, Research & Development Service
Date Approved: April 4, 2022

SAHANA MISRA
Digitally signed by SAHANA MISRA
Date: 2022.04.06 10:12:58 -07'00'

Sahana Misra, M.D.
Chief of Staff
Date Approved: April 4, 2022

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: SOPs are available at: http://www.portland.va.gov/research/R&D Forms.asp