RESEARCH AND DEVELOPMENT COMMITTEE OPERATING PROCEDURES

SOP RD-001

VA Northeast Ohio Healthcare System
Cleveland, OH 44106

Service Line(s):
Research

Signatory Authority:
Associate Chief of Staff/R&D

Effective Date:
February 11, 2022

Responsible Owner:
R&D Committee Coordinator

Recertification Date:
February 28, 2027

1. PURPOSE AND AUTHORITY

a. The purpose of this standard operating procedure (SOP) is to establish procedures for the Research and Development Committee. The Research and Development Committee (RDC) is responsible for ensuring the effective operation of the research program and making appropriate recommendations to the Medical Center Director based on the Committee's oversight and evaluation of the research program.

b. This SOP sets forth mandatory procedures and processes to ensure compliance with VHA Directive 1200.01, Research and Development Committee, dated January 24, 2019 (amended January 8, 2021).

2. PROCEDURES

a. **R&D Committee Meetings.** The RDC meets at least monthly; a quorum must be present at each meeting. On rare occasions, there may be a cancellation of a monthly meeting due to lack of quorum.

(1) **Meeting Materials.** Materials for an RDC meeting will be distributed to the RDC by the RDC Coordinator usually five business days prior to the respective meetings. For normally scheduled meetings, these materials will include an agenda and any materials requiring RDC review, such as: minutes (typically from the prior RDC meeting), any available minutes from the subcommittees for the preceding time span following the last RDC meeting, materials pertaining to RDC membership appointments, non-compliance issues, submissions requiring full board review, VA funding applications, and any relevant policy or continuing education materials.

(2) **Minutes.** Minutes for each meeting will be documented and disseminated to the facility leadership council. Minutes will include all required information as detailed in VHA Directive 1200.01.

(3) **RDC Member Conflict of Interest.** No regular or alternate voting member may participate in the review (initial, continuing, or modification) of any research project in which the member has a conflict of interest (COI), except to provide information as requested. It is the responsibility of each RDC member to disclose any COI in a study

submitted for review and recuse him/herself from the deliberations and vote by leaving the room. RDC members with a conflicting interest are excluded from being counted towards quorum. All recusals by members with COI are recorded in the minutes. Members who are assigned to review research in which they have a conflict of interest must notify the RDC Coordinator or other administrative staff so another reviewer can be assigned. Committee members are considered to have a conflict of interest when reviewing research if they are involved in the design and/or conduct of the research such that they are listed as research personnel on the protocol.

(4) **Emergency Meetings.** The RDC may hold unscheduled meetings in response to emergent issues. The Chairperson or Vice-Chairperson of the RDC in consultation with the ACOS/R&D, AO/R&D, or RDC Coordinator may initiate an emergency meeting due to unforeseen circumstances. Emergency RDC meetings must meet the following conditions:

(a) There must be a quorum present in person or by teleconference or video conference for any meeting (emergency or otherwise). Quorum must be present to conduct business and must be present for each vote.

(b) All members must be invited to this meeting and have received any materials to be reviewed.

(c) Minutes will be recorded in accordance with this SOP and any applicable VA handbooks, regulations, or directives.

b. **Annual Review of the Research Program.** In fulfilling the responsibility of the effective operation of the research program, the following items will be assessed/reviewed annually. These may include: Quality assurance activities, reports to the committee by the ACOS/R&D, AO/R&D, or other research staff members, subcommittee reports, facility reports or activities, and other appropriate sources.

(1) The RDC will perform a review of the Research Service. A summary of these reviews and evaluations will be sent to the medical center Director annually. This review will address the following aspects of the program:

(a) Planning and developing broad objectives for the research program so that it supports the VA's mission and determining the extent to which the research program has met its objectives.

(b) An annual review of the Research Safety and Security Program (including planned training, compliance, security issues, etc.), and Review of the Subcommittee of Research Safety.

(c) An annual review of The Animal Care and Use Program (including inspection reports, budgets, space, support staff, training, quality improvement activities, compliance issues, and goals for the next year), and review of the Institutional Animal Care and Use Committee (IACUC composition, IACUC arrangements).

(d) An annual review of the Human Research Protection Program (including credentialing and training status report, budget, space, support staff, quality improvement activities, compliance issues, and goals for the next year) and review of the Institutional Review Board (including IRB composition or IRB arrangements).

(e) Reviewing and evaluating all any committees that serve in lieu of VA committees, such as, but not limited to, VA Central IRB and commercial IRBs. Review of an external committee would focus on facility-specific aspects of these relationships, rather than the subcommittee itself. For example, evaluation of the number of projects handled by the committee, changes in MOUs or other agreements, change in processes, and challenges.

c. **RDC Membership.** R&D Committee members are appointed, in writing, by the VA medical facility Director. All RDC members must hold VA appointments (permanent, term, IPA, or WOC). The number, composition, and terms of voting members will meet requirements as detailed in VHA Directive 1200.01.

(1) **Ex Officio, Non-voting Members.** The following individuals are designated to attend R&D Committee meetings as ex officio, non-voting members as their attendance assists the R&D Committee in fulfilling its responsibilities: the medical facility Director, Chief of Staff, Administrative Officer for R&D, and Associate Chief of Staff for R&D. Their attendance is requested, but not mandatory.

(2) **Guests and Consultants.** Consultants or other guests may attend RDC Meetings at the discretion of the AO/R&D, ACOS/R&D, and/or RDC Chairperson. These guests may present materials and/or contribute to discussion – provided they have no conflict of interest regarding the topic at hand – but may not contribute to quorum or vote.

(3) **Election of Chairperson.** Voting members must elect a Chairperson every 2 years. The Chairperson must be approved and officially appointed, in writing, by the medical facility Director for a term of 2 years. The committee may also appoint a Vice Chair(s) to serve when the Chairperson is absent or has a conflict of interest that requires recusal.

(4) **Training Requirements.** The Chair and voting members of the R&D Committee will maintain training in the ethical principles of human research protection as required by VHA Directive 1200.01.

(5) **New Member Orientation.** Once the RDC voting member has been appointed by the medical center Director, the RDC Coordinator will initiate the orientation process. The following subjects and materials may be reviewed:

(a) VHA Directive 1200.01, Research and Development Committee

(b) VANEOHS research submission guidance, which details requirements for submitting new projects for review

(c) VAIRRS/IRBNet guidance, including overview of process for accessing meeting materials and completing reviews

(d) Reviewer Checklists

(6) **Continuing Education.** Training is continuous for RDC members and staff throughout their service on the RDC. Multiple avenues of educational opportunities are available locally and nationally, including, but not limited to:

(a) In-service and educational offerings at convened RDC meetings

(b) Research Service research forums

(c) Identification and dissemination by the ACOS/R&D, RDC Coordinator, RCO, or other administrative staff of new information that might affect the research program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to RDC members and staff via email or during RDC meetings.

(d) Opportunities to attend national and local human subject protection related conferences and seminars (PRIM&R, ORPP&E educational offerings, etc.)

d. **Research and Development Committee Review of Research.** All VA research except for any emergency use of a test article 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. Reviews by the R&D Committee must ensure relevance of the research to VA's mission and the care of Veterans, scientific merit of the research proposal, and other components as detailed in VHA Directive 1200.01. The R&D Committee has the authority to review research and approve the research, require modifications to obtain approval, or disapprove the research.

(1) **Initial Review.** The materials required for submission for all new (initial) protocols are outlined in the VANEOHS Research Submission Guidance, which can be found at https://www.clevelandvaresearch.org/research-submissions. New projects submitted for review at VANEOHS follow the process outlined below:

(a) Administrative Review. All new studies are initially submitted to the R&D Coordinator and R&D support staff for administrative review. This review ensures the basic submission requirements have been met prior to submission to the committee(s) for review. This includes, but not limited to, confirming the investigator has submitted a complete package and ensuring compliance with required research credentialing, education, and training. The administrative review process also allows a pre-review of any R&D Committee-related issues, such as the inclusion of non-Veterans, so problems may be addressed prior to forwarding the project to applicable committees for formal review. If applicable, the R&D administrative staff will correspond with the Principal Investigator about any necessary revisions or missing documents.

(b) Privacy and Information Security Reviews. The R&D Coordinator works directly with the Privacy Officer (PO) and Information System Security Officer (ISSO) at initial submission and throughout the initial review process to coordinate privacy and information security reviews, as applicable and as required by VHA policy. The R&D Coordinator meets regularly, typically weekly, with the PO, ISSO, and IRB administrative staff to facilitate PO and ISSO review of research. The R&D Committee must ensure ISSO and PO reviews have been completed as required by VHA policy before a study is given final approval. The R&D Committee can approve contingent on ISSO and PO review; once the review(s) are completed, final RDC approval can be provided via designated review.

(c) Exempt Determination. If the project meets criteria for exempt human subjects research, the investigator will submit a request for exemption with their study materials. Following administrative review, the project will be forwarded to the IRB Office for an exempt determination.

(d) Subcommittee or External Committee Review. Once the administrative review has been completed and any issues addressed, the project is forwarded to any applicable subcommittees, including IACUC, SRS, and IRB (internal or external), for formal committee review.

(e) R&D Committee Review. New projects are forwarded to the R&D Committee for review typically after any subcommittee or external committee reviews and/or exempt determinations have been completed, as applicable. The protocol and all applicable documents must be available for all members to review. A quorum must be present during the review and approval of the study unless a designated review is used.

(2) **R&D Committee Review of Research Overseen by a Subcommittee.**

(a) The R&D Committee may approve a protocol contingent on the protocol being approved by one or more subcommittees. 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 there were no major changes made by the subcommittee(s). Major changes would be those that affect funding, scientific merit, or inclusion of non-Veterans. 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.

(b) The R&D Committee must receive notice from the subcommittee that the research protocol has been approved. If any modifications requested by the R&D Committee would affect subcommittee review, the project will be sent back to the applicable subcommittee(s) for re-review.

(c) The R&D Committee may disapprove a study even if approved by all subcommittees, if the project does not meet the research review components as defined

in VHA Directive 1200.01, or other serious concerns as defined by the R&D Committee. However, the R&D Committee may not approve research that has been disapproved by an applicable subcommittee.

(d) After initial R&D Committee approval, the RDC does not need to review and approve continuing reviews or amendments, unless those amendments are requesting the inclusion of non-Veterans that was not previously approved. However, the R&D Committee should be provided sufficient documentation of continuing reviews and amendments in the subcommittee minutes that are provided to the R&D Committee.

(3) **R&D Committee Review of Research Overseen by an External IRB.**

(a) The R&D Committee will determine, and document in the RDC reviewer checklist, that the research:

1. Supports the VA mission and is relevant to the care of Veterans

2. Is scientifically meritorious

3. Ensures the security of VA Data and storage of data and specimens in accordance with all applicable requirements, as detailed in VHA Directive 1200.01.

(b) New studies being submitted to external IRBs should first be submitted to the VANEOHS R&D Coordinator for administrative review, prior to submission to the external committee. The R&D Coordinator or R&D support staff will conduct their administrative review, ensure all VA required elements of informed consent are present, and ensure initial any applicable PO and ISSO reviews are completed prior to submission to an external IRB. The R&D Coordinator will inform the study team when the administrative review is complete, and the project may be submitted to the external committee.

(c) The full protocol must be available for review by the R&D Committee. The R&D Committee should also receive a copy of the approval letter from the external IRB.

(d) After initial R&D Committee approval, the RDC does not need to review and approve continuing reviews or amendments, unless those amendments are requesting the inclusion of non-Veterans that was not previously approved. However, the R&D Committee should be provided sufficient documentation of continuing reviews and amendments in the committee minutes that are provided to the R&D Committee.

(4) **R&D Committee Review of Research as the Only Oversight Committee.**

(a) For protocols that require modification to obtain approval, the R&D Committee must communicate their action to the VA Investigator. Minor changes may be reviewed and approved by the Chair or a designated voting member of the R&D Committee and provided final approval via designated review. Minor changes are defined as changes that do not affect funding or scientific merit. The final approval must be noted in the

minutes of the next R&D Committee when reported to the full R&D Committee at its next convened meeting.

(b) Continuing Review. With the exception of exempt human subjects research studies, the RDC must conduct continuing reviews for studies under the sole oversight of the RDC according to VHA Directive 1200.01. For exempt research under sole RDC oversight, a project status update is required annually per local policy.

1. For studies requiring R&D Committee continuing review, the RDC must set the time frame for continuing review at initial study approval. The time frame may not exceed one year. If the VA research activity can be approved by a R&D Committee through a designated review process, such as exempt human subject research protocols and protocols approved by expedited review by the IRB, then continuing reviews may be done by designated review.

2. The local SOP "RD-003, Research and Development Committee Project Status Update and Continuing Review Procedures" provides full details on local requirements for RDC continuing review and project status updates.

(c) Review of Amendments. Amendments to approved research must be submitted to the R&D Committee for approval.

1. If the VA research activity can be approved by a R&D Committee through a designated review process, such as exempt human subject research protocols and protocols approved by expedited review by the IRB, the review and approval of amendments may be done by designated review. If the changes being requested would make the project ineligible for designated review, the amendment will be referred to the full R&D Committee for convened board review.

2. If the modifications or amendments being requested would change the research criteria such that the project would be under subcommittee oversight, the amendment request will be referred to the applicable subcommittee for review. For example, if an amendment to an exempt human subjects research study under sole R&D Committee oversight is requesting the addition of a procedure that would require IRB oversight, then the amendment request would be sent to the IRB for review and, if approved by the IRB, the project would transition to IRB oversight.

(d) **Convened Board Review**. For submissions being reviewed by the convened R&D Committee, the R&D Coordinator or R&D support staff will assign a primary reviewer based on their expertise and/or reviewer workload. The primary reviewer and all R&D Committee voting members will be provided access to the study materials prior to the meeting, typically 5 business days in advance. The primary reviewer will review the materials prior to the meeting, complete a reviewer checklist, and present a brief summary of the research, including any issues identified, as well as their recommendation, to the convened board during the meeting. The board will vote to approve the research, require modifications to obtain approval, or disapprove the research. If the board requires modifications to the research prior to approval, this will

be communicated to the investigator. The R&D approval date will be the date the convened board voted to approve the research. An R&D approval letter will then be generated, signed by the ACOS/R&D, and sent to the Principal Investigator.

(5) **Designated Review.** Research activities eligible for designated review, as detailed in VHA Directive 1200.01, may be approved by the R&D Committee Chair, or a voting member designated by the Chair, outside of a convened board meeting via the designated review process.

(a) When a research submission is eligible for designated review per VHA 1200.01, the RDC Coordinator or R&D support staff will assign one of the RDC voting or alternate voting members as a designated reviewer, based on their expertise and/or reviewer workload. All voting and alternate voting members of the RDC have been designated by the RDC Chair as eligible reviewers for conducting designated reviews. The RDC Coordinator may select the reviewer in consult with the RDC Chairperson, ACOS/R&D or AO/R&D.

(b) When designated review is taking place following contingent approval at a convened R&D Committee meeting, the reviewer must be presented with materials sufficient to review and make a decision based on the contingencies approved at the meeting. For example, if a study is approved contingent on Privacy Officer (PO) and/or Information System Security Officer (ISSO) approval, the reviewer should be presented with a copy of the completed PO and/or ISSO reviews. The reviewer does not need to re-review aspects of the study that were already reviewed and approved by the full committee unless changes were made.

(c) The reviewer will review the submission, complete a reviewer checklist, and indicate in their checklist whether the research submission is approved, deferred to return to the full R&D Committee, or not approved. If deferred or not approved, the reviewer must provide an explanation; this information will be communicated to the investigator. If the reviewer would like to request modifications to the study materials before approval, the reviewer should communicate directly with the investigator (and include the R&D Coordinator on all correspondence). The R&D Coordinator must receive final copies of all revised documents. The date of approval is the date of final approval by the designated reviewer once all changes have been made. All designated reviews will be reported to the R&D Committee in the next agenda and minutes.

(d) The R&D approval date will be the date the designated review checklist was signed and marked approved by the reviewer. An R&D approval letter will then be generated, signed by the ACOS/R&D, and sent to the Principal Investigator.

e. **Research and Development Committee Records.** Adequate documentation of the activities of the R&D Committee will be maintained according to the requirements detailed in VHA Directive 1200.01.

f. **Participation of Non-Veterans as Research Subjects.** Non-Veterans may be entered into a VA-approved research study according to the guidelines documented in

VHA Directive 1200.01. The R&D Committee is responsible for reviewing and approving the inclusion of non-Veterans in VA research. This approval will be documented in writing to the investigator. If the VA research activity can be approved by a R&D Committee through a designated review process, such as exempt human subject research protocols and protocols approved by expedited review by the IRB, the review and approval of non-Veterans may be done by designated review.

3. REFERENCES

a. VHA Directive 1200.01, Research and Development Committee, dated January 24, 2019 (amended January 8, 2021).

b. RD-003, Research and Development Committee Project Status Update and Continuing Review Procedures, dated April 1, 2021, available at https://www.clevelandvaresearch.org/research-sops.

4. REVIEW

Review is required at minimum at recertification. This review is documented on the VAIRRS/IRBNet site (see https://gov.irbnet.org/release/index.html)

5. RECERTIFICATION

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

6. SIGNATORY AUTHORITY

Neal Peachey 411157

Digitally signed by Neal Peachey 411157
Date: 2022.02.11 09:15:30 -05'00'

Neal Peachey, PhD
Associate Chief of Staff/R&D
Date Approved: February 11, 2022

DISTRIBUTION: SOPs are available at: https://www.clevelandvaresearch.org/research-sops