SUBJECT: Research & Development Committee

1. **PURPOSE:**
   
   To define the responsibilities and operations of the Minneapolis VA Health Care System's Research and Development Committee.

2. **DEFINITIONS:**
   
   - **ACOS/R:** Associate Chief of Staff for Research
   - **CI:** Continuous Improvement
   - **CIRB:** Central Institutional Review Board
   - **COS:** Chief of Staff
   - **HRPP:** Human Research Protection Program
   - **IACUC:** Institutional Animal Care and Use Committee
   - **IBC:** Institutional Biosafety Committee
   - **IPA:** Intergovernmental Personnel Agreement
   - **IRB:** Institutional Review Board
   - **ISO:** Information Security Officer
   - **MCD:** Medical Center Director
   - **MVAHCS:** Minneapolis VA Health Care System
   - **PO:** Privacy Officer
   - **R&D:** Research and Development
   - **RDC:** Research and Development Committee
   - **SOP:** Standard Operating Procedure
   - **SRS:** Subcommittee on Research Safety
   - **VA:** Veterans Affairs
   - **VHA:** Veterans Health Administration
   - **VMU:** Veterinary Medical Unit
   - **WOC:** Without Compensation Employee

3. **OVERVIEW:**

   **Research** is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. It is a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalized knowledge.

   **Veterans Affairs (VA) research** is research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the Research and Development Committee (RDC) before it is considered VA research and before it can be initiated.

   The Minneapolis VA Health Care System (MVAHCS) RDC is responsible through the Chief of Staff (COS) to the Medical Center Director (MCD) for maintaining the highest ethical and scientific standards throughout the facility's research and development program.

   The Research and Development (R&D) program is focused on advancing Veterans' health and health care by assuring scientific excellence; the ethical conduct of research; protection of human
subjects; the welfare of laboratory animals; the safety of those involved in the research program; and the security of research laboratories, other research resources, and research data.

The MCD is the Institutional Official responsible for all aspects of the research program. The MCD appoints members of the RDC and its subcommittees. The MCD is responsible for suspending or terminating research when concerns about research conduct are raised and/or substantiated. The MCD delegates the authority to administer the R&D program to the Associate Chief of Staff for Research (ACOS/R), who reports to the COS. The RDC advises the MCD through the COS on professional and administrative aspects of the R&D program.

The RDC acts as the local committee charged with oversight of all R&D activities within a facility and is responsible for maintaining high standards throughout the R&D program. It serves as the oversight committee to subcommittees. The RDC assigns responsibility to provide scientific review, and some administrative responsibilities, to the appropriate subcommittees and individuals. All R&D activities within the facility, whether funded or unfunded, are within its purview. Research may not be initiated at MVAHCS until the investigator has received an Authorization to Conduct Research memo signed by the ACOS/R. This memo is generated following the notification of the ACOS/R of final RDC approval. The memo from the ACOS/R documents project approval by all relevant subcommittees or other entities and the RDC.

The RDC accomplishes its responsibilities through the following activities and procedures:

- Planning and developing research program objectives to ensure that the program supports the Veterans Health Administration (VHA) missions.
- Determining the extent to which the research program has met its objectives.
- Overseeing all research activities at MVAHCS.
- Reviewing all written agreements that define areas of jurisdiction between the RDC/subcommittees and other institutions.
- Annually reviewing the activities of all subcommittees and ensuring that they are providing substantive review of studies under their oversight. The minimal components of a substantive review are described in Section 5.
- Providing direct oversight of research studies that do not fall under the purview of any of the subcommittees (see section 5).

In fulfilling its responsibilities of ensuring effective oversight and making appropriate recommendations to the MCD, the RDC relies on information from a variety of sources including strategic planning meetings and retreats, investigator and staff focus groups, continuous improvement (CI) activities and reports, annual reviews, meeting minutes and reports of the subcommittees, regular reports from other advisory groups and individuals (e.g. MVAHCS’ Privacy Officer, Information Security Officer, Research Compliance Officers), and other sources.

The RDC may also fulfill other functions as assigned by the MCD.

4. PROCEDURES:

The RDC is assisted in fulfilling its roles and responsibilities through the actions of its subcommittees. The subcommittees established by the RDC include: the MVAHCS Institutional Review Board (IRB), the VA Central Institutional Review Board (CIRB), the Institutional Animal Care and Use Committee (IACUC), and the Subcommittee on Research Safety (SRS).
a) Research and Development Committee:

It is the responsibility of the RDC to:

i) Review and vote to approve or disapprove all subcommittee minutes and initial approvals.
   
   (1) Approval of all initial reviews must take place after final (not contingent) subcommittee approval.
   
   (2) Such approval must be communicated to the RDC via documentation of subcommittee review and non-contingent approval.
   
   (3) To ensure adequacy of each subcommittee’s review procedures, the RDC must approve Standard Operating Procedures (SOPs) from all subcommittees.

ii) Establish a Conflict of Interest Committee charged with review of Financial Conflict of Interest statements submitted by VA investigators.

iii) Annually review and vote to approve or disapprove the Subcommittee on Research Safety’s (SRS) safety manual.

iv) Annually conduct a review and evaluation of each subcommittee, in addition to the monthly review of meeting minutes and other reports.
   
   (1) Annually provide a checklist containing all required elements for annual reviews as described in Guidance for R&D Committee Annual Reviews and Evaluations of Subcommittees and Research Programs (June 17, 2011) to each subcommittee to facilitate the adequate evaluation.

v) Ensure that copies of RDC meeting minutes and subcommittee meeting minutes are sent to the MCD and COS for their review and appropriate action.

vi) Evaluate requests to include non-Veterans as research subjects. VHA Directive 1200.01 §13 describes requirements for enrolling non-Veterans in VA research. The RDC will evaluate inclusion of non-Veterans either before IRB approval (for studies involving greater risk to participants) or after IRB approval (for studies that generally pose lower risk). Specifically:

(1) Studies requiring RDC pre-review: Any human study involving outpatient care for research purposes (1200.01 §13.a [1]) or hospital care for research purposes (1200.01 §13.a [2]) will be identified during IRB pre-review, then sent for RDC pre-review of non-Veteran recruitment, which will occur during a fully convened meeting. Following RDC pre-review, the proposal would proceed with applicable IRB review and then return for RDC review.

(2) Studies that would not require RDC pre-review: Any human study that benefits Veterans or Veterans well-being, but would not include Veterans as subjects, such as surveys of VA providers or studies involving Veterans’ family members (1200.01 §13.b) or studies involving National Guard or active duty military personnel (1200.01 §13.c) will be identified during IRB prereview and may move forward with applicable IRB review. The proposal would proceed to all other applicable subcommittees before being reviewed by RDC via either designated review or a fully convened meeting, as appropriate. The RDC review must include evaluation of the inclusion of non-Veterans as research subjects.
(3) Following RDC review, all projects including non-Veterans must acknowledge the approval of non-Veterans in the final RDC approval memo.

b) MVAHCS Institutional Review Board (IRB) and Central Institutional Review Boards (CIRBs):
The MVAHCS Human Research Protection Program (HRPP) is charged with the oversight of all research activities involving the use of human subjects. The HRPP includes the Minneapolis VA Health Care System Institutional Review Board (MVAHCS IRB) and each Central Institutional Review Board (CIRB) with which MVAHCS holds a reliance agreement, collectively referred to as the IRBs.

i) It is the responsibility of the IRBs to:

(1) Perform initial and continuing reviews, as well as approve changes/amendments to all human research protocols and monitor adverse and unanticipated events.

(2) Perform all functions required under 38 CFR 16 (Common Rule) and ensure adherence to all applicable regulations and policies including VHA Directive 1200.05. The HRPP SOPs provide detailed information regarding IRB/CIRB policies and procedures relating to this charged duty.

ii) RDC Oversight: The RDC maintains oversight of the HRPP and the IRBs through review and approval of IRB and CIRB minutes, regular updates from the HRPP Administrator (ex officio non-voting member of the RDC), other frequent communications with HRPP and IRB staff, and the formal annual review of the HRPP program.

c) Institutional Animal Care and Use Committee (IACUC):
The MVAHCS IACUC is the local committee charged with ensuring compliance with animal research regulations and guidelines.

i) IACUC responsibilities include:

(1) Initial and continuing review as well as approval of changes/amendments to all animal research protocols at the MVAHCS.

(2) Assuring continued accreditation of the animal subjects research program.

(3) Conducting a twice annual evaluation of the animal research facility to identify deficiencies related to animal welfare laws, regulations, or policy. The IACUC will take appropriate actions to correct deficiencies identified during this evaluation and report findings and corrective measures taken to the RDC, the MCD, and accrediting agencies.

ii) RDC Oversight: The RDC maintains oversight of the IACUC through review and approval of IACUC minutes, regular updates from the institution's Veterinary Medical Officer (voting member of the RDC), other frequent communications from the IACUC Chair and Veterinary Medical Officer, and formal annual review of the IACUC program.

d) Subcommittee on Research Safety (SRS):
The Subcommittee on Research Safety, and the Institutional Biosafety Committee (IBC), a subcommittee of the SRS, are collectively responsible for evaluation of chemical, biological, radiological, and physical hazards to employees and the facility.

i) The MVAHCS SRS is charged with:
(1) Oversight of the control of hazardous agents in MVAHCS research laboratories to ensure compliance with all applicable rules and regulations.

(2) Oversight of the safety of personnel involved in research including ensuring compliance with all applicable rules and regulations.

(3) Reviewing and voting to approve or disapprove initial reviews, continuing reviews, and protocol amendments for all research protocols under the primary oversight of the IACUC or the HRPP that involve hazardous agents or other safety concerns.

(4) Reviewing and voting to approve or disapprove initial reviews, continuing reviews, and amendments for all protocols for which SRS is the subcommittee of record (“lab-only” studies).

(5) Coordination of all safety-related activities including safety training, safety inspections, accident reporting, and liaison activities with facility safety committees and officials.

(6) Annually updating the Research Service Red Safety Manual which provides detailed SOPs relating to safety issues and the conduct of research, and submission of this manual to the RDC for annual review and approval.

ii) The Institutional Biosafety Committee (IBC), a sub-committee of SRS, is registered with the NIH to review recombinant DNA research at the MVAHCS.

(1) The IBC assesses the safety of recombinant DNA studies, and identifies and mitigates any potential risk to public health or the environments.

(2) Studies requiring IBC review must receive IBC approval before final SRS approval is granted.

iii) RDC Oversight: The RDC maintains oversight of the SRS and IBC through review and approval of SRS minutes, regular updates from the SRS Chair (ex officio non-voting member of the RDC), other frequent communications from the SRS Chair, and formal annual review of the SRS program.

5. **RDC-ONLY STUDIES:**

All research conducted at the MVAHCS must be under the oversight of either the RDC or one of its subcommittees. RDC-only studies are studies that do not meet criteria for assignment to any VA Research and Development subcommittee (i.e. IRB/CIRB, IACUC, or SRS). Types of studies that might be under RDC-oversight-only include:

- Research conducted wholly or in part at MVAHCS in which the activities at MVAHCS have been evaluated and determined to not be human subjects research or to be IRB exempt.

- Research under the oversight of a committee at the University of Minnesota (e.g. IRB, IACUC and/or biosafety) that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments), on VA property, and/or while on VA time.

- A funded research infrastructure support entity (e.g. Center for Care Delivery Outcomes Research, Cooperative Studies Program, Network of Dedicated Enrollment Sites).

- Other protocols that do not meet criteria for assignment to any VA research subcommittee.
• Studies no longer under the purview of a subcommittee but still open for data analysis and/or manuscript preparation.

**Exception:** Systematic reviews conducted under the auspices of the VA Evidence-Based Synthesis Program. These do not require RDC oversight since they are funded with clinical dollars and are developed primarily for the use of VA operational and clinical partners.

a) **Overview of Review Requirements:** Review of both initial and continuing RDC-only protocols must be substantive. To conduct a substantive review, reviewers should consider the following:

- Is this research? Is this VA research? (see section 3 above for definitions)
- Are the research procedures consistent with sound scientific research design principles?
- Is the research relevant to the mission of the VA and the VA population?
- Have mechanisms been implemented to ensure that potential conflicts of interest are managed?
- For continuing reviews and amendments, have any changes to the protocol been made? If there are changes, have they been approved by the RDC? Are the changes of sufficient magnitude to require additional subcommittee oversight?

b) **Initial Review:** For all new RDC-only studies, the RDC coordinator will ascertain the status of the PI to make sure he/she is eligible to conduct research in VA. To be included on the RDC agenda, the protocol and a completed application must be submitted to the RDC coordinator at least 2 weeks prior to a regularly scheduled RDC meeting.

The RDC coordinator will assign each study to a primary reviewer to review the scientific soundness of the application and to ensure the appropriateness of the project for RDC-only review. The primary reviewer will communicate any concerns to the investigator through the RDC Coordinator. Any modifications made by the investigator will be relayed back to the primary reviewer.

A designated member review process may be assigned for projects that fall into one of the following categories:

1. Minor changes to a protocol required by the R&D Committee, following full board review;
2. Initial approval of protocols approved contingent on the full approval of a subcommittee, provided the RDC verifies that final approval of the subcommittee did not require substantive change to the proposal reviewed by the RDC;
3. Initial approval for protocols approved contingent upon completion of the PO and ISSO review;
4. Initial approval of exempt human subject research protocols and protocols approved by expedited review by the IRBs;
5. Initial approval of protocols that do not involve human subjects, biosafety level (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.
For studies in the above categories, the RDC Chair or a voting member designated by the Chair may conduct an initial review outside of a convened meeting. All other proposals will be reviewed in a convened meeting at which a full quorum is present.

The RDC coordinator will make the project application and any supporting materials available for review to the entire committee approximately one week prior to each convened meeting. If the new study is reviewed at a convened meeting, a quorum must be present during the review and approval. At that meeting the RDC will review the preliminary determination that the protocol meets criteria for an RDC-only project and if it does, the study will be discussed and voted upon. If not, it will be referred to the appropriate subcommittee(s) for review.

The RDC Minutes will include the name of the primary or designated member reviewer.

c) **Continuing Review:** Studies that are under RDC-only oversight will be requested to submit continuing review forms on an 11-month cycle. The RDC committee approval expires 365 days after the previous approval. Studies must receive review within this timeframe.

- Continuing reviews will be reviewed as outlined above (Section 5b).
- The RDC coordinator will send two reminders to investigators requesting the materials required for continuing review including a link to the materials. The reminders will be sent approximately 8 weeks prior to the due date for the continuing review and then again at approximately 4 weeks.
- The due date will be 1 week prior to the RDC meeting scheduled the month prior to the expiration of the study’s RDC approval.
- If the continuing review is not received 1 week prior to the due date, the RDC chair will send a notice to the investigator stating that if the continuing review is not submitted by the due date, the study will not be reviewed at the next RDC meeting.
- If the continuing review documents are not received by the due date and the study is not reviewed, then the RDC chair will send a second notice to the investigator after the RDC meeting indicating that approval to conduct research has expired, and all research activities associated with the study (data collection, data analysis, etc.) must stop. An expiration of RDC approval is not considered a suspension or termination.

(1) Activities that occur without a current RDC review are considered non-compliant. For example, data collected during a lapse in RDC approval cannot be described (e.g., in a publication) as being part of an RDC-approved study.

(2) Retroactive approval for work done after the expiration of RDC approval will not be granted. If the investigator wishes to terminate the study, closure documents must be submitted to the RDC.

(3) If the investigator wishes to resume work on the study, the continuing review documents must be submitted to the RDC for consideration and approval at the next scheduled RDC meeting. Even if the continuing review materials have been submitted to the RDC, all activities must stop until RDC re-approval is granted for the study.

d) **Amendments:** Amendment requests must be submitted for proposed changes to the study protocol and be approved by the RDC.

i) Amendments consisting solely of an addition or removal of personnel may be administratively processed by the RDC Coordinator.
6. **RDC MEMBERSHIP:**

The membership of the MVAHCS RDC, supplemented as needed by advisors or consultants, will reflect the types and amounts of research being conducted at the MVAHCS. New RDC members are nominated by the ACOS/R, current RDC members, subcommittee members and/or the facility’s staff, and appointed by the Medical Center Director. Ideally RDC membership will include at least one representative from each of the RDC subcommittees, from each of the major MVAHCS Research Centers (e.g. Center for Chronic Disease Outcomes Research [CCDOR], Geriatrics Research, Education, and Clinical Center [GRECC], Brain Sciences Center), from the investigational pharmacy or Pharmacy Service, and from the Veterinary Medical Unit.

**a) Voting Members**

- The RDC must consist of at least five voting members with a diversity of demographics and expertise
- All voting members must hold a valid VA status (VA-paid employee, WOC, or IPA).
- Voting members must be appointed by the MCD.
- Voting members must include:
  1. At least two members from the MVAHCS staff with major patient care or management responsibilities.
  2. At least two members who are VA investigators actively engaged in R&D programs or who can provide R&D expertise.
  3. At least one member who holds an academic appointment at the MVAHCS’s affiliated institution, University of Minnesota
  4. A voting member may fill more than one criterion for required membership (e.g. the member may have both patient care responsibilities and be actively engaged in R&D programs)

**b) Ex-Officio Non-Voting Members**

Ex-Officio non-voting members include the:

1. Medical Center Director (MCD)
2. Chief of Staff (COS)
3. Associate Chief of Staff, Research & Development (ACOS/R)
4. Deputy ACOS/R
5. Administrative Officer, Research & Development (AO/R)
6. Information Security Officer
7. Privacy Officer
8. IRB Administrator
9. SRS Chair

The ACOS/R serves as Executive Secretary of the Committee. Other ex-officio members may be appointed to the RDC if their expertise will assist the RDC in fulfilling its responsibilities.
c) **Election of Chair**

- Committee members, exclusive of ex officio members, must elect a Chairperson every 2 years.
- The Chairperson must be approved and officially appointed, in writing, by the MCD for a term of 2 years.
- The Chairperson may be reappointed without any lapse in time.
- The Chairperson may not simultaneously chair a subcommittee of the RDC.

d) **Terms of Appointment**

Voting members serve terms of 3 years, and may be reappointed without any lapse in time if it is deemed in the Committee's best interest. The terms shall be staggered to provide partial change in membership annually.

e) **Consultant(s)**

1) Research Compliance Officer(s)

f) **Alternate RDC Members**

Alternates must be appointed by the MCD. Alternate members must identify the primary member(s) for whom they may substitute. Alternates may only vote in the absence of the primary member.

g) **Ad Hoc Reviewers**

The RDC may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the committee. Such ad hoc members may not vote with the committee.

7. **TRAINING OF RDC CHAIR AND MEMBERS:**

Committee members should be up to date with CITI human subjects training. MVAHCS may also require other training. Members will receive updated versions of the RDC SOP as they are issued. The ACOS/R may provide further guidance and training as needed.

8. **MANAGEMENT OF CONFLICT OF INTEREST:**

In order to maintain public trust in the VA and safeguard the integrity and quality of VA research, RDC members and VA investigators must comply with the Standard of Ethical Conduct of Executive Branch Employees and the Federal criminal code. RDC members and VA investigators must comply with VA requirements on potential financial conflicts of interest in research. Penalties and disciplinary action can result if the ethics regulations are violated.

RDC members with outside consulting, employment, or royalty payments must ensure that these activities do not present any actual or perceived financial conflict of interest and must recuse themselves from RDC activities including relevant discussions and votes for which any conflict of interest may exist.

Voting members of the RDC must recuse themselves if the item before the committee presents a potential conflict of interest. When this occurs, the following information will be recorded in the minutes:
9. **RDC MEETINGS:**

The Research and Development Committee will meet at least once monthly. A quorum must be present to conduct business. If a quorum of members cannot be physically present at the meeting, members may participate through teleconference/videoconference.

The RDC may hold unscheduled meetings at the discretion of the chair in response to emergent issues. A quorum must be present for the meeting, whether in person or by teleconference or video conference.

a) **Agenda**

An agenda will be developed before each meeting of the RDC and distributed to members at least 3 working days before the meeting whenever possible.

b) **Minutes**

- Minutes will be recorded and maintained for each RDC meeting.
- The minutes will document the presence of a quorum, and the attendance or absence of voting and non-voting members, including ex officio members and consultants, indicating the category of their membership. If an alternate member is present in place of a voting member, the minutes will indicate this fact and identify who the alternate is replacing.
- The minutes will provide a complete record of all items of business brought before the Committee and the action taken. All actions taken by the Committee will be recorded in the minutes.
- The minutes of the meeting will be reviewed by and signed by the Chairperson, Executive Secretary (ACOS/R), Medical Center Director and Chief of Staff.
- Minutes will be maintained by the Research Office.

c) **Voting Procedures**

- Votes by the Committee shall be recorded by the RDC coordinator. The members present for each vote will be recorded in the minutes.
- Voting categories and definitions are as follows:
  - Yes ....................................... Approve
  - No ........................................ Disapprove
  - Abstain............................... Decline to vote either for or against
  - Defer ................................... Delay vote until the reason for deferral is resolved
  - Table ................................. Delay vote indefinitely
  - Recuse ................................. Does not vote because of conflict of interest
- If a voting member must recuse, then the member will announce the recusal and leave the room during the vote. Members who recuse themselves will be identified in the minutes.
as a recusal and as having left the room. The recusing member may not be counted toward the quorum.

- Voting tabulations will be recorded in the meeting minutes.

d) Procedures for Tracking Outstanding Business Items

For every RDC meeting, the agenda will include a line item for outstanding business. The meeting documents will include a list of unresolved business items requiring RDC action as well as a list of those items which have been resolved in the prior month. The information relating to outstanding business and the effort by the RDC to resolve those items will be reflected in the minutes.

e) Records

The RDC coordinator will use an electronic protocol management system to maintain the minutes of the RDC, subcommittee minutes, annual reports from subcommittees, written correspondence, membership attendance rosters, and voting totals for the RDC and all subcommittees.

The RDC records will include documentation of initial and continuing reviews as well as changes/amendments for protocols that do not require review by any of the subcommittees (i.e. RDC-only studies).

RDC records will be archived as directed by National Archives and Records Administration Request for Records Disposition Authority DAA-0015-2015-0004. Protocols approved by the RDC will be kept for 6 fiscal years, and disapproved protocols or those withdrawn by the investigator will be retained for 3 fiscal years. Files related to the ongoing operations of the RDC will be kept for 3 fiscal years (implementation records, including SOPs, policies, agreements with non-VA review committees, committee/subcommittee assessments and compliance) or 6 fiscal years (RDC records, including membership rosters, appointment letters, CVs, training records, meeting minutes and related documentation).

10. APPENDICES:

Research Protocol Review Process at the Minneapolis VA
Research Study Approval Flow Chart at the Minneapolis VA (process diagram)

11. REFERENCES:

VHA Directive 1200 “Research and Development Program” (13 May 2016)
VHA Directive 1200.01 “Research and Development Committee” (24 January 2019)
VHA Directive 1200.05 “Requirements for the Protection of Human Subjects in Research” (07 January 2019)
VHA Handbook 1200.07 “Use of Animals in Research” (23 November 2011)
12. **R&D COMMITTEE APPROVAL:** 03 December 2019

13. **RECISSIONS:** Minneapolis Research Service SOP R&D-001 “Research & Development Committee” (01 October 2019).

14. **EXPIRATION DATE:** N/A

15. **FOLLOW-UP RESPONSIBILITY:** Research and Development (R&D) Committee