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
MVAHCS—Minneapolis VA Health Care System
RDC—Research and Development Committee
MCD—Medical Center Director
ACOS/R—Associate Chief of Staff for Research
R&D—Research and Development
VHA—Veterans Health Administration
CI—Continuous Improvement
COS—Chief of Staff
IRB—Institutional Review Board
IACUC—Institutional Animal Care and Use Committee
SRS—Subcommittee on Research Safety
RIPS—Research Information Protection Subcommittee
IBC—Institutional Biosafety Committee
WOC—Without Compensation
IPA—Intergovernmental Personnel Act
HRPP—Human Research Protection Program
VMU—Veterinary Medical Unit
PO—Privacy Officer
ISO—Information Security Officer

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. VHA Directive 1200 §5.mm.

VA Research is research conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded. VHA Handbook 1200.01 §3.b.

The Minneapolis VA Health Care System (MVAHCS) Research and Development Committee (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 scope of the roles and responsibilities of the RDC includes assuring the scientific quality of research projects, protection of human rights in research, safety of personnel engaged in research, animal welfare, and the security of research data and research areas as outlined in VHA Handbook 1200.01.

The MCD is the institutional official responsible for all aspects of the research program. 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 governing body of the Research Service at MVAHCS and serves as the oversight committee to all of its subcommittees. The RDC assigns scientific review and some administrative responsibilities, including research compliance 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 the MVAHCS until the investigator has received an Authorization to Conduct Research memo signed by the ACOS/R. This memo indicates that the project has been approved by the RDC and/or all relevant subcommittees or other entities.

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

- Planning and developing research program objectives to ensure that the program supports VHA’s missions
- Determining the extent to which the research program has met its objectives
- Overseeing all research activities at the 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 listed below, Section 5.
- Providing direct oversight to research studies that do not fall under the purview of any of the subcommittees (see below 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 & staff focus groups, CI activities & reports, annual reviews & reports of the subcommittees, regular reports from other advisory groups and individuals (eg MVAHCS’ Privacy Officer, Information Security Officer, Research Compliance Officers) and other sources.

The RDC also fulfills other functions as assigned by the MCD.

4. RDC SUBCOMMITTEES
The RDC is assisted in fulfilling its roles and responsibilities through the actions of its subcommittees. The subcommittees established by the RDC include: the Institutional Review Boards (IRB), the Institutional Animal Care and Use Committee (IACUC) and the Subcommittee on Research Safety (SRS).

The RDC:

- Reviews and votes to approve or disapprove all sub-committee minutes and initial approvals. Approval of all initial reviews must take place after final (not contingent) subcommittee approval. Such approval must be communicated to the RDC via written notification signed by at least one voting member of the sub-committee.
- Reviews and votes to approve or disapprove the Subcommittee on Research Safety’s (SRS) safety manual annually.
- Is not required to approve SOPs from either the Human Research Protection Program or the Institutional Animal Care and Use Committee.
- Ensures that copies of the RDC meeting minutes and subcommittee meeting minutes are sent to the MCD and COS for their review and appropriate action.

a. Human Research Protection Program (HRPP)
The MVAHCS HRPP is charged with the oversight of all research activities involving the use of human subjects. The HRPP empanels one or more Institutional Review Boards (IRBs) to perform initial and
continuing reviews, as well as approve changes/amendments to all human research protocols and monitor adverse and unanticipated events. The IRBs must perform all functions required under 38 CFR 16 (Common Rule) and ensure adherence to all applicable regulations and policies including VHA Handbook 1200.05. In addition, the IRBs must maintain accreditation as required by VHA regulations (VHA Handbook 1200.05). The HRPP SOPs provide detailed information regarding the policies and procedures relating to the MVAHCS Human Research Protection Program.

The RDC maintains oversight of the HRPP and the IRBs through review and approval of IRB 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.

b. Institutional Animal Care and Use Committee (IACUC)
The MVAHCS IACUC is charged with the oversight of all research activities involving the use of animal subjects in accordance with all applicable rules and regulations including those in VHA Handbook 1200.07. This includes initial and continuing review as well as changes/amendments to all animal research protocols at the MVAHCS. In addition, the IACUC assures accreditation of the animal research program. The IACUC also evaluates the animal research facility twice annually to identify deficiencies related to animal welfare laws, regulations or policy. The IACUC will take appropriate actions to correct deficiencies determined in this evaluation and reports on findings and corrective measures taken to the RDC and the MCD.

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.

c. Subcommittee on Research Safety (SRS)
The MVAHCS SRS is charged with:
- The oversight of the control of hazardous agents in MVAHCS research laboratories to ensure compliance with all applicable rules and regulations including those in VHA Handbook 1200.06.
- The oversight of the safety of personnel involved in research including ensuring compliance with all applicable rules and regulations including those in VHA Handbook 1200.08.
- Reviewing and voting to approve or disapprove initial reviews for all research protocols under the primary oversight of the IACUC or the HRPP that involve hazardous agents or other safety concerns.
- Reviewing and voting to approve or disapprove initial protocols for which SRS is the subcommittee of record (“lab-only” studies).
- Coordination of all safety-related activities including safety training, safety inspections, accident reporting, and liaison activities with facility safety committees and officials.

The SRS annually updates the Research Service Red Safety Manual which provides detailed SOPs relating to safety issues and the conduct of research. The RDC will review and vote on the Research Service Red Safety Manual annually.

The RDC maintains oversight of the SRS 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.
The Institutional Biosafety Committee (IBC), a sub-committee of SRS, is registered with the NIH to review recombinant DNA research at the MVAHCS. The IBC assesses the safety of rDNA studies and identifies and mitigates any potential risk to public health or the environments.

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. Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or Subcommittee on Research Safety (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 includes use of VA resources such as investigator time or office space.
- A funded research infrastructure support entity (e.g. Center for Chronic Disease 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 IACUC or SRS 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 (e.g. VA Center for Health Promotion and Disease Prevention).

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, 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?

The RDC may only vote to approve, disapprove or defer. Contingent approvals are not allowed.

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 R&D Review of Research Project form (Appendix 10) 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 (an RDC member who will be present at the next meeting) to review to ensure 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.
In addition, the RDC coordinator will make these materials available to the entire committee approximately one week prior to the meeting. 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 on. If not, it will be referred to the appropriate subcommittee(s) for review.

The RDC Minutes will include the name of the primary reviewer.

c. Continuing Review Studies that are under RDC-oversight-only must submit continuing review forms on an 11 month cycle. The Authorization to Conduct Research expires 12 months after the previous approval.

- Continuing reviews will be reviewed as outlined above (Section 5b) for initial reviews.
- 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 about 8 weeks prior to the due date for the continuing review and then again at about 4 weeks.
- The due date is defined as 1 week prior to the RDC meeting scheduled the month before the expiration of the study’s ACR.
- If the continuing review is not received 1 weeks prior to the due date, then the RDC chair will send a notice to the investigator stating that if the continuing review is not submitted by the due date, then 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 that the ACR has lapsed, 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.
  - Activities that occur without a current RDC approval 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.
  - Retroactive approval for work done after the lapse of an ACR will not be granted. If the investigator wishes to terminate the study, then closure documents must be submitted to the RDC.
  - If the investigator wishes to resume work on the study, then 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 convened RDC. (A copy of the current Amendment Request Form is in the Appendix)

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 facility. New RDC members are nominated by the ACOS/R, current RDC members, subcommittee members and/or the facility’s staff. 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. Health Services Research Center of Innovation, Geriatrics Research, Education and Clinical Center, 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 be compensated full-time or permanent part-time Federal employees
- Voting members must be appointed by the MCD.
- Voting members must include:
  - At least two members from the facility’s staff with major patient care or management responsibilities.
  - At least two members who are VA investigators actively engaged in R&D programs or who can provide R&D expertise.
  - At least one member who holds an academic appointment at the MVHCS’s affiliated institution, University of Minnesota.
  - 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. Administrative Officer, Research & Development (AO/R)
5. Information Security Officer
6. Privacy Officer
7. IRB Administrator
8. 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. Membership Requirements (all but ex-officio members):
All voting members must be compensated full-time or part-time Federal government employees. 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)
- Research Compliance Officer(s)

f. Alternate RDC Members
Alternates may be appointed by the MCD. Alternate members may only vote if they are representing an absent member, at the request of the RDC chair.

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. The applicable laws and regulation also apply to WOC and IPA employees conducting VA research or participating on an RDC. 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:
- Name of the member
- Subject of the vote
- Whether or not the member remained in the room during the discussion or vote.

9. RDC MEETINGS
The Research and Development Committee will meet at least monthly except for 1 month during the year, if it appears that a quorum (i.e. a majority of voting members) cannot be obtained. 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 R&D Committee 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 R&D Committee and distributed to members at least 3 working days before the meeting whenever possible.

b. Minutes
- Minutes will be recorded and maintained for each meeting of the R&D Committee.
- 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, including
the number voting for, against, or abstaining. Members who recuse themselves from the vote will be identified and the minutes will document whether the member was present for the discussion. If the member is recused, the member must not be present for the vote and may not be counted toward the quorum.

- 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. Records
The RDC coordinator will maintain paper and/or electronic copies of the minutes of the R&D Committee and the subcommittees, annual reports from all subcommittees, all written correspondence, and membership rosters for the R&D Committee 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 (DAA-0015-2015-0004 § 7.7.1), and disapproved protocols or those withdrawn by the investigator will be retained for 3 fiscal years (DAA-0015-2015-0004 § 7.7.2). 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, as defined in DAA-0015-2015-0004 § 7.8.1) or 6 fiscal years (RDC records, including membership rosters, appointment letters, CVs, training records, meeting minutes and related documentation, as defined in DAA-0015-2015-0004 § 7.8.2).

10. APPENDICES

A. RDC Review forms
   RDC Review of Research Project Form
   RDC Amendment Form

B. Oversight Committee Assignment
   Research Protocol Review Process at the Minneapolis VA
   Research Study Approval Flow Chart at the Minneapolis VA (process diagram)

11. REFERENCES:
VHA Directive 1200
VHA Handbook 1200.01
VHA Handbook 1200.05
VHA Handbook 1200.06
VHA Handbook 1200.07
VHA Handbook 1200.08
National Archives and Records Administration Request for Records Disposition Authority DAA-0015-2015-0004

12. REVISION: 09 September 2014

13. EXPIRATION DATE: none
14. FOLLOW-UP RESPONSIBILITY: Research and Development Committee

Date of Research & Development Committee approval: 2/7/2017