

<p>R&amp;D Committee - 1 of 23</p> <p>VAMHCS HUMAN RESEARCH PROTECTION STANDARD OPERATING PROCEDURE</p>
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SOP: HRP 01.03

<b>Version</b>	5.3	<b>Origin</b>	Version 5.2
<b>Reviewed/Revised</b>	Jessica Mendoza	8/6/13	
<b>Changes</b>	Changes based on ORO 2 <sup>nd</sup> response to RAP update: <ul style="list-style-type: none"> <li>• Footer corrected on pages 20-22</li> </ul>	<b>New Version #</b>	5.3
<b>Approved</b>	Christopher T. Bever, ACOS/R&D		
	Date		
<b>File Name</b>	\\R&D Committee (HRP 01.03) 2013v5.3		

VAMHCS RESEARCH AND DEVELOPMENT COMMITTEE

OBJECTIVES:

- To maintain high scientific and regulatory standards throughout the Veterans Affairs Maryland Health Care System (VAMHCS) Research & Development (R&D) Program through review and approval of research protocols and Research Service Standard Operating Procedures (SOPs) and guidelines;
- To maintain high scientific and regulatory standards throughout the VAMHCS R&D Program through evaluation of audit reports, reports of subject complaints, and reports of investigator non-compliance;
- To advise the Medical Center Director (MCD) on professional and administrative aspects of the R&D Program;
- To comply with applicable VHA, VAMHCS and R&D Service policies.

BACKGROUND & SCOPE:

The VAMHCS Research & Development Committee (RDC) is responsible, through the Chief of Staff (COS), to the MCD, for advising & assisting the MCD in providing oversight, planning, and execution of the VAMHCS R&D program, and for maintaining high standards throughout the research program. These standards include ensuring the scientific and ethical quality of Veterans Affairs (VA) research projects, the protection of human subjects in research, the safety of personnel engaged in research, the welfare of laboratory animals, the security of VA data, and the security of Veterans Health Administration (VHA) research laboratories.

The VAMHCS RDC is assisted by the Associate Chief of Staff for R&D (ACOS/R&D), the Deputy ACOS for R&D (DACOS/R&D), the Administrative Officer for R&D (AO/R&D), the Human & Animal Research Protections Officer (HARPO), the VAMHCS Research Compliance Officer (RCO), and VAMHCS Research Service staff in carrying out its duties. The RDC assists the MCD on professional and administrative procedures involving the R&D Program. The RDC is appointed by the MCD and is responsible for maintaining the quality and meeting the objectives of the research program. The RDC is accountable, through the COS, to the MCD for its actions and recommendations.

**Comment [ALK1]:** Carol F will not be called Deputy. I am not sure what the title is.

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Research in which the VAMHCS is engaged may not be undertaken without review and written approval of the RDC and its appropriate subcommittees and/or entities. VA research is defined as research that:

- Is conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, or utilizing VA resources (including VA funding),
- Is conducted completely or partially in VA facilities or at approved off-site locations/facilities and/or including space leased to, and used by, VA.
- directly involves recruitment of or interactions with veterans associated with the VAMHCS or its satellites;
- involves VAMHCS medical records or VAMHCS databases, or otherwise derives data from intervention or interaction with human subjects.

Research that does not meet at least one of the above criteria is not applicable for RDC approval. The research may be funded by VA, by other sponsors, or be unfunded<sup>1</sup>.

Research will be reviewed to ensure that it is scientifically sound, ethical, minimizes risk, maintains confidentiality, and minimizes financial conflict of interest.

The following categories of research are prohibited at the VA:

- Projects involving fetuses, *in utero* or *ex utero* (including human fetal tissue)
- Projects involving *in vitro* fertilization
- Projects involving embryonic stem cells
- Projects involving *in vitro* fertilization
- Research that is "planned emergency research" such that the investigator is seeking a waiver of prospective informed consent
- Projects involving a recruitment strategy that requires "cold calls" to veterans and/or asking veterans for social security numbers during a phone call.

The following categories of research require a Chief Research and Development Officer (CRADO) waiver or other special requirements:

- Research involving children
- Research involving prisoners
- International research
- Research involving pregnant women & FDA Class D or X drugs
- Research involving participants with impaired decision making capacity
- Research involving banking of human biological specimens

The RDC is advised by the following subcommittees

- The University of Maryland Baltimore (UMB) Institutional Review Board (IRB). The UMB IRB is an IRB of record for VAMHCS human subjects research. A memorandum of understanding (MOU) sets forth the agreement between the VAMHCS and the UMB for this service. This MOU follows Veterans Affairs Office of Research and Development (VAORD) and Veterans Affairs Office of Research Oversight (VAORO) guidelines<sup>2</sup>. No human research may be initiated or amended without the approval of both the RDC and the IRB.
- The Veterans Affairs Central Institutional Review Board (CIRB). The VA Central IRB is an IRB of record for ORD-funded VA research projects that have more than one VA site engaged in human subjects research, as well as single site pilot studies that, if successful, will eventually have multiple VA sites engaged in human subjects research. A

<sup>1</sup> VHA Handbook 1200.01 Par 3.b

<sup>2</sup> [http://www1.va.gov/oro/docs/Checklist\\_Developing\\_MOU\\_010705.pdf](http://www1.va.gov/oro/docs/Checklist_Developing_MOU_010705.pdf)

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memorandum of understanding (MOU) sets forth the agreement between the VAMHCS and the VA Central IRB. This MOU follows VAORD and VAORO guidelines<sup>3</sup>.

- The UMB Institutional Animal Care and Use Committee (IACUC). The UM SOM IACUC is the IACUC of record for VAMHCS animal research. A memorandum of understanding sets forth the agreement between the VAMHCS and the UMB for this service. No animal research may be initiated or amended without the approval of both the RDC and the IACUC.
- Subcommittee on Research Safety (SRS). The SRS advises the RDC by reviewing all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to submission for R&D funding. All research projects involving biological, chemical, physical, and radiation hazards must be approved by SRS and then by the RDC prior to commencement.
- Research Space & Resources Subcommittee (RSRS). The RSRS advises the RDC on the assignment of VAMHCS laboratory space to VAMHCS investigators, the use of VAMHCS core laboratory facilities, and short-term and long-term strategic planning of VAMHCS research facilities.

The functions of the subcommittees are described in greater detail in the SOPs of the individual subcommittees (See "See Also" section).

To avoid possible conflict of interest (COI) among institutional officials, the VAMHCS MCD, COS, and ACOS/R&D do not serve as voting members of the IRB, IACUC, or RDC but instead serve as non-voting ex officio members.

No VAMHCS organizational official or entity at any level can approve research that has not been reviewed and approved by the applicable subcommittees (IRB, IACUC, SRS) and the RDC. However, research reviewed and approved by the subcommittee(s) may be subject to review and disapproval by the MCD or other institutional officials. The MCD and institutional officials may not approve research not approved by the applicable subcommittee(s) or the RDC and cannot overturn IRB/IACUC/SRS or RDC decisions to suspend or terminate a study (i.e., decisions may not be more lenient than the IRB). The RDC ensures that the applicable subcommittee(s) is notified of all VAMHCS decisions regarding approvals and disapprovals of research.

Except for actions preparatory for RDC meetings and administrative functions, all business will be conducted at a convened RDC meeting in the presence of a quorum.

### RESPONSIBILITIES:

#### 1. RDC Responsibilities Related to the Facility's Research Program

The RDC assists the MCD in fulfilling responsibilities for the VAMHCS research program. The RDC is responsible for ensuring the effective operation of the research program and making appropriate recommendations to the MCD based on the RDC's oversight and evaluation of the research program. The RDC will accomplish its responsibilities through the following activities or procedures:

- 1.1. Planning and developing broad objectives for the R&D Program so that it supports VA's mission.
- 1.2. Determining the extent to which the R&D Program has met its objectives.
- 1.3. Overseeing all research activities at the VAMHCS.
- 1.4. Reviewing all written agreements including those that establish the VA Central IRB, UMB IRB and UM SOM IACUC as the subcommittees of record for human and animal research respectively.

<sup>3</sup> [http://www1.va.gov/oro/docs/Checklist\\_Developing\\_MOU\\_010705.pdf](http://www1.va.gov/oro/docs/Checklist_Developing_MOU_010705.pdf)

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- 1.5. Reviewing the budgetary and other resource needs of the R&D Program, including the Human Research Protection program (HRPP), at least annually, and making appropriate recommendations regarding these needs. This review needs to include: personnel, materials and supplies, space, capital equipment, training, and education.
  - 1.6. Reviewing and evaluating VAMHCS RDC subcommittees: the UMB IRB, the VA Central IRB, the UM SOM IACUC, the UM Institutional Biosafety Committee (IBC); the SRS, RSRS, and other subcommittees and entities as needed. A summary of these reviews and evaluations will be presented to the RDC and sent to the MCD annually.
  - 1.7. In fulfilling its responsibilities of ensuring the effective oversight of the research program and making appropriate recommendations to the MCD, including the suspension of a research study or remedial or restrictive action regarding a principal investigator, the Committee will rely on a variety of information sources including activities of the RDC, quality assurance activities, reports to the committee by the ACOS for R&D, AO for R&D, or other research staff members, subcommittee reports, facility reports or activities, and other appropriate sources. Specific issues from which information needs to be received include, but are not limited to:
    - 1.7.1. Compliance with all policies related to personnel as defined in VHA research manuals, Handbooks, and Directives.
    - 1.7.2. An annual review of the Research Safety and Security Program including planned training, compliance, security issues, etc.
    - 1.7.3. An annual review of the Animal Care and Use Program including inspection reports, IACUC composition, IACUC arrangements, budgets, space, support staff, training, quality improvement activities, compliance issues, and goals for next year.
    - 1.7.4. An annual review of the Human Research Protection Program including IRB composition or IRB arrangements, credentialing and training status report, budget, space, support staff, quality improvement activities, compliance issues, and goals for next year.
  - 1.8. Fulfilling such other functions as may be specified by the MCD and VHA procedures.
2. RDC Responsibilities Related to the Evaluation of Research Activities The RDC is responsible for establishing policy to ensure that all research has been reviewed and approved for scientific quality, ethical use of human subjects, animals and biohazards and for appropriateness for the VAMHCS.
- 2.1. This review must promote the
    - Maintenance of high standards of protocol review;
    - Protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel.
    - Welfare and appropriate use of animals in research.
    - Safety of personnel engaged in research and of the research environment (through compliance with VHA Handbook 1200.08, "Safety of Personnel Engaged in Research", see Appendix C).
    - Security of research laboratories where hazardous agents are stored or utilized and of all Biosafety Level 3 (BSL-3) research laboratories;
    - Security of VA data, VA protected information (VAPI), and VA sensitive information;
    - Availability of adequate resources (financial and other) to conduct and complete the research;
    - Relevance of research to, and in support of, the missions of the VHA and the VAMHCS;
    - Stringent review for "just-in-time" submissions.
  - 2.2. For protocols not meeting criteria for assignment to any subcommittee, the RDC is the review and approving committee of record
3. RDC Responsibilities in Research Safety The RDC is responsible for:

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- 3.1. Reviewing all VAMHCS research proposals, including:
    - 3.1.1. Ensuring the SRS review of those protocols and/or submissions for funding that involve safety hazards to personnel and/or the environment;
    - 3.1.2. Prior to review of a proposal, ensuring that a complete list of chemicals designated or identified by Occupational Safety and Health Administration (OSHA) and/or Environmental Protection Agency (EPA) as "hazardous"<sup>4</sup> has been reviewed and approved by the Facility Safety Officer;
  - 3.2. Reviewing and acting upon SRS minutes;
  - 3.3. Appointing a Research Safety Coordinator (RSC) who is responsible for supervising and operating the Research Safety Program;
  - 3.4. Appointing a Biological Safety Officer (BSO);
  - 3.5. Ensuring the development and implementation of the laboratory Chemical Hygiene Plan. Appointing a Chemical Hygiene Officer (CHO) to provide technical guidance on the implementation of the Plan;
  - 3.6. Overseeing compliance with VHA Handbook 1200.08 by Principal Investigators (PIs) conducting research at the facility;
  - 3.7. Ensuring the development and implementation of safety protocols by the PI for individual research projects as needed;
  - 3.8. Ensuring that the Research Office provides support to the SRS to assist in their functions;
  - 3.9. Ensuring that the minutes of SRS meetings are documented correctly and maintained by the Research Service;
  - 3.10. Providing the ACOS/R&D, and facility or Veterans Integrated Service Network (VISN) safety officials with adequate information to evaluate the performance of the R&D safety program;
  - 3.11. Ensuring coordination with other regulatory programs or committees such as the Radiation Safety Officer (RSO) and/or Radiation Safety Committee;
  - 3.12. Reviewing accident and injury trends reported by SRS. Recommending and ensuring the implementation of corrective action;
  - 3.13. Reviewing all citations issued by regulatory agencies and ensuring that prompt corrective actions are taken by appropriate committee members and PIs, and coordinating the necessary responses to regulatory agencies.
4. The Medical Center Director is the institutional official responsible for all aspects of the research program, including human subjects protection, animal welfare care and use, privacy & security of VA data, biosafety and safety of research personnel. This includes:
- Ensuring that research in which the facility is engaged is approved by the appropriate R&D Committee subcommittees;
  - Ensuring there are adequate resources and administrative support, including personnel, space, equipment, and training, for the R&D Committee and its subcommittees to fulfill their responsibilities;
  - Ensuring appropriate education and training for members of the R&D Committee, the research administration staff, and other staff involved in research;
  - Appointing the members of the R&D Committee following the specifications in Procedures Item #1;
  - Delegates authority to one or more individuals to
    - provide comments or suggestions to CIRB in response to CIRB's initial review considerations
    - respond to VA CIRB's approval of the study on behalf of the VAMHCS as to whether the VAMHCS chooses or declines to participate in the study,
    - serve as a liaison between the VAMHCS and both local site researcher and CIRB;

<sup>4</sup> VHA Handbook 1200.8 subpar. 6c(8), subpar. 6e(2), and/or applicable state requirements

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- Ensuring that the RDC and its subcommittees function independently and that concerns over undue influence of committee/subcommittee members are handled appropriately.
5. The ACOS/R&D is the delegated authority for management of the R&D program and is responsible for administering the operations of the RDC. This includes:
- Notifying the investigator when a research project can be initiated. This notification occurs only after the research project has been approved by all relevant RDC subcommittees and after the R&D Subcommittees' notifications of approval have been approved by the R&D Committee.
  - Notifying the RDC when there is a potential for institutional COI related to research activity (technology transfer, large contracts, etc.).
  - The ACOS/R&D is also responsible for notifying the investigator of RDC actions regarding continuing review by the RDC and subcommittees
  - Functioning as Executive Secretary of the RDC
  - ~~Conducting an annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation~~
  - Ensuring that information pertaining to all requests for WOC appointments for research have been appropriately justified and the appointments are in compliance with all applicable research, Human Resource Management, and other VA policies
  - Providing an annual quality assurance review of research employees involved in human subject research to ensure the employees are working within their scopes of practice and their privileges allowed by the facility's by-laws and granted to them by the facility
  - Providing an annual quality assurance review of Cooperative Research and Development Agreements (CRADAs) and other agreements in support of the research program or specific research projects and an assessment of the impact of these agreements on the research program, when applicable
  - Ensuring that all minutes of the RDC and its subcommittees, including those from subcommittees at VA facilities or at the affiliate, are sent to the MCD and COS for review and appropriate action.
6. The RDC Chair is responsible for:
- 6.1. Conducting RDC meetings and RDC business according to this SOP;
  - 6.2. Notifying the ACOS/R&D when a research protocol has been approved;
  - 6.3. Notifying the ACOS/R&D of RDC determinations requiring actions by the ACOS/R&D.
7. The RDC Coordinator or designee is responsible for:
- 7.1. Ensuring that investigators submit all applicable documents for RDC approval;
  - 7.2. Routing the protocol/amendment materials to the applicable subcommittees or individuals;
  - 7.3. Reviewing protocol documents, subcommittee minutes and other approvals by relevant individuals to determine whether studies have completed requirements for RDC approval;
  - 7.4. Distributing an agenda and relevant documents to subcommittee and Committee members at least 3 days prior to meetings'
  - 7.5. Recording attendance, maintenance of a quorum, discussions, decisions/actions, and votes in meeting minutes;
  - 7.6. Communications to and from the RDC Chair and others for matters involving the RDC actions;
  - 7.7. Notifying the IRB of any protocols that are disapproved by the RDC
  - 7.8. Maintaining the files of RDC records in a secure and organized fashion in the Research Service Office;
  - 7.9. Acting as a non-voting member of the RDC.

Comment [ALK3]: Can we take this out?

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8. The Investigator is responsible for:
  - 8.1. Confirming with the applicable service chief that they have been awarded the appropriate credentials and privileges to conduct research at VA prior to initiating any research;
  - 8.2. Complying with all applicable personnel and other VA requirements whether the investigator is compensated, WOC, or IPA;
  - 8.3. Obtaining the complete approval of all appropriate non-research entities and the R&DC and its appropriate Committee subcommittees, and written notification from the ACOS for R&D prior to initiating a research project;
  - 8.4. Submitting the new projects to RDC within 60 days of receiving IRB approval (this includes exempt studies and non-human subjects research);
  - 8.5. Developing a research plan that is scientifically valid; minimizes risk to human subjects, animals used in research, and personnel; and contains a sufficient description of the research including all procedures and the plan for statistical analysis, to allow the R&D Committee subcommittees to fully review the research project;
  - 8.6. Developing and implementing plans for data use, storage, and security that are consistent with VA Directive 6500, Information Security Program, and its implementing Handbooks and other legal requirements;
  - 8.7. Preparing and submitting information, at least annually or as required, on their research program(s) and on each project to the appropriate RDC subcommittee for continuing review as required by the respective RDC subcommittees. For exempt and non-human subjects research, annual updates must be sent to the RDC;
  - 8.8. Ensuring that all research proposals submitted for funding, from any source, support the mission of VHA and enhance the quality of health care delivery to Veterans.

**DOCUMENTS:**

Appendix A	Organizational Chart of the R&D Committee
Appendix B	Flowchart of the Implementation of the VAMHCS HRPP
Appendix C	Responsibilities of the SRS (VHA Handbook 1200.08)
Appendix D	

## Acronyms

**SEE ALSO:**

Research Service SOP	"Subcommittee on Research Safety" (R&D 1.06)
UMB HRPP Policies & Procedures	Available through the UM HRPO

**PROCEDURES:**

1. RDC General Operations
  - 1.1. The RDC meets at least monthly, except for 1 month during the year if it appears that a quorum cannot be obtained.
  - 1.2. A quorum must be present to conduct business and for each vote
  - 1.3. Physical presence of members at meetings is preferred, however teleconferencing or videoconferencing may be considered as long as the member has received all pertinent materials prior to the meeting and must be able to participate actively and equally in all discussions.
  - 1.4. The RDC may hold unscheduled meetings in response to emergent issues.
    - 1.4.1. There must be a quorum present in person or by teleconference or video conference for any unscheduled meetings.
    - 1.4.2. A quorum must be present to conduct business and for each vote.
2. Composition of the Research & Development Committee (RDC)

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- 2.1. The members of the RDC are appointed by the MCD and must reflect the types and amount of research being conducted at the VAMHCS. Nominations for membership may be from current RDC members, subcommittee members, and the facility's staff.
- 2.2. Voting Members: The membership of the RDC shall consist of at least 5 members appointed by the MCD to represent each of the following groups.
- At least two members from the staff of the VAMHCS who have major patient care or management responsibilities.
  - At least two members who are VAMHCS employees who are actively engaged in major R&D programs or can provide R&D expertise reflective of the types of research being conducted within the VAMHCS.
  - At least one member with an academic appointment from the UMB who is a fulltime or part-time permanent federal employee;
- 2.2.1. All members must be compensated full-time or part-time permanent federal employees;
- 2.2.2. A voting member may fill more than one criterion for required membership, for example, the member may have both major patient care or management responsibilities and be actively engaged in major R&D programs;
- 2.2.3. If possible, there should be a representative of the Investigational Drug Service or Pharmacy Service who may be a voting member or an ex officio non-voting member;
- 2.2.4. If possible, it is recommended, but not required, that at least one voting member of the RDC be chosen from the Centers of Excellence (COE) or Cooperative Studies Programs (CSP);
- 2.2.5. If possible, there should be one member with expertise in biostatistics and research design (may be a voting member or an ex officio non-voting member).
- 2.2.6. One member should have expertise in animal research techniques and biomedical animal study settings (may be a voting member or an ex officio non-voting member).
- 2.2.7. If possible, at least one member from each of the following should be members: the IACUC, the SRS, and other subcommittees of the RDC (may be voting members or ex officio non-voting members).
- 2.2.8. The members should have diverse backgrounds with consideration as to race, gender, ethnicity, and expertise
- 2.2.9. Alternate members must be appointed by the MCD. The roster must identify the primary member(s) for whom each alternate member may substitute. The alternate member's qualifications must be comparable to those of the primary member to be replaced. The alternate member can only vote in the absence of the primary member.
- 2.2.10. The RDC may require attendance by RDC subcommittee members, but subcommittee members who are not also members of the RDC must recuse themselves (i.e., leave the room or hang up from a conference call) before an RDC vote is taken.
- 2.2.11. RDC members must complete the following mandatory trainings available through the VA Talent Management System (TMS). These include VA Privacy training, VA Privacy & Information Security Awareness training, Good Clinical Practice training, and Human Subject Protection (CITI) training.
- 2.3. Terms of Members
- 2.3.1. It is recommended that no member serve more than 3 years; however the Director may approve terms of greater than 3 years with a possibility for extension. Members may be reappointed without any lapse in time if it is deemed in the Committee's best interest.
- 2.3.2. The terms must be staggered to provide partial change in membership annually.
- 2.4. Election of Chairperson

Comment [ALK4]: Can we remove this

Comment [ALK5]: This is not done through TMS

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- 2.4.1. Committee members, exclusive of ex officio members, must elect a Chairperson and a Vice-Chairperson every 1 or 2 years.
- 2.4.2. The Chairperson and Vice-Chairperson must be approved and officially appointed, in writing, by the MCD for a term of 1-2 years.
- 2.4.3. The Chairperson and Vice-Chairperson may be reappointed without any lapse in time
- 2.4.4. The Chairperson must not simultaneously chair a subcommittee of the R&D Committee.
- 2.5. RDC member conflict of interest (COI)
- 2.5.1. VA investigators and members of the RDC must avoid actual or perceived financial conflicts of interest in the research they conduct or review. They must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal criminal code, all VA, National Institutes of Health (NIH), Food and Drug Administration (FDA), VAMHCS and UMB COI policies, with the most stringent of these polices being the operative default criterion. This obligation also applies to WOC employees and IPAs conducting VA research or participating on the RDC.
- 2.5.2. Failure to follow these ethics laws and regulations can have serious consequences. If criminal ethics statutes are violated, civil fines and imprisonment can result. Severe administrative disciplinary action can result from violating ethics regulations, including suspension from employment, termination of employment, and other administrative punishment
- 2.5.3. RDC members must complete the VA conflict of interest declaration, and update it as appropriate. COI declarations are kept on file in the VAMHCS Research Office.
- 2.5.4. RDC members with outside consulting, employment, or royalty payment opportunities must ensure that these activities do not present any actual or perceived financial conflict of interest, and must recuse themselves from the review of proposals for which any conflict of interest may exist. Such members may not be present during the deliberations or the vote on such research proposals
- 2.5.5. The RDC Coordinator should be informed of COI prior to the meeting and note this in the agenda. Members may also recuse themselves from discussion and votes at the time of Committee meetings.
- 2.5.6. At the Committee's discretion, members with a COI may be present for questions or information regarding the study; however they may not be present for the discussion or the vote. Care must be taken to ensure that a quorum is maintained.
- 2.5.7. At the start of each RDC meeting, the members are asked if there are any COI. Members identifying a COI at this time or at any time during the meeting shall recuse themselves from discussions and voting on the study in question (at the request of the Committee, these members may be present to answer questions or present information). Recusals (and presence for questions) are documented in the minutes.
- 2.6. Non-voting members. To avoid possible conflict of interest among institutional officials, the following VAMHCS individuals serve as non-voting members of the RDC: MCD, COS, ACOS/R&D, the deputy ACOS/R&D and the AO/R&D, Research Compliance Officer (RCO), Privacy Officer (PO), and Information Security Officer (ISO). Ad hoc consultants who provide required expertise on issues related to the VA R&D program are non-voting attendees.
- 2.7. Independence of RDC members and Subcommittee members
- 2.7.1. If a member of the RDC or subcommittee perceives that his/her decision about a research project is being influenced unduly by pressure of any sort from superiors, colleagues, or others,
- 2.7.1.1. s/he must immediately notify one of the following:
- the RCO,

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- the Chair/RDC,
  - the ACOS/R&D, Deputy ACOS/R&D, or AO/R&D, or
  - the MCD as Institutional Official.
- 2.7.1.2. If anyone other than the RCO receives the report, the RCO will be notified immediately. The RCO then notifies the Chair/RDC and MCD.
- 2.7.1.3. The Chair/RDC, Vice-Chair or members have direct access to the MCD for appeal if they experience undue influence or if they have concerns about the IRB or RDC.
- 2.7.1.4. If there is an allegation that the MCD is applying undue influence, the RCO notifies the Director, VISN 5 and the regional office of ORO.
- 2.7.1.5. The RCO investigates all reports of undue influence. If necessary, Regional Counsel, the VAMHCS COI Officer, an Independent Committee, the HRPO, or others may be consulted.
- 2.7.1.6. The RCO makes a report to the Chair/RDC and the MCD or the Director, VISN 5. The RCO also notifies the IRB for matters involving financial COI or other matters over which the IRB has jurisdiction.
- 2.7.2. Corrective actions are undertaken as appropriate.
3. Subcommittees
- 3.1. The RDC has established the subcommittees listed in the "Background & Scope" section above and will establish any subcommittee(s) deemed necessary for the efficient and effective management and oversight of the R&D Program.
- 3.2. Subcommittee members, including the VA members of the UMB IRB and IACUC, are appointed by the MCD.
- 3.3. Scientific review is conducted through the subcommittee process.
- 3.3.1. Departmental/division review is required prior to IRB and IACUC review.
- 3.3.2. RDC delegates scientific review to the IRB and IACUC.
- 3.4. Findings and recommendations of the subcommittees are recorded and reported to the RDC through Subcommittee meeting minutes. Each subcommittee must make available to the R&D Committee a complete, unredacted\* final set of minutes prior to the R&D Committee meeting. \*IACUC minutes are redacted when sent to the RDC; however the full minutes are available to RDC members in the IACUC office during business hours.
- 3.5. The RDC must approve final subcommittee minutes. RDC may act upon draft subcommittee minutes.
- 3.6. Continuing review requires approval by relevant non-research committees and RDC subcommittees. The RDC does not perform continuing review, however, it does approve subcommittee actions through review of subcommittee minutes. For IRB-exempt studies, non-human subjects research, or other projects that are not reviewed by subcommittees, the RDC does review and approve annual updates.
- 3.7. Each subcommittee must maintain adequate records, and retain such records according to VHA Directive 6500. These records must include the following:
- Copies of all research proposals and their amendments and any accompanying materials,
  - All continuing or final reports,
  - Minutes of its meetings,
  - Copies of all written correspondence,
  - A membership list of all voting, non-voting, and ex-officio members including their appointed roles,
  - Written records documenting actions taken to carry out the subcommittee's responsibilities,
  - Standard Operating Procedures (SOPs),
  - All communications to and from investigators, other committees, subcommittees, and other entities or individuals.

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- 3.8. Subcommittee documents are kept in the RDC protocol files OR are available through electronic files maintained by the RDC or the subcommittees.
4. Process for Submitting Protocols for RDC and/or Subcommittee Review: Initial Review, Continuing Review and Protocol Amendments
- 4.1. The principal investigator or designee submits required documents for initial review, continuing review and protocol amendments to the RDC Coordinator. For new human protocols the investigator must submit the protocol to RDC within 60 days of receiving IRB approval.
- 4.2. The RDC Coordinator works with investigators to ensure that materials are submitted to relevant subcommittees. The "Worksheet for RDC Submissions" assists investigators and documents receipt of necessary documents.
- 4.3. The protocol review process is tracked and coordinated by the RDC Coordinator (or designee).
- 4.4. The RDC Coordinator performs an administrative review of all documents and ensures that required materials are routed to all applicable subcommittee and entities ("assigned individuals"). It is possible that protocols/amendments may need to be submitted to more than one subcommittee.
- 4.5. The RDC may not approve a study that has been disapproved by the IRB, IACUC, SRS, or other applicable subcommittee.
- 4.6. For details on the submission of human research protocols, see Appendix D.
- 4.7. For details on the submission of animal research protocols, see Appendix E.
- 4.8. For details on the submission of laboratory research protocols, see Appendix F.
- 4.9. Possible COI of Investigator and research team members:
- 4.9.1. VA investigators, research team members, and R&D Committee members must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal criminal code. The obligation to follow applicable ethics laws and regulations also applies to WOC employees and IPAs conducting VA research or participating on a R&D Committee. R&D Committee members, VA investigators, and research team members must comply with VA requirements on financial conflicts of interest in research. Failure to follow these ethics laws and regulations can have serious consequences.<sup>5</sup>
- 4.9.2. If during the process of IRB/IACUC submission a conflict of interest is identified, the IRB/IACUC will not grant final approval to the project until the conflict has been managed and/or resolved. If COI is identified, the IRB/IACUC proceeds according to their policies and procedures.
- 4.9.3. There are potential circumstances where individual COI is discovered during RDC submission or is not processed by the oversight committee (for example, non-UM employees who are team members). If this occurs, the project is referred to the Research COI Officer for evaluation and management. RDC final approval is not granted until a management plan is found to be acceptable. See HRP 01.17 for details on evaluation and management of COI.
- 4.10. Possible Institutional COI
- 4.10.1. An institutional COI may occur when the institution, or any of its senior management, has an external relationship or financial interest in a company or organization that itself has a financial interest in a VA investigator's research project. Examples are technology transfer agreements, large contracts for research-related services, etc.

<sup>5</sup> If criminal ethics statutes are violated, civil fines and imprisonment can result. Severe administrative disciplinary action can result from violating ethics regulations, including suspension from employment, termination of employment, and other administrative punishment [1200.01 15a]

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- 4.10.2. The ACOS/R&D or designee notifies the RDC when there is potential for institutional conflict of interest related to VAMHCS research.
- 4.10.3. The RDC proceeds according to HRP 01.17 "Research Conflict of Interest", Section 2.

4.11. RDC subcommittees may vote for the following actions:

- Approval.
- Approved with conditions<sup>6</sup> – the notification memo will specify what is required for a recommendation of approval. Once made, modifications shall be reviewed and approved by the appropriate subcommittee or Chair. If conditions are administratively approved, the full subcommittee is informed at the next scheduled meeting
- Disapproved – The proposal is rejected based on serious concerns about scientific integrity, ethical matters, safety of subjects or personnel, utilization of VA resources, etc. The investigator shall be notified of the issues; the proposal may be resubmitted after revisions are made.
- Deferred – A proposal is set aside if there are major concerns that must be resolved before the subcommittee will reconsider the proposal for approval. A deferred proposal must be reviewed again by the fully convened Committee. The materials, information, modifications, or conditions necessary for reconsideration by the subcommittee will be stipulated in the notification memo.

4.12. Based on the outcome of the review of the subcommittees and other entities ("assigned individuals"), the RDC Coordinator places the following list onto the agenda for the next scheduled RDC meeting (see Item 11 for a complete list of agenda items):

- a list of studies (initial and continuing reviews) that are recommended for approval (studies that have completed the RDC Worksheet process, including review by all relevant subcommittees and entities) ("Approval List");
- A list of notifications of modifications, updates, closed studies and other such transactions.

Studies that are deferred or disapproved are recorded in subcommittee meeting minutes and/or on the RDC Worksheet.

5. RDC Final Actions for Protocol Approval

5.1. RDC subcommittees and assigned individuals review the protocol and other supporting documents as in Item 3 above. Examples of "assigned individuals" include the ISO, PO, IDP, and RSO.

5.2. The RDC will not approve research studies until the ISO and PO have reviewed the application and provided summary input prior to IRB review regarding whether or not the study meets information security policy and privacy policy.

5.3. Prior to the next scheduled meeting, the RDC Administrator posts Subcommittee minutes, the study lists (see 4.12 above) into a network share-folder accessible by RDC members.

5.4. At the convened meeting, the RDC votes on the subcommittee minutes, the "Approval List", and the study lists (see 4.12 above).

5.4.1. The RDC may not approve a project that has been disapproved by a subcommittee.

However, it may vote to:

- require additional actions to secure approval,
- accept actions or recommendations of a subcommittee, or
- disapprove a project recommended by a subcommittee.

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Decisions by the IRB/IACUC/SRS/IBC to disapprove, suspend or terminate a study cannot be overruled

- 5.5. On occasion, there is a protocol that does not qualify for subcommittee review (for example, non-human, non-animal research protocols would not go to either the IRB or IACUC). In this case, it is the RDC that reviews and approves the individual study.
    - 5.5.1. The RDC Coordinator processes the protocol as in 4 above, in consultation with the RDC Chair or other consultant.
    - 5.5.2. The RDC Coordinator documents his/her findings on the "RDC Reviewer Checklist". Other "assigned individuals" perform and document their evaluations as applicable.
    - 5.5.3. When all necessary reviews have been obtained, the RDC Coordinator places the study onto the agenda of the next scheduled meeting in the list of protocols requesting approval.
    - 5.5.4. If the RDC requires additional actions to secure approval, the RDC Coordinator notifies the Investigator of the issues.
    - 5.5.5. The revised protocol returns to the convened RDC for final approval.
  - 5.6. On occasion, the VA Central IRB will be the IRB of record rather than the UMB IRB. Clarification on this will follow as an addendum to this SOP.
  - 5.7. The ACOS/R&D notifies investigators when the RDC has approved or disapproved the protocol. Research cannot be initiated at the VAMHCS until the PI has received notification of approval from the ACOS/R&D. (The RDC Coordinator notifies Investigators when the RDC has required additional actions to secure approval).
6. RDC Approval Period and Dates of Approval
    - 6.1. The RDC cannot approve a protocol for a period longer, or a date beyond, that granted by the IRB/IACUC.
    - 6.2. The R&D approval date is the date at which the fully convened committee voted to approve the protocol and must be a date later than the IRB/IACUC approval date. The R&D approval date is not the same as the IRB/IACUC approval date, which determines when the IRB/IACUC continuing review will take place.
  7. RDC Continuing Review
    - 7.1. The RDC shall ensure review of all projects at least once a year to assess scientific progress and continued appropriateness of the research to the overall VA mission. This includes IRB-exempt studies, nonhuman subjects research and other projects that do not fall under the IRB, IACUC or SRS.
    - 7.2. The process for Continuing Review is similar to that for initial review (Items #3 and #4 above). Applicable subcommittees conduct continuing review. Assigned individuals (entities) review the renewal if there have been changes affecting privacy, information security, radiation safety or with the study drug(s).
    - 7.3. Protocols will not lapse at the VAMHCS as long as they are submitted to RDC within 60 working days of IRB and IACUC continued approvals.
    - 7.4. Investigators will be notified of the RDC actions as in item 10 below.
  8. RDC Review of Modifications/Amendments
    - 8.1. In general, the process for Modification/Amendment Requests is similar to that used for initial review.
    - 8.2. At pre-review, the RDC Coordinator, in consultation with the RDC Chair, determines that the modification/amendment has received applicable subcommittee approval(s) and lists the modifications/amendments as notifications.
    - 8.3. Modifications/amendments are acknowledged by the convened RDC.
    - 8.4. The ACOS/R&D generates a letter to the PI acknowledging the modification/amendment.

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**9. RDC Consideration of Other Matters**

- 9.1. The RDC must also consider matters involving employment, budgets and resources, publications, quality improvement and compliance issues, evaluation of its programs and subcommittees, committee and subcommittee appointments, agreements with affiliates.
- 9.2. The RDC must plan and develop broad objectives for the research program so that it supports VA's mission.
- 9.3. The RDC must determine the extent to which the research program has met its objectives
- 9.4. The RDC must review all written agreements and MOUs with the University regarding its "in lieu of" subcommittees and individuals;
- 9.5. The RDC must review and evaluate all RDC subcommittees, including the UMB IRB, UM SOM IACUC and UMB IBC. A summary of these reviews and evaluations must be sent to the MCD annually.
- 9.6. Review of RDC subcommittee operations must be conducted as an ongoing function of the R&D Committee. The review must be conducted at least annually and must be accomplished in part by: reviewing the minutes of each subcommittee that reviews VA research protocols (whether those of the VA or non-VA institutions when allowed); by close communication with the subcommittees; and through Quality Assurance and Quality Improvement activities.
- 9.7. The RDC must ensure and review annual evaluations of :
  - the Research Safety and Security Program (including planned training, compliance, security issues, etc.
  - the Animal Care and Use Program (including inspection reports, IACUC composition, IACUC arrangements, budgets, space, support staff, training, quality improvement activities, compliance issues, and goals for the next year),
  - the Human Research Protection Program (including IRB composition or IRB arrangements, credentialing and training status report, budget, space, support staff, quality improvement activities, compliance issues, and goals for the next year), and
- 9.8. As appropriate the RDC will review and consider, other reviews of quality assurance activities, reports to the committee by the ACOS/R&D, AO/R&D, RCO, other staff or facility reports or activities, including the suspension of a research study or remedial or restrictive action regarding a principal investigator.
- 9.9. For administrative items under consideration, the RDC will vote to approve, disapprove, or table for additional clarification or information, or forward recommendation to the ACOS/R&D for appropriate resolution or action.

**10. Communication of RDC Findings and Actions**

- 10.1. All formal communications of the RDC shall be in writing.
- 10.2. Protocol Notifications to investigators:
  - 10.2.1. The ACOS/R&D notifies investigators when the RDC has approved or disapproved the protocol.
  - 10.2.2. The ACOS/R&D notifies investigators of protocol continuing review following RDC action.
  - 10.2.3. Notifications of actions required to secure approval deferred notifications of protocol deferral may be made by the RDC Coordinator. (The revised protocol must go to the convened RDC via the standard processes for approval, Items 3-8 above).
  - 10.2.4. Research cannot be initiated at the VAMHCS until the PI has received notification from the ACOS/R&D
- 10.3. Other official communications from the ACOS/R&D to the COS, MCD, VA Central Office or other federal agencies shall be executed as necessary.

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**11. R&D Committee Meeting Agendas**

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11.1. The RDC Coordinator, in consultation with the Chair, prepares meeting agendas for the RDC meeting.

11.2. The following shall be included in the RDC meeting agenda:

- The scheduled date, time and location of the meeting
- Review of minutes of last R&D meeting
- Review and approval of IRB minutes
- Review and approval of IACUC minutes
- Review and approval of SRS minutes
- List of protocols for RDC action
  - Human Approval lists, including new and continuing reviews and modifications
  - Animal Approval lists, including new and continuing reviews and amendments
  - SRS Approval and conditional approval lists, including new and continuing reviews and amendments
  - Notifications of other transactions
- ACOS/R&D-Research Service report
- Baltimore Research & Education Foundation (BREF) report
- HARPO report
- RCO report
- Review of adverse events, data safety monitoring and other significant protocol specific issues through the HARPO and RCO reports
- ISO report
- PO report
- New or revised SOPs
- Other business as listed in #9 above.

**12. R&D Committee Meeting Minutes**

12.1. Minutes shall be recorded and maintained for each meeting of the RDC.

12.2. The minutes shall contain:

- A list of all voting members and non-voting members, including ex officio members, indicating their membership category and whether they are present or absent. If an alternate is present in place of a voting member, the minutes need to indicate this fact and name who the alternate member is replacing;
- The presence of a quorum;
- A record of all items of business or information brought before the Committee.
- A record of all motions presented to the Committee and the number of members voting for and against the motion or abstaining or recused.
- A note of recusals due to possible conflict of interest.

12.3. All minutes of the R&D Committee and its subcommittees, including those from "in lieu of" subcommittees at VA facilities or at the affiliate, must be sent to the MCD through the ACOS/R&D and COS for review and appropriate action. Minutes must be signed by the RDC Chair and the ACOS/R&D before being forwarded to the MCD through the Chief of Staff

12.4. Prior to the next meeting, the minutes will be made available to all members of the Committee. The minutes will be reviewed and approved, with edits as necessary, by the Committee.

**13. RDC Maintenance of Written Procedures of Operations**

13.1. The operations of the RDC shall comply with written SOPs and other official VA policies and procedures in order to ensure the proper conduct of high quality research within the VAMHCS.

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- 13.2. All persons involved with the research program, including all committee and subcommittee members, research administrative staff, research investigators, research study coordinators and research study assistants, shall be informed of these SOPs for appropriate compliance.
- 13.3. Administrative records pertaining to the RDC shall be maintained by the Research Service and shall include the following categories:
- Written operating procedures
  - Rosters of RDC and subcommittee membership
  - Copies of correspondence relating to membership appointments.
  - Training records
  - RDC correspondence (other than protocol related documents)
  - Minutes of R&D convened meetings and subcommittee meetings
- 13.4. The Research Service shall maintain information relative to the qualifications and VA appointment status of each principal investigator (e.g. credentials and documentation of training)
- 13.5. For each approved project, the R&D administrative files shall contain the following items. The files may be in paper and/or electronic form.
- All materials submitted by the Principal Investigator (PI) for initial review.
  - All materials and correspondence from the PI to the Research Service related to protocol continuing review, and study termination.
  - IRB approved consent form
  - All study related correspondence sent or received by the RDC or any RDC subcommittee
  - Any other related communication regarding the study received by the Research Service.
14. Access to / retention of RDC records
- 14.1. All research records shall be kept confidential and secure in filing cabinets in the Research Administrative Offices. Normal access is limited to the ACOS/R&D, the Deputy ACOS/R&D, the Administrative Officer for Research, research administrative staff, Chairs of the RDC or its subcommittees, authorized VA representatives, officials of federal or state regulatory agencies and appropriate accreditation organizations.
- 14.2. Other access to RDC records is limited to those who have legitimate need, as determined by the Research Service, the RDC and/or VA Central Office (VACO).
- 14.3. Research records shall be retained according to the VHA Records Control Schedule (RCS) 10-1 for the research study and/or research records. The R&D records relating to an investigator who leaves the VAMHCS shall be retained according to the VHA Records Control Schedule (RCS) 10-1 for research records.
- 14.4. The RDC, through the RDC Coordinator, has access to accurate and complete records that indicate the following for each active research protocol:
- Date of original IRB approval, found in ~~BRAAN~~ other CICERO protocol management systems,
  - Date of original RDC approval, found in the ePROMISE database,
  - Date of most recent IRB approval (in the /CICERO protocol management system),
  - Date by which the next IRB continuing review must occur (/CICERO protocol management systems)
  - IACUC records,
  - SRS records,
  - IBC application and approval records,
  - Radiation Use application and approval records.

## REFERENCES

VAMHCS HUMAN RESEARCH PROTECTION  
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VHA Handbook 1200.01	Research and Development (R&D) Committee Handbook
VHA Handbook 1200.05	Requirements for the Protection of Human Subjects in Research
VHA Handbook 1200.06	Control of Hazardous Agents in VA Research Laboratories
VHA Handbook 1200.7	Use of Animals in Research
VHA Handbook 1200.08	Safety of Personnel Engaged in Research

**Appendix A**

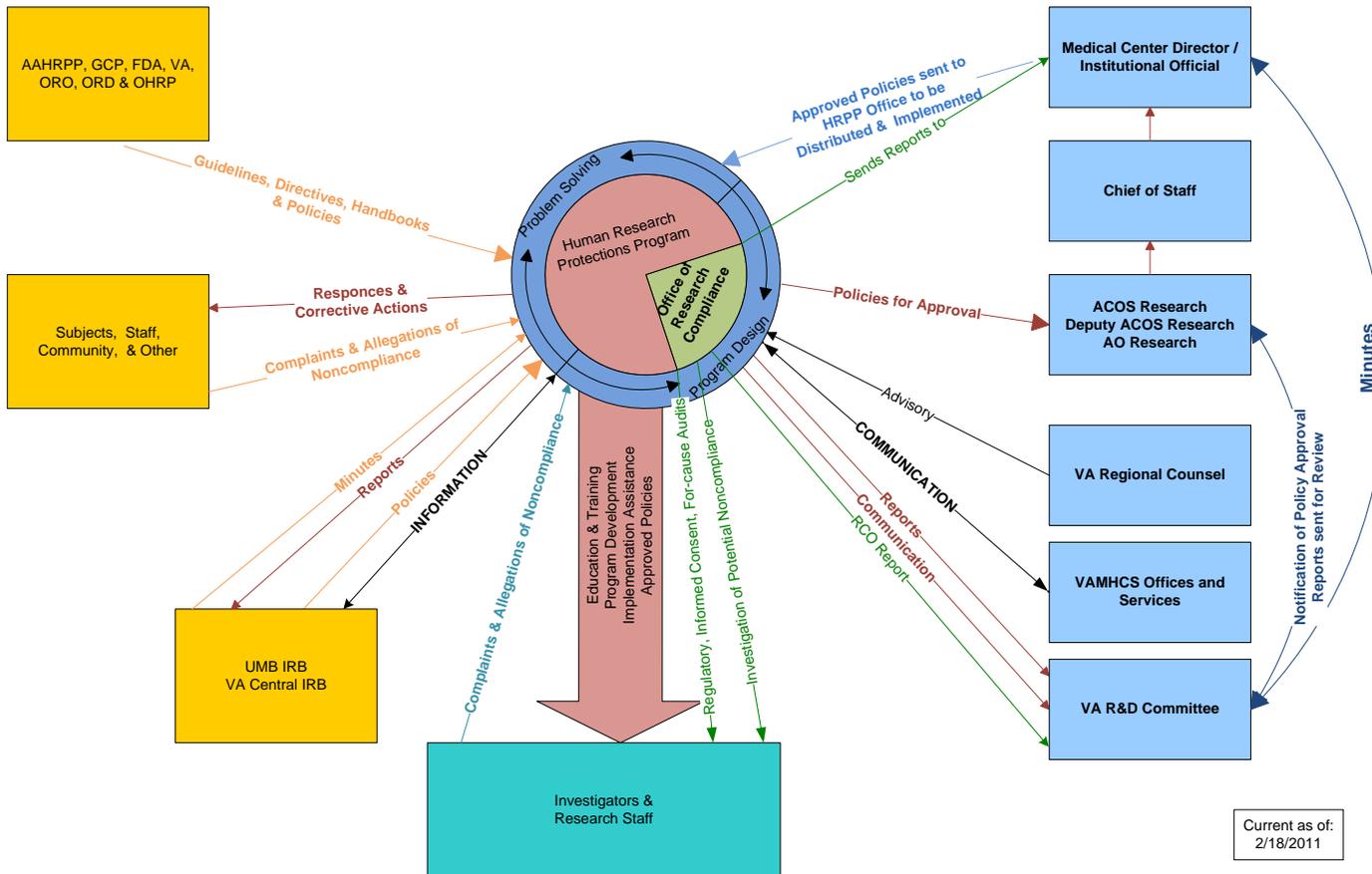
## Organizational Chart for R&D Committee

Available in the Research Service Office

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**APPENDIX B: Flowchart of the Implementation of the VAMHCS HRPP**

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APPENDIX C:

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PRINCIPAL RESPONSIBILITIES of the SRS  
(See VHA Handbook 1200.08, Par 7 for a detailed list)

- Reviewing all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to submission for R&D funding. This includes a review of all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding located off-site
- Providing written notification of the results of SRS review to the R&D Committee, the Research Office, and the PI;
- Reviewing annually all active research protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source. The date of continuing review is based on the date of SRS approval. Research protocol changes not included in the original application must be documented on an amended RPSS (see App. F) and must be submitted to and reviewed by SRS prior to the implementation of the changes.
- Ensuring that a complete list of all products containing chemicals designated or identified by OSHA or EPA as "hazardous" has been submitted to the Safety Officer for review and approval prior to the submission of a protocol for local review.
- Coordinating all safety-related activities in research laboratories including mandatory and non-mandatory training, safety inspections, accident reporting, and liaison activities with all facility safety committees and officials.
- Reporting operational problems or violations of directives to the Research Office within 30 days of occurrence or detection, unless SRS determines that a report has been previously filed by the PI.
- Identifying the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising the R&D Committee and Employee Health Practitioner on the need for such surveillance
- Maintaining adequate documentation of all the SRS or equivalent subcommittee activities;
- Forwarding minutes of SRS to the RDC;
- Ensuring that all laboratory personnel receive annual research specific safety training;
- Holding SRS meetings at least quarterly;
- Ensuring coordination with other regulatory programs, personnel, or committees such as the Radiation Safety Officer or Radiation Safety Committee;
- Ensuring the collection of appropriate personnel samples to make employee exposure determinations whenever the proposed use of laboratory chemicals may potentially exceed OSHA Permissible Exposure Limits or Action Levels;
- Evaluating annually the effectiveness of the laboratory's Chemical Hygiene Plan and making necessary revisions;
- Ensuring the review of investigation reports of all lost-time injuries and all significant adverse environmental events;
- Ensuring the proper reporting of injury and illness trends to the R&D Committee, as appropriate.
- Requesting, when appropriate, the appointment of an ad hoc committee (consisting of members with appropriate expertise) to investigate and report on occupational injuries, illnesses, and adverse environmental events;

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- Ensuring the development of a policy for the preservation of employee medical and OSHA exposure records and environmental records (i.e., hazardous waste, air monitoring);
- Cooperating with appropriate medical center personnel to review the quantity and type of hazardous waste generated by each PI annually;
- Providing technical assistance, where appropriate, in recycling programs and reduction of the quantity of waste.

Additional local (VAMHCS) responsibilities:

- Ensuring the development and implementation of the laboratory Chemical Hygiene Plan;
- Appointing a Chemical Hygiene Officer (CHO) to provide technical guidance on the implementation of the Plan;
- Assuring that the CHO is a standing member of the SRS;
- Appointing a Biological Safety Officer;
- Ensuring coordination with other regulatory programs or committees such as the VAMHCS Radiation Safety Committee;
- Overseeing the development and implementation of safety protocols in compliance with VHA handbook 1200.08 by PIs conducting research within the VAMHCS;
- Reviewing all citations by regulatory agencies and ensuring that prompt corrective actions are taken by appropriate committee members and PIs, and coordinating the necessary responses to regulatory agencies;
- Providing the ACOS/R&D and facility or VISN safety officials with adequate information to evaluate the performance of the R&D safety program;
- Reviewing accident and injury trends reported by the SRS and recommending and ensuring the implementation of corrective actions;
- Ensuring that the minutes of the SRS are documented accurately and maintained by the Research Service Office

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## APPENDIX D: Acronyms

ACOS	Assistant Chief of Staff
AO	Administrative Officer
BREF	Baltimore Research & Education Foundation
BSO	Biological Safety Officer
CHO	Chemical Hygiene Officer
CITI	Human Subjects Protection training
COI	Conflict of Interest
COIO	Conflict of Interest Officer
COS	Chief of Staff
CR	Continuing Review
CRADA	Cooperative Research and Development Agreements
CRADO	Chief Research & Development Officer
FCOI	Federal Conflicts of Interest
GRS	Grant Review Subcommittee
HRPO	Human Research Protections and Oversight and Compliance Subcommittee
IACUC	Institutional Animal Care and Use Committee
IDP	Investigational Drug Pharmacist
IRB	Institutional Review Board
ISO	Information Security Officer
MCD	Medical Center Director
MOU	Memorandum of Understanding
ORD	Office of Research Development
ORO	Office of Research Oversight
PI	Principal Investigator
PO	Privacy Officer
R&D	Research and Development
RCO	Research Compliance Officer
RDC	Research and Development Committee
RSC	Research Safety Coordinator
RSO	Radiation Safety Officer
RSRS	Research Space and Resources Subcommittee
SOP	Standard Operating Procedures
SRS	Subcommittee on Research Safety
UMB	University of Maryland Baltimore
VA	Veterans Affairs
VAMHCS	Veterans Affairs Maryland Health Care System
VHA	Veterans Health Administration
VISN5	Veterans Integrated Service Network

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