

## SOP 17 VA RESEARCH SERVICE R&D COMMITTEE

### 1.0 PURPOSE AND SCOPE

#### 1.1 Purpose and Scope

*This SOP specifies the requirements for the establishment and conduct of the Research and Development Committee (R&D) at the VA Research Service, Charleston. This entire SOP is applicable to the VA Research Service only.*

### 2.0 ORGANIZATIONAL STRUCTURE

2.1 *The R&D Committee is responsible, through the Chief of Staff (COS) to the Medical Center Director, for oversight of the research program and for maintaining high standards throughout the R&D program. These standards include assuring the scientific quality of research projects, protection of human subjects in research, safety of personnel engaged in research, the welfare of laboratory animals, security of VA data and the security of VHA research laboratories. The R&D Committee advises the Medical Center Director on professional and administrative aspects of the R&D program. All R&D activities within the facility, whether funded or unfunded, are within its purview. No research may be undertaken without R&D Committee and appropriate subcommittee(s) review and approval.*

2.2 *The members of the R&D Committee are appointed by the medical center Director and must reflect the types of research being conducted at the facility. Nominations for membership may be from current R&D Committee members, subcommittee members, and the facility's staff. The membership of the R&D Committee shall consist of representatives appointed in writing by the Medical Center Director from each of the following groups:*

- 1) *At least one member who holds an academic appointment at the affiliated institution and is either a full-time VA employee or a part-time VA employee.*
- 2) *At least two members from the staff of the VA medical center selected because they have major patient care or management responsibilities.*
- 3) *At least two members who are VA investigators selected because they are actively engaged in major R&D programs or can provide R&D expertise. (Note: All voting members must be compensated full-time or part-time VA Employees). The expertise of the committee should reflect the types of research being conducted at the facility. Health Services Research and Development Service (HSR&D), Rehabilitation Research and Development Service (RR&D), and Cooperative Studies Program*

*(CSP) programs should be represented when there are active programs in these areas. Similarly, nursing and allied health professionals should be represented whenever there is research interest or activity in these professional areas.*

*4) Whenever possible, one member of the committee selected according to the criteria listed above should have expertise in biostatistics and research design. A member with expertise in animal research techniques and biomedical animal study settings should be appointed if there is interest or activity in research using animal subjects. The members should have diverse backgrounds with consideration given to race, gender, and ethnicity and include at least one non-physician.*

*5) An R&D Committee may, at its discretion, invite individuals (Ad Hoc Members) 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.*

*6) Ex officio (non-voting) members include the Medical Center Director, the COS, the Administrative Officer for Research (AO/R&D) of the facility, the Information Security Officer, the Facility Privacy Officer, and the VA IRB Liaison. The ACOS/R&D functions as Executive Secretary of the Committee.*

*a) The Information Security Officer must conduct a thorough review of each human subjects protocol and document that review.*

*b) The Privacy Officer must conduct a thorough review of each human subjects protocol and document that review.*

*7) The facility Research Compliance Officer will serve as a non-voting consultant to the R&D Committee. The RCO will not serve as a protocol reviewer for the R&D Committee.*

*2.3 Members of R&D Committees other than those who are ex officio:*

*1) Must be compensated full-time or part-time VA employees). If the members are not full-time or part-time compensated VA employees, they may only provide individual advice to the R&D Committee, or exchange facts and information.*

*2) Must have a major commitment of their professional time to the VA, except for representatives of the Partnership Council (Deans Committee).*

3) *Serve terms of 3 years. Members 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.*

2.4 *The committee members, exclusive of ex officio members, shall elect a chairperson on an annual basis. The Chairperson must be approved and officially appointed, in writing, by the medical center Director for a term of 1 year. The Chairperson may be reappointed without any lapse in time. The Chairperson must not simultaneously chair a subcommittee of the R&D Committee. The Committee members, exclusive of ex-officio members, may elect a vice-Chairperson. The vice-Chairperson must also be approved and officially appointed, in writing, by the medical center Director for a term of 1 year. The vice-Chairperson may be reappointed without any lapse in time and must assume the responsibilities of the Chairperson when the Chairperson is not available.*

2.5 *The R&D Committee may establish subcommittees deemed necessary for the efficient and effective management and oversight of the R&D program and may use advisors who are selected for specific tasks and who do not have a vote. At a minimum, subcommittees shall be appointed to oversee R&D activities related to:*

1) **Human Studies.** *Every VA medical center conducting research involving human subjects or human biological specimens shall have or establish an IRB, or arrange for securing the services of an IRB established by an affiliated VA facility or an academic affiliate. The use of a commercial IRB is prohibited. (NOTE: For research involving human subjects, the primary review of the research protocol must be the responsibility of the IRB. Per VHA Handbook 1200.5, the R&D Committee cannot approve a study that is disapproved by the IRB but the R&D Committee may disapprove a study approved by the IRB.)*

2) **Animal Studies.** *Every VA medical center conducting research involving the use of live vertebrate animals shall establish an Institutional Animal Care and Use Committee (IACUC). The use of a commercial IACUC is prohibited.*

3) **Safety and Security.** *Every VA medical center conducting research shall establish either a Subcommittee on Research Safety (SRS), an Institutional Biosafety Committee (IBC) or multiple subcommittees dealing with different aspects of research safety and security of VHA research laboratories. The use of a commercial SRS is prohibited.*

### 3.0 CONFLICT OF INTEREST

3.1 *VA investigators 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 an R&D Committee. R&D Committee members and VA investigators must also comply with VA procedure(s) on financial conflicts of interest in research. 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/or other administrative punishment.*

- 3.2 *R&D Committee 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.*
- 3.3 *When conducting the initial or subsequent review of research programs or projects, R&D Committee members must be cognizant of any financial conflicts of interest related to the Principal Investigator (PI), others working on the research project, or others that may influence the conduct of, and the reporting on the research (such as a sponsor). Such conflicts must be resolved prior to approval of VA research projects.*

#### **4.0 RESPONSIBILITIES**

- 4.1 *The R&D Committee assists the medical center Director in fulfilling responsibilities for the facility's research program. The R&D Committee is responsible for ensuring the effective operation of the research program and making appropriate recommendations to the medical center Director based on the Committee's oversight and evaluation of the research program; planning for research and development in the facility and assuring the continuing high quality of the facility's R&D program; planning and developing broad objectives of the R&D program so that it supports the patient care mission of the facility; determining the extent to which the R&D program has met its objectives; and critically evaluating the quality, design, desirability, and feasibility of each new R&D proposal, continuing R&D project, or application for funding to assure maintenance of high scientific standards, protection of human subjects, including privacy and confidentiality, adequate safety measures, and proper use of animal subjects. The committee is also responsible for:*

- 1) *Recommending the distribution of R&D funds, space, personnel, equipment and supplies, and use of animal facilities and other common resources.*

- 2) *Recommending approval of the receipt and use of non-VA financial support for research and development to be conducted in the facility or by members of the VA staff even if conducted outside the facility.*
- 3) *Reviewing the budgetary and other resource needs of the R&D program, at least annually, and making appropriate recommendations to the medical center Director based on the Committee's oversight and evaluation of the research program.*
- 4) *Ensuring that manuscripts, abstracts, and other presentations satisfactorily acknowledge VA support and affiliation.*
- 5) *Recommending policies for the recruitment and development of personnel supported by R&D funds.*
- 6) *Forming the search committee for recruitment to the position of ACOS/R&D and advising the Medical Center Director/Chief Executive Officer (CEO) on the recommendation of candidates to the Chief Research and Development Officer (CRADO).*
- 7) *Fulfilling such other functions as specified by the Medical Center Director/CEO.*
- 8) *Reviewing all written agreements that establish a committee from another VA or non-VA entity in lieu of a required committee or subcommittee for the R&D Committee.*
- 9) *Reviewing and evaluating all subcommittees or committees both within the VA facility and at external entities that function in lieu of subcommittees, such as IRBs, IACUC, or Biosafety committees. A summary of these reviews and evaluations must be sent to the medical center Director.*
- 10) *Reporting to the VA Privacy Officer, any unauthorized use, loss, or disclosure of individually-identifiable patient information.*
- 11) *Reporting to the VA information Security Officer, violations of VA information security requirements.*
- 12) *In fulfilling its responsibilities of ensuring the effective oversight of the research program and making appropriate recommendations to the medical center Director, the Committee needs to rely on a variety of information sources including activities of the R&D Committee, 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:*

- a) Compliance with all policies related to personnel as defined in VHA research manuals, Handbooks, and Directives. These can be found at: <http://www/vhapublications/>. **NOTE:** All information related to compliance matters must be treated as confidential.*
- b) An annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation.*
- c) Information pertaining to all requests for WOC appointments for research ensuring that all have been appropriately justified and the appointments are in compliance with all applicable research, Human Resource Management, and other VA policies.*
- d) 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.*
- e) An annual quality assurance review of Cooperative Research and Development Agreements and other agreements in support of the research program or specific research projects and the assessment of the impact of these reports on the research program, when applicable.*
- f) An annual review of the Research Safety and Security Program including planned training, compliance, security issues, etc. g) 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.*
- g) 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.*

4.2 *Scientific review of research and development is a primary responsibility of the R&D Committee. Each program is to be reviewed formally at least once a year. In addition to the assessment of scientific progress, the review evaluates the budget, requirements for space, personnel, equipment and supplies, the*

*relationship of the program to the total R&D activity of the medical center, and the role of the PI at the medical center. The committee may accomplish local review by the following mechanisms:*

*1) The R&D Committee may establish a Research Review Subcommittee. Its members should be knowledgeable about the VA R&D program and the local facility's environment and it may use ad hoc experts as needed. Its findings and recommendations are recorded and forwarded to the committee included in the quarterly report of the local review.*

*2) The R&D Committee as a whole may evaluate research or development programs and may employ ad hoc consultants for this purpose. Such consultants may be asked to submit written evaluations of the programs or, when necessary, to present their recommendations to the committee in person. R&D funds may be used to pay for the services of consultants who are not employed by the Federal Government.*

*3) The committee may use the information generated by VHA Headquarters review to complement the local review process.*

*4.3 The R&D Committee is responsible for the scientific quality and appropriateness of all research and development conducted by VA personnel including WOC and Intergovernmental Personnel Act (IPA) employees when veteran patients are involved in the research, whether at the VA facility or at another facility regardless of funding source and including programs that do not receive VA funding. No research may be undertaken without R&D Committee and appropriate subcommittee(s) review and approval.*

*4.4 In conducting an initial review (full board, expedited or exempt protocols), the R&D Committee must evaluate scientific quality, the relevance to both VA's mission and the facility's research program, and the ability of the investigator to perform and complete the research. In addition, the review must include information on the use, storage, and security of VA data and VA sensitive information including VAPI; the budget; the requirements for space, personnel, equipment, and supplies; the role of the investigator at the facility; the investigator's qualifications; and other information deemed relevant by the R&D Committee.*

*1) In conducting an initial review, the R&D Committee must consider the findings of its Subcommittees.*

*2) The initial approval of research requires a majority vote of the convened quorum.*

- 3) *The initial approval of research must include a specific approval period, not to exceed 1 year.*
- 4.5. *A continuing review of research for studies not reviewed by a subcommittee must be reviewed by the R&D Committee. The PI will submit a continuing review form with an updated abstract describing the progress of the research and these will be reviewed by the R&D Chair. The results of the continuing reviews will be listed in the R&D agenda and minutes. A letter acknowledging continuation of the protocol will be sent by the ACOS/R&D.*
- 4.6 *The initial or continuing review of research projects that involves the use of veterans' data or another person's data (identified or de-identified) must include an assessment of the mechanisms in place to ensure:*
  - 1) *Security of data and all files;*
  - 2) *Confidentiality of data, including data derived from research subjects;*
  - 3) *Release of data in accordance with VHA regulations and policies; and*
  - 4) *Control of the data so that reuse of the data is within an approved research protocol and in compliance with VHA procedures.*
- 4.7 *The R&D Committee may approve or disapprove a research project, program, or center. Approval of the R&D Committee may only occur after all applicable subcommittees have granted final approval. If the R&D Committee finds that it has received insufficient information to review the research, it may defer the review until all required information has been obtained.*
- 4.8 *The R&D Committee may review requests for study modifications. In fulfilling its responsibilities of ensuring the effective oversight of the research program, the Committee may rely on a variety of information sources. Based on the information available, the committee can either approve or disapprove study modifications.*
- 4.9 *If a subcommittee of the R&D Committee disapproves the research project, program, or center, the R&D Committee may not approve it.*
- 4.10 *Once approved by the R&D Committee, the research becomes VA approved research. **NOTE:** Research may be initiated only after R&D Committee approval has been obtained.*
- 4.11 *If a research protocol requires review by a facility's non-research committee(s) or subcommittee(s), such as the Radiation Safety Committee, this review may be conducted at any time, but the research may not be initiated until the nonresearch*

*committee has approved it, the R&D Committee has completed its review at a convened meeting, and the investigator is notified of the approval.*

4.12 **“Just-In-Time” Procedures.** *“Just-In-Time” procedures allow research projects to be submitted for funding consideration prior to receiving final R&D Committee approval to conduct the research. Research protocols that are to be submitted to VA for funding consideration must undergo a preliminary review and receive concurrence from the R&D Committee prior to submission of the protocol to VA under a “Just-In-Time” procedure.*

1) *During this preliminary review, the R&D Committee must assess the appropriateness of the scientific methodology, the relevance of the research to VA’s mission, the investigator qualification to conduct the research, and adequacy of the resources.*

2) *In its preliminary review of the application the R&D Committee must consider items described in item 1 (above).*

3) *Concurrence of the R&D Committee does not represent approval to conduct the research. The investigator must submit the protocol to the R&D Committee for formal approval to initiate the research. If the protocol requires IRB, IACUC, and/or Subcommittee on Research Safety (Biosafety) review, the protocol must be submitted to those subcommittees prior to submitting it to the R&D committee.*

## **5.0 FUNCTIONS**

5.1 *All protocols that come before the R&DC for initial review will receive a scientific review. The RDPM and the R&DC Chair will select a scientific reviewer who is an expert in the area that the protocol addresses. All of the reviewers receive a critique sheet (see attachment) that indicates what they should be looking for while doing the review. Each reviewer should provide a written review.*

5.2 *The R&D Committee shall meet at least monthly, except for 1 month during the summer if it appears that a quorum cannot be obtained. A quorum (a majority of voting members) must be present to conduct business.*

5.3 *An agenda should be developed before each meeting of the R&D Committee and distributed to members at least 3 working days before the meeting whenever possible. At a minimum, the agenda should include the following:*

1) *Approval of minutes of previous meeting (date).*

2) *Unfinished business (list pending items and individual responsible).*

- 3) *New business (identify individual responsible when necessary).*
  - a) *Standing recurring reports (identify individual responsible).*
  - b) *Issues not previously addressed by the body.*
  - c) *Any other item that warrants review/discussion by the committee and is not routinely reviewed by such.*
- 4) *Announcements.*
- 5) *Date, time, and place of the next meeting.*

5.4 *Minutes of all committee meetings shall be recorded. The minutes document attendance or absence of members and provide a complete record of all items of business or information brought before the committee. Motions presented to the committee shall be recorded verbatim to include the action taken by the committee. Votes on motions shall be reported to indicate whether the action is unanimous or by divided vote with a statement of the number of members voting for and against the motion. Minutes of all R&D Committee meetings shall be recorded in the following format:*

- 1) *Identification of the R&D Committee to be centered at the top of the page, including VA medical center name and number.*
- 2) *The first paragraph should include:*
  - a) *Place, date and time of the meeting.*
  - b) *Name of presiding officer (chairperson).*
  - c) ***List of attendees.*** *The attendance record will list all individuals identified as members. Members will be marked **ABSENT** if Chairperson or recorder has not been notified in advance. Members will be marked **EXCUSED** if the Chairman or recorder was notified in advance.*
- 3) *Succeeding paragraphs should identify the recommendations, date of the meeting when the recommendation was initially made, action taken to date or a realistic date to expect resolution and the status as **CLOSED** or **PENDING**.*

***NOTE:*** *A recommendation should not be carried for more than 2 meetings awaiting a resolution; otherwise, there must be clear documentation that a plan of action is being followed and an anticipated date for resolution is noted.*

4) *Minutes shall not be recorded verbatim except for recommendations. The substance of the discussion shall be reported clearly and concisely. After summation of the discussion, the minutes shall reflect:*

- a) **Conclusion:** *What was concluded from the discussion? (Example: "The follow-up action plan was ineffective, and the issue is not considered resolved at this time.") If analysis of the data occurred in the meeting, then the conclusion of the analysis should be in the minutes.*
- b) **Recommendation:** *Include who or what is expected to change.*
- c) **Action:** *Include what action is appropriate in view of the cause, scope, and severity of the problem and who is responsible for implementing the action.*
- d) **Follow-Up/Evaluation:** *Identify the date a status report is due on the action plan, the date the action plan will be implemented, or the date the action plan will be evaluated for accomplishment of expected outcome/impact of changes made.*

5) *Minutes shall be signed by both the chairperson and the executive secretary and are submitted to the Medical Center Director/CEO, the COS, and the Clinical Executive Board for review and signature. No later than 3 weeks after each committee meeting, copies of the minutes, together with any comments the Medical Center Director/CEO may care to make, will be distributed to all members of the committee and made available upon request to any investigator.*

Note: Research is a systematic investigation designed to contribute to generalizable

6) *Minutes shall be maintained by the local research office and made available to VHA Headquarters upon request.*

  
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R. Amanda C. LaRue, Ph.D.  
Associate Chief of Staff for Research

## APPENDIX A: RESEARCH SUBMISSION PROCESS FLOWCHART

### Research Submission Process

