# THE RESEARCH AND DEVELOPMENT (R&D) COMMITTEE HANDBOOK

**1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook establishes the responsibilities for, and operations of, the Research and Development (R&D) Committee, which functions at the facility level.

**2. SUMMARY OF MAJOR CHANGES.** This Handbook is a major revision to the current VHA procedures governing the Research and Development's responsibilities and operations. It also addresses emerging issues and recent concerns related to research including information security, and credentialing and privileging of physicians and other applicable research employees. The provisions of the Handbook must be implemented no later than July 31, 2007.

**3. RELATED DIRECTIVE.** VHA Directive 1200.

**4. RESPONSIBLE OFFICE.** The Office of Research and Development (12) is responsible for the contents of this VHA Handbook. Questions may be addressed to (202) 254-0183.

**5. RESCISSION.** This VHA Handbook rescinds M-3, Part 1, Chapters 2 and 3.

**6. RECERTIFICATION**. This VHA Handbook is scheduled for recertification on, or before, the last working date of January 2012.

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## THE RESEARCH AND DEVELOPMENT (R&D) COMMITTEE HANDBOOK

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# THE RESEARCH AND DEVELOPMENT (R&D) COMMITTEE HANDBOOK-

## 1. PURPOSE

This Veterans Health Administration (VHA) Handbook establishes the responsibilities for, and operations of, the Research and Development (R&D) Committee, which functions at the facility level.

## 2. BACKGROUND AND SCOPE

a. Every Department of Veterans Affairs (VA) facility conducting research must have, or establish, an R&D Committee. A VA facility may also secure the services of an R&D Committee from another VA facility, from the Veterans Integrated Service Network (VISN), a regional VA R&D Committee that serves multiple VA facilities, or other VA entity through the use of a written agreement that describes the responsibilities of all parties. Renewal of the agreement must comply with the Office of Research and Development (ORD) established time frames or it is to be automatically terminated. If terminated, that committee may no longer serve as the R&D Committee for the facility. ***NOTE:*** *Guidelines for all such written agreements are to be found on the ORD web site at* http://www.research.va.gov .

b. 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. Those standards include ensuring the scientific and ethical quality of VA research projects, the protection of human subjects in research, the safety of personnel engaged in research, the welfare of laboratory animals, security of VA data, and the security of VHA research laboratories. ***NOTE:*** *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, utilizing VA resources, and/or on VA property including space leased to, and used by, VA. The research may be funded by VA, by other sponsors, or be unfunded.*

(1) The R&D Committee is assisted by the Associate Chief of Staff (ACOS) for R&D and the Administrative Officer (AO) for R&D in carrying out its duties. ***NOTE:*** *In small research programs a Research Coordinator may be appointed in lieu of an ACOS for R&D.* The R&D Committee assists the medical center Director on professional and administrative procedures involving the R&D Program.

(2) Research in which the facility is to be engaged may not be undertaken without review and approval of the R&D Committee and its appropriate subcommittees.

(3) The R&D Committee may serve as the R&D Committee of record for another VA facility. In doing so, it must fulfill all R&D Committee responsibilities for that VA facility including oversight of its subcommittees. The R&D Committee may not serve as the R&D Committee of a non-VA institution.

## 3. DEFINITIONS

a. **VA Data or VA Information.** VA data or VA information is all information that is obtained, developed, or produced by, or for VA or its employees as part of its business activities.

b. **VA Protected Information (VAPI).** VAPI is VA sensitive information, Privacy Act Information (PAI), Protected Health Information (PHI), or other VA information that has not been deliberately classified as public information for public distribution. VA information that VA would have to release under the Freedom of Information Act (FOIA) is not VA protected information. All VA protected information needs to be classified as one of the following: VA Proprietary, VA Restricted, or VA Highly Restricted.

c. **VA Sensitive Information.** VA sensitive information is all Department data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provision such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and information that can be withheld under FOIA. Examples of VA sensitive information include:

(1) Individually-identifiable medical, benefits, and personnel information;

(2) Financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, investigatory, and law enforcement information;

(3) Information that is confidential and privileged in litigation, such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege; and

(4) Other information which, if released, could result in violation of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of federal programs.

## 4. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR

The medical center Director is responsible for:

a. The R&D facility's R&D Program, and is assisted by an R&D Committee. The medical center Director serves as the Institutional Official responsible for all aspects of the research program. ***NOTE:*** *The term medical center Director includes Chief Executive Officer or equivalent titles.*

b. Retaining institutional responsibility for the research program at the facility if the facility's R&D Committee of record is that of another VA facility.

c. Ensuring that research in which the facility is engaged is approved by the R&D Committee.

d. Ensuring there are adequate resources and administrative support, including personnel, space, and equipment, for the R&D Committee and its subcommittees to fulfill their responsibilities.

e. Providing appropriate educational and training opportunities for members of the R&D Committee, the research administration staff, and other staff envolved in research.

## 5. RESPONSIBILITIES OF THE INVESTIGATOR

Investigators are responsible for:

a. Holding specific credentials and privileges awarded by the VA facility and VHA (where applicable) to conduct research in VA. Investigators must be qualified through education and experience.

b. Complying with all applicable personnel and other VHA policies, whether the investigator is compensated, WOC, or IPA.

c. Obtaining the R&D Committee and its appropriate subcommittee approvals prior to initiating research.

d. 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 to fully review the research project. Information on such issues as budgetary issues and/or needs, source of funding, space, and required personnel needs must also be submitted for review.

e. Developing and implementing plans for data use, storage, and security that is consistent with VA, VHA, and other Federal statues, regulations, and policies.

f. Preparing and submitting information annually on their research program(s) and on each project to the R&D Committee that allows the R&D Committee to review the progress of the research, the use of resources, and any problems, serious events, or need for further resources. This information may be in the form of the Institutional Review Board (IRB) continuing review of applications for human studies, the Institutional Animal Care and Use Committee (IACUC) continuing review of applications for animal studies, or as otherwise specified by the R&D Committee.

## 6. MEMBERSHIP

a. 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.

b. The R&D Committee must consist of at least five voting members. Whenever possible, one member of the Committee needs to have expertise in biostatistics and research design. If the facility has any Centers, such as Centers of Excellence, (e.g., Health Services Research and Development (HSR&D), Rehabilitation Research and Development (RR&D), or Cooperative Studies Program (CSP) Centers), it is recommended, but not required, that at least one voting member of the R&D Committee be chosen from the Center. ***NOTE:*** *Further guidance on Centers being represented on the R&D Committee may be obtained from ORD.* The members need to have diverse backgrounds with consideration as to race, gender, ethnicity, and expertise. Voting members of the R&D Committee must include:

(1) At least two members from the VA facility's staff who have major patient care or management responsibilities.

(2) At least two members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise.

(3) In facilities affiliated with academic institutions, at least one member who holds an academic appointment, and is either a full-time Federal employee or a part-time permanent Federal employee.

c. All voting members must be compensated full-time or permanent part-time Federal government employees.

d. 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.

e. If the facility conducts research involving the use of investigational drugs, consideration needs to be given to including a representative from the investigational pharmacy or Pharmacy Service as either an ex officio nonvoting member or a voting member.

f. If the R&D Committee serves as the R&D Committee of another VA facility, it is recommended, but not required, that at least one representative from that other facility be included. The representative will be appointed by the other facility's medical center director and the medical center director of the facility having responsibility for the R&D Committee will concur on the appointment.

g. Ad hoc members may be invited to assist the R&D Committee because of their competence in special areas in the review of issues requiring expertise beyond, or in addition to, that available on the Committee. Such ad hoc members may not contribute to a quorum or vote with the Committee. Unless the ad hoc members are permanent VA or Federal employees, they may only provide <u>individual</u> advice to the R&D Committee, or exchange facts and information.

h. Ex-officio (non-voting) members include the medical center Director, the COS, the ACOS for R&D, the AO for R&D, and compliance officers (or those who are responsible for compliance) of the facility. The ACOS for R&D functions as Executive Secretary of the Committee. Other ex-officio members may be appointed to the Committee if their appointments

assist the R&D Committee in fulfilling its responsibilities. If the ex-officio members are not full or permanent part-time compensated VA or Federal employees, they may only provide individual advice to the R&D Committee, or exchange facts and information.

i. Alternate members, if any, serve if they are formally appointed as alternate members. The R&D Committee's written procedures must describe the appointment process and the functions of alternate members. 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. If the alternate member and the primary member both attend an R&D Committee meeting, only the primary member may vote and only the primary member counts towards the quorum.

j. Voting members are appointed by the medical center Director in writing and serve terms of 3 years. Members may be reappointed without any lapse in time if it is deemed in the Committee's best interest. If the R&D Committee is the R&D Committee for a second VA facility, the medical center Director of the second facility must appoint its representative(s), when applicable. The terms of members must be staggered to provide partial change in membership annually.

k. Committee members, exclusive of ex-officio members, must 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.

l. All members of the R&D Committee must fulfill the educational requirements specified by VHA's ORD and other applicable Federal regulations found on ORD's web site at: www.research.va.gov.

m. It is recommended, but not required, that at least one member from each of the following serve on the R&D Committee: the IACUC, the Biosafety Committee, the IRB, the Scientific Review Subcommittee, the Continuing Review Committee, and other subcommittees of the R&D Committee.

n. Where applicable, other ORD policies may require that additional members be included on the R&D Committee.

## 7. CONFLICT OF INTEREST

The mission of ORD is to discover knowledge, develop VA researchers and health care leaders, and create innovations that advance health care for the nation's veterans and the nation. In order to fulfill this mission, VHA must preserve public trust in the integrity and quality of research carried out by its investigators and in its facilities. One way to maintain

public trust and safeguard the integrity and quality of VA research is to ensure that VA investigators and members of R&D Committees avoid actual or perceived financial conflicts of interest in the research they conduct or review.

a. Like all VA employees, 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 a R&D Committee. R&D Committee members and VA investigators must also comply with future 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.

b. 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.

c. 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.

***NOTE:*** *To get help assistance in these matters, individual researchers and R&D Committee members may contact either the local Regional Counsel, or ethics officials in the VA Central Office, Office of General Counsel. The ethics staff in VA Central Office can be reached by phone at (202) 273-6334 or 6335, by FAX at (202) 273-6403, or by mail at the following address:*

*Office of the General Counsel (023)*
*VA Central Office*
*810 Vermont Avenue, NW*
*Washington, D.C. 20420*

e. The Office of General Counsel (OGC) maintains a web site with information on ethics at http://vaww.gc.va.gov/law/employment/ethics/index.htm**.** For further information on the subjects, a web site based course addressing financial conflict of interest in research is available and more information may be found by contacting ORD.

## 8. SUBCOMMITTEES OF THE R&D COMMITTEE

a. The R&D Committee may establish any subcommittee(s) deemed necessary for the efficient and effective management and oversight of the R&D Program. At a minimum,

subcommittees must be appointed to oversee R&D activities related to human studies, animal studies, and biosafety including biosecurity. Other subcommittees that assist the R&D Committee fulfill its responsibilities may include a: Scientific Review Subcommittee, Continuing Review Subcommittee, and Research Space Subcommittee. Subcommittee members may be compensated Federal employees, WOC, or IPAs. Findings and recommendations of the subcommittees are recorded and reported to the R&D Committee.

(1) **Human Studies.** Every VA facility conducting research involving human subjects must have, or must establish an IRB, or the facility must secure the services of an IRB as described in VHA Handbook 1200.5.

(2) **Animal Studies.** Every VA facility conducting research involving the use of live vertebrate animals must establish an IACUC, or secure the services of an IACUC as allowed in VHA Handbook 1200.7.

(3) **Safety and Security.** Every VA facility conducting research must 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 all VHA research laboratories, as required in VHA Handbook 1200.8, and other applicable regulations and policies. ***NOTE:*** *Biosecurity issues may be assigned by the R&D Committee to another subcommittee or retained by the R&D Committee.*

(4) **Scientific Review Subcommittee.** The R&D Committee may establish a Scientific Review Subcommittee. This subcommittee's membership must include at least three members with scientific training, and the members must be knowledgeable about research methodology, the review of research projects, the R&D Program, and the local facility's environment. The Scientific Review Subcommittee's major responsibility is the scientific review of all new research projects and programs. Ad hoc experts may be used as needed.

(5) **Continuing Review Subcommittee.** This subcommittee may be established by the R&D Committee, and may establish a Continuing Review Subcommittee. This subcommittee must include at least three voting members of the R&D Committee, including at least one investigator and one individual with patient care or management responsibilities (see subpar. 10d).

b. Members of the subcommittees may serve as members of the R&D Committee. If a subcommittee does not have one of its members serving as a member of the R&D Committee, the subcommittee needs to designate a member to serve as a liaison with the R&D Committee. ***NOTE:*** *As stated in subpar. 8a(5), all members of the Continuing Review Subcommittee must be voting members of the R&D Committee.*

c. In lieu of establishing a subcommittee, the R&D Committee may obtain these services from another VA, from an academic affiliate's institution, or from other sources as allowed by VA policies. The committees that function in lieu of a subcommittee must follow all requirements for an internal subcommittee. The facility's representative to these "in lieu of" committees must be appointed by the facility's medical center Director. For the purposes of this Handbook, the committees that function in lieu of a subcommittee are to be referred to as subcommittees. These subcommittees must:

(1) Fulfill all requirements and responsibilities of the subcommittee it replaces and must agree to fulfill these responsibilities in accordance with VHA policies.

(2) Be established through a Memorandum of Understanding (MOU) or other written agreement which defines definitions for all roles and responsibilities of each party. The agreement must include how the affiliate's or other VA committee(s) report information to the R&D Committee, including information on adverse events, research misconduct, research impropriety, conflict of interest, privacy concerns, and security concerns including data security. The written agreement must either be renewed within the time frame required by ORD, or it is automatically terminated. If terminated, the "in lieu of" subcommittee may no longer serve as a subcommittee of the facility's R&D Committee. If it is a required subcommittee, then the facility must establish the subcommittee, develop another MOU, or obtain the services of another "in lieu of" subcommittee as required by this Handbook.

d. Each subcommittee must maintain adequate records, which are to be maintained until expiration of the authorized retention period, a minimum of 5 years. These records must include the following:

(1) Copies of all research proposals and their amendments reviewed by the Committee and any accompanying materials.

(2) All continuing or final reports.

(3) Minutes of its meetings.

(4) Copies of all written correspondence.

(5) A membership list of all voting, non-voting, and ex-officio members including their appointed roles.

(6) Written records documenting actions taken to carry out the Committee's responsibilities.

(7) Standard Operating Procedures (SOPs).

(8) All communications to and from investigators, other committees, subcommittees, and other entities or individuals.

***NOTE:*** *To decrease redundancy and increase efficiency, some of these required subcommittee records may be maintained elsewhere, such as with the R&D Committee records. If they are maintained in such a way, the R&D programs operating procedures must indicate this so that documentation can be retrieved.*

e. Each subcommittee must make available to the R&D Committee a complete, unredacted set of minutes (draft or final) prior to the R&D Committee meeting, at which the protocols listed and other information contained within the minutes are to be discussed. ***NOTE:*** *If other VHA policies require a more stringent requirement, that requirement must be followed.*

(1) If draft minutes are submitted, formally-approved minutes must be sent to the R&D Committee prior to the following R&D Committee meeting.

(2) If the approved minutes differ substantially from the draft minutes, the subcommittee must ensure the R&D Committee considers whether the difference would alter any R&D Committee decisions that were based on the draft minutes.

f. Copies of all written subcommittee correspondence to and from VA investigators must be sent to the R&D Committee or VA research office at the facility.

g. Research records may be electronic or paper. When original signatures are required on documents, either a paper copy of the signature sheet must be maintained or an electronic signature may be used. If an electronic signature is used, it must meet all of the requirements of VA, the Office of Human Research Protection, the Food and Drug Administration (FDA), and any other Federal requirements.

## 9. R&D COMMITTEE RESPONSIBILITIES RELATED TO THE FACILITY'S RESEARCH PROGRAM

The R&D Committee assists the medical center Director in fulfilling responsibilities for the facility's research program. The 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. The R&D Committee must accomplish its responsibilities through the following activities or procedures:

a. Planning and developing broad objectives for the R&D Program so that it supports VA's mission.

b. Determining the extent to which the R&D Program has met its objectives.

c. Reviewing the budgetary and other resource needs of the R&D Program, 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.

d. Overseeing all R&D activities for each VA facility for which it serves as the R&D Committee of record.

e. Reviewing all written agreements that establish:

(1) A committee from another VA or non-VA entity in lieu of a required committee or subcommittee for the R&D Committee.

(2) The R&D Committee, or one of its subcommittees, that functions as a committee or subcommittee of another VA facility.

f. 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.

g. 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:

(1) 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.*

(2) An annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation.

(3) 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.

(4) 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.

(5) 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.

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

(7) 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.

(8) 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.

h. Fulfilling such other functions as may be specified by the medical center Director and VHA procedures.

## 10. R&D COMMITTEE RESPONSIBILITIES FOR THE REVIEW OF RESEARCH

a. The R&D Committee is responsible for reviewing all research for scientific quality and appropriateness in which the facility is to be engaged, and for all R&D within all VA facilities for which it serves as the R&D Committee of record to promote the:

(1) Maintenance of high scientific standards,

(2) Protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel.

(3) Welfare and appropriate use of animals in research.

(4) Safety of personnel engaged in research.

(5) Security of research laboratories where hazardous agents are stored or utilized and of all Biosafety Level 3 (BSL-3) research laboratories.

(6) Security of VA data, VAPI, and VA sensitive information.

(7) Availability of adequate resources (financial and other) to conduct and complete the research.

(8) Relevance of research to, and in support of, VHA's mission.

b. Each research project, including those within all facility research programs and research centers, must be reviewed and approved initially and at least annually thereafter. The period for continuing review must be determined as part of the initial review. The continuing review period for studies reviewed by the IRB or IACUC may be established by those subcommittees. The R&D Committee as a whole may review research proposals or may establish a Scientific Review Subcommittee. In conducting its review, the R&D Committee must consider the findings of its subcommittees. ***NOTE:*** *Paragraph 10k defines the R&D Committee's responsibilities for review of protocols that must be submitted for funding under a "Just In Time" procedure.*

c. An initial review of projects requires a review by a convened meeting at which there is a quorum consisting of a majority of voting members of the R&D Committee. ***NOTE:*** *A Scientific Review Subcommittee may review the projects and present its findings to the R&D Committee for final approval.*

(1) In conducting an initial review, 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. ***NOTE:*** *VA data, VA sensitive information, and VAPI are defined in paragraph 3.*

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

(3) The initial approval of research requires a majority vote of the convened quorum.

(4) The initial approval of research must include a specific approval period, not to exceed 1 year.

d. A continuing review of research may be conducted by the full R&D Committee or by a Continuing Review Subcommittee. In either case, continuing review must be conducted in accordance with the written operating procedures established by the R&D Committee.

(1) Continuing review of research may occur during a convened meeting or through other mechanisms described in the R&D Committee's written operating procedures.

(2) A continuing review must assess the research activities that have occurred, the progress of the research, and any issues that may impact on the progress of the research including compliance issues.

(3) A continuing approval of research requires a majority vote of the members of the committee conducting the continuing review (Continuing Review Subcommittee or the R&D Committee) in accordance with the R&D Committee's written operating procedures. A quorum (a majority of voting members) must be present during the vote.

(4) Continuing approval of research must include a specific approval period, not to exceed one year.

(5) Continuing approvals must be presented to the R&D Committee for concurrence and must be included in R&D Committee meeting minutes.

e. 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.

***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 can not approve a study that is disapproved by the IRB but the R&D Committee may disapprove a study approved by the IRB. If the research does not involve human subjects as defined by Title 38 Code of Federal Regulations (CFR) 16, primary responsibility for review resides with the R&D Committee.*

f. The R&D Committee may approve, approve with conditions, or disapprove a research project, program, or center. The final 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.

(1) If the R&D Committee initiates its review prior to all required subcommittees granting approval, the R&D Committee may conditionally approve the protocol pending the approval of the subcommittee(s).

(2) If the subcommittee does not require any significant changes to the protocol, the Chairperson of the R&D Committee, or the Chairperson's designee who is a voting member of the committee, must review the subcommittee's findings and may grant final approval for the R&D Committee. The R&D Committee must be notified of this action at the next convened meeting.

(3) If the subcommittee has required significant changes to the protocol, the protocol including the changes, must be reviewed by the R&D Committee at a convened meeting.

g. If a subcommittee of the R&D Committee disapproves the research project, program, or center, the R&D Committee may not approve it.

h. 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.*

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

k. **"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, other Federal agencies, or other entities for funding consideration must undergo a preliminary review and receive concurrence from the R&D Committee prior to submission of the protocol to VA or other Federal agencies or entities 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) The R&D Committee must develop SOPs for the preliminary review. SOPs may include the requirement for full-board review or an expedited review procedure.

(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.

## 11. R&D COMMITTEE OPERATIONS

a. The R&D Committee must meet at least monthly, except for one month during the year, if it appears that a quorum cannot be obtained. VHA recommends, but does not require, that R&D Committee members be physically present at the meeting.

b. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In that case, the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions.

c. The R&D Committee may develop procedures that would allow the committee to hold unscheduled meetings in response to emergent issues. There must be a quorum present in person or by teleconference or video conference for any unscheduled meetings. A quorum, i.e., a majority of voting members, must be present to conduct business and must be present for each vote.

d. Minutes for each meeting must be recorded. The minutes need to include the following information:

(1) A list of all voting members and non-voting members, including ex officio members, indicating the category of their membership 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.

(2) The presence of a quorum.

(3) Actions taken by the Committee, to include:

(a) The type of action.

(b) The vote on the action, including the number voting for, against, and abstaining. In addition, any recused member from the vote must be named, and whether the person was

present during the discussion, and the vote must be noted. ***NOTE:*** *If the member decided to be recused, the member must not be present for the discussion or vote.*

(c) The basis for requiring changes to a research project, program, or center to obtain approval.

(d) Any required follow-up and which committee, subcommittee, or person is responsible for the follow-up.

(e) The basis for disapproving a research project, program, or center when this occurs.

(f) Action taken on minutes submitted to the Committee if not recorded in other R&D Committee records.

(4) 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 medical center Director through the ACOS for R&D and COS for review and appropriate action. They may also be sent through other committees such as Executive Committee of the Medical Staff or the Executive Leadership Committee.

e. The PI must be notified in writing of the R&D Committee's decision to approve, approve with conditions, disapprove a proposed research activity, or if modifications are required to secure R&D approval. The PI must be notified in writing of the results of the R&D Committee's annual review of the project. If the R&D Committee disapproves or requires modifications of proposed research to obtain approval, the appropriate committees or subcommittees that also reviewed the protocol (e.g., IACUC, IRB, Research Safety and Radiation Safety), must be notified in writing. ***NOTE:*** *If modifications are required by the R&D Committee, the applicable subcommittees must review and approve the amendment prior to the amendment being initiated.*

f. SOPs or other written procedures must be maintained for all recurring processes. These processes include, but are not limited to: review of protocols and/or communication with the medical center Director, the COS, investigators, and other committees; and subcommittees.

g . Review of subcommittee operations must be conducted as an ongoing function of the R&D Committee. That review needs to 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/or Quality Improvement activities.

## 12. R&D COMMITTEE RECORDS

a. The adequate documentation of all the activities of the R&D Committee must be maintained, including, but not limited to, the following:

(1) Copies of all research proposals, all amendments reviewed, and any accompanying materials.

(2) All continuing and final reports.

(3) Minutes of the R&D Committee and subcommittees.

(4) Copies of all written correspondence.

(5) Membership lists for the R&D Committee and all subcommittees.

(6) Written records documenting actions taken to carry out the committees' responsibilities for review of research as listed in paragraph 10, and for oversight of the research program as listed in paragraph 9, if not recorded adequately in the R&D Committee minutes.

b. Records are the property of VA and must be maintained for a minimum of 5 years. ***NOTE:*** *Record retention may be longer depending upon other policies and regulations such as Food and Drug Administration (FDA) regulations or medical record retention policies.*

**13. REFERENCES**

a. Title 38 CFR 16.

b. VHA Handbook 1200.5.

c. VHA Handbook 1200.06.

d. VHA Handbook 1200.7.

e. VHA Handbook 1200.8.

f. VA Directive 6504

g. VHA Handbook 1605.1

h. VA Handbook 5011/5

i. VA Directive and Handbook 6102

j. VA IT Directive 06-02

k. It Directive Memorandum 06-05

l. IT Directive Memorandum 06-06

m. VA Directive 6210

n. VA Directive 6212

o. VA Directive 6502

p. VA Handbook 6502.1

q. VA Handbook 6502.2

r. VA Directive 6504

s. VHA Directive 2004-002