

RESEARCH AND DEVELOPMENT (R&D) COMMITTEE

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

a. This Handbook is a major revision to the current VHA procedures governing the R&D Committee'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.

b. The major change in this revision allows the R&D Committee to focus on oversight of the local research program rather than individual protocols. This is accomplished by permitting the R&D Committee to assign scientific review and some administrative responsibilities, including compliance issues, to more appropriate subcommittees and individuals. These changes enable the R&D Committee to prioritize their deliberations around broad areas of program development, risk management, and quality and performance activities.

c. In addition, the R&D Committee is no longer required to review individual protocols.

3. RELATED ISSUES. VHA Directive 1200.01.

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) 461-1703.

5. RESCISSION. VHA Handbook 1200.01, dated April 9, 2009, is rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on, or before, the last working date of June 2014.

Gerald M. Cross, MD, FAAFP
Acting Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Publication Distribution List 6/19/09

CONTENTS

RESEARCH AND DEVELOPMENT COMMITTEE

PARAGRAPH	PAGE
1. Purpose	1
2. Background	1
3. Definitions	1
4. Scope	2
5. Responsibilities of the Medical Center Director	3
6. Responsibilities of the Chief of Staff (ACOS) and Administrative Officer (AO) for R&D	3
7. Responsibilities of the ACOS for R&D.....	4
8. Responsibilities of the Investigator	4
9. Responsibilities of the R&D Committee	5
10. R&D Committee Responsibilities for the Review of Research	6
11. R&D Committee Operations	7
12. R&D Committee Records	8
13. R&D Committee Membership	9
14. Subcommittees of the R&D Committee	11
15. Conflict of Interest	13
16. References	14

RESEARCH AND DEVELOPMENT COMMITTEE

1. PURPOSE

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

b. The major change in this revision allows the Research and Development (R&D) Committee to focus on oversight of the local research program rather than individual protocols. This is accomplished by permitting the R&D Committee to assign scientific review and some administrative responsibilities, including compliance issues, to more appropriate subcommittees and individuals. These changes enable the R&D Committee to prioritize their deliberations around broad areas of program development, risk management, and quality and performance activities.

2. BACKGROUND

The research mission of the Department of Veterans Affairs (VA) is conducted within individual VA medical centers according to the highest ethical standards with accountability to all involved stakeholders. Responsibility for oversight and maintaining high standards is assigned to the R&D Committee.

3. DEFINITIONS

a. **VA Data or VA Information.** VA data or VA information owned or in the possession of VA or any entity acting for, or on behalf of VA.

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

c. **VA Sensitive Information.** VA sensitive information is all VA 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 (VA Handbook 6500). 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 provisions such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and information that can be withheld under the Freedom of Information Act (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. SCOPE

a. Every VA facility conducting research must have, or establish, an R&D Committee of record. 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 roles and responsibilities of all parties. Renewal of the agreement must occur 60 days prior to the review of proposals by R&D subcommittee or it is to be automatically terminated. If terminated, that committee may no longer serve as the R&D Committee of record for the facility.

b. The R&D Committee is responsible, through the Chief of Staff (COS) to the medical center Director for:

(1) Advising and assisting the medical center Director in providing oversight, planning, and execution of the local research Program; and

(2) Assisting the medical center Director in maintaining high standards throughout the R&D Program. Those standards include ensuring the:

(a) Scientific and ethical quality of VA research projects;

(b) Protection of human subjects in research;

(c) Safety of personnel engaged in research;

(d) Welfare of laboratory animals;

(e) Security of VA data; and

(f) Security of VHA research laboratories.

c. 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. For purposes of this Handbook "ACOS for R&D" includes the Research Coordinator.*

d. Research in which the facility is to be engaged may not be undertaken without review and written approval of all appropriate subcommittees of the R&D Committee. The investigator must not initiate a research project until after being notified in writing by the ACOS for R&D that the project has been approved by all relevant committees, subcommittees, or other entities. The Institutional Review Board (IRB), Subcommittee on Research Safety (SRS), Animal Care and Use Committee (IACUC) and other such entities must notify the R&D Committee of project approvals via a written communication signed by a voting committee member for the committee. The R&D Committee must notify the Associate Chief of Staff (ACOS) for R&D of project approvals via a written communication signed by a voting R&D Committee member for the committee. Notifications need not be in the form of minutes, nor is a separate document needed for each approved project. A single memorandum that lists by title, project number, or similar unique identifier all of the protocols receiving final approval at a given meeting is sufficient. Once R&D Committee approval has been given, the research becomes VA approved research.

e. 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.

5. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR

The medical center Director, acting in the capacity of the Institutional Official, is responsible for:

a. The facility's research 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 including but not limited to: human subjects protection, animal welfare care and use, privacy and security of VA data, and biosafety. *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 appropriate R&D Committee subcommittees.

d. 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.

e. Ensuring appropriate education and training for members of the R&D Committee, the research administration staff, and other staff involved in research.

f. Ensuring that investigators meet the requirements of Paragraph 8.

g. Appointing the members of the R&D Committee following the specifications in Paragraph 13.

6. RESPONSIBILITIES OF THE CHIEF OF STAFF AND ADMINISTRATIVE OFFICER FOR R&D

The primary responsibilities of the COS and AO for R&D are defined in the VHA Handbook 1200 series.

7. RESPONSIBILITIES OF THE ACOS FOR R&D

The ACOS for R&D is responsible for:

a. Notifying the investigator when a research project can be initiated. This notification occurs only after the research project has been approved by all applicable R&D Committee subcommittees, and after the R&D subcommittees' notifications of approvals have been approved by the R&D Committee. The ACOS for R&D is responsible for notifying the investigator of approval after continuing review by the R&D Committee and subcommittees.

b. Functioning as Executive Secretary of the R&D Committee.

c. Conducting an annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation.

d. 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.

e. 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.

f. 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.

g. Ensuring that all minutes of the R&D Committee and its subcommittees, including those from subcommittees at VA facilities or at the affiliate, are sent to the medical center Director and COS for review and appropriate action.

8. RESPONSIBILITIES OF THE INVESTIGATOR

The investigator is responsible for:

a. 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.

- b. Complying with all applicable personnel and other VA requirements whether the investigator is compensated, WOC, or IPA.
- c. Obtaining the complete approval of all appropriate non-research entities and R&D Committee subcommittees, and written notification from the ACOS for R&D prior to initiating a research project.
- 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 subcommittees to fully review the research project.
- e. 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.
- f. Preparing and submitting information, at least annually or as required, on their research program(s) and on each project to the appropriate R&D Committee subcommittee for continuing review as required by the respective R&D Committee subcommittees.
- g. 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. *NOTE: Examples of research that may not support the mission of VHA includes research involving children or prisoners.*

9. RESPONSIBILITIES OF THE R&D COMMITTEE

- a. 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 through oversight of the R&D Committee's subcommittees and making appropriate recommendations, including space and resource needs, to the medical center Director based on the Committee's oversight and evaluation of the research program.
- b. The R&D Committee must accomplish its responsibilities through the following activities or procedures:
 - (1) Planning and developing broad objectives for the research program so that it supports VA's mission;
 - (2) Determining the extent to which the research program has met its objectives;
 - (3) Overseeing all research activities for each VA facility for which it serves as the R&D Committee of record; and
 - (4) Reviewing all written agreements that establish:

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

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

(5) Reviewing and evaluating all R&D subcommittees both within the VA facility and at external entities that function in lieu of R&D subcommittees, such as affiliate Institutional Review Boards (IRBs), Institutional Animal Care and Use Committee (IACUC), or biosafety committees. A summary of these reviews and evaluations must be sent to the medical center Director annually.

c. In fulfilling its responsibilities of ensuring the effective oversight of the research program and making appropriate recommendations to the medical center Director, including the suspension of a research study or remedial or restrictive action regarding a principal investigator, the R&D Committee needs to rely on a variety of information sources including:

(1) 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.

(2) Review of subcommittee activities including:

(a) Annual reviews of the Research Safety and Security Program (including planned training, compliance, security issues, etc.);

(b) 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); and

(c) 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).

d. The R&D Committee is responsible for fulfilling such other functions as may be specified by the medical center Director and VHA procedures. These functions may include review and approval of individual research projects. *NOTE: The R&D Committee may not approve human subjects' research if it has not been approved by an IRB (see Title 38 Code of Federal Regulations section 16.112).*

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

a. The R&D Committee is responsible for establishing policy to ensure that all research in which the facility is to be engaged has been reviewed and approved for the ethical use of human subjects, animals, and biohazards. This review must promote:

(1) Maintenance of high standards of protocol review, and relevance to the mission of VA;

- (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; and
- (6) Security of VA data and VA sensitive information.

b. If a research protocol requires review by a facility's non-research entities, 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 entity has approved the project, and the project has been approved by all applicable R&D Committee subcommittees, and the investigator has been notified in writing by the research office.

c. For protocols not meeting criteria for assignment to any subcommittee, the R&D Committee is the review and approving committee of record.

d. Concurrence of the R&D Committee or subcommittee under a just in time review process does not represent approval to conduct the research. The investigator must submit the protocol to all applicable R&D Committee subcommittees and any other relevant committees or entities, and have written approval before initiating the research.

11. R&D COMMITTEE OPERATIONS

a. The R&D Committee must meet at least monthly, except for 1 month during the year, if it appears that a quorum (i.e. a majority of voting members) cannot be obtained. VHA recommends, but does not require, that R&D Committee members be physically present at the meeting. 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.

b. The R&D Committee may develop procedures that allow the Committee to hold unscheduled meetings in response to emergent issues.

(1) There must be a quorum present in person or by teleconference or video conference for any unscheduled meetings.

(2) A quorum must be present to conduct business and must be present for each vote.

c. 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. *NOTE: If the member is recused, the member must not be present for the vote, and may not be counted toward the quorum.*

d. 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. Standard operating procedures or other written procedures must be maintained for all recurring processes. These processes include, but are not limited to, communication with the medical center Director, the COS, investigators, and committees or subcommittees.

f. Review of R&D Committee 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.

12. R&D COMMITTEE RECORDS

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

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

(2) Copies of all written correspondence.

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

b. 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. **NOTE:** *Records are the property of VA and the policy for record retention is outlined in VHA Records Control Schedule (RCS) 10-1. 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. R&D COMMITTEE MEMBERSHIP

a. **Appointment of Members.** The members of the R&D Committee are appointed by the medical center Director and must reflect the types and amount 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. **Number of Members.** The R&D Committee must consist of at least five voting members.

(1) Whenever possible, one member of the Committee needs to have expertise in biostatistics and research design.

(2) 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.

(3) The members need to have diverse backgrounds with consideration as to race, gender, ethnicity, and expertise.

c. **Voting Members**

(1) Voting members of the R&D Committee must include:

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

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

(c) 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.

(2) All voting members must be compensated full-time or permanent part-time Federal employees.

(3) 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.

(4) 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.

(5) 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 must 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 must concur on the appointment. 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.

(6) If a facility has alternate members, they must be appointed by the facility Director. 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.

(7) All members of the R&D Committee must fulfill the educational requirements specified by VHA's ORD and other applicable requirements found on ORD's Website at: <http://www.research.va.gov/programs/PRIDE/>.

(8) The R&D Committee may require attendance by R&D subcommittee members, but subcommittee members who are not also members of the R&D committee must recuse themselves (i.e., leave the room or hang up from a conference call) before an R&D Committee vote is taken.

d. **Terms of Members**

(1) Voting members are appointed by the medical center Director in writing and serve terms of 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) The terms of members must be staggered to provide partial change in membership annually.

e. **Election of Chairperson.** Committee members, exclusive of ex officio members, must elect a Chairperson every 1 or 2 years.

(1) The Chairperson must be approved and officially appointed, in writing, by the medical center Director for a term of 1 to 2 years.

(2) The Chairperson may be reappointed without any lapse in time.

(3) The Chairperson must not simultaneously chair a subcommittee of the R&D Committee.

f. **Ex officio Members**

(1) Ex officio (non-voting) members include the medical center Director, the COS, the ACOS for R&D, the AO for R&D, and research compliance officers (or those who are responsible for compliance) of the facility. The ACOS for R&D functions as Executive Secretary of the R&D Committee.

(2) Other ex officio members, such as the information security officer, may be appointed to the Committee if their appointments assist the R&D Committee in fulfilling its responsibilities.

(3) Others 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. These individuals may not contribute to a quorum or deliberate or vote with the Committee.

14. 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.

(1) At a minimum, subcommittees must be appointed to oversee R&D activities related to human studies, animal studies, and biosafety including biosecurity.

(2) Findings and recommendations of the subcommittees are recorded and reported to the R&D Committee.

(3) The R&D Committee must approve final subcommittee minutes.

(4) Continuing review requires approval by relevant non-research committees and R&D Committee subcommittees, and ACOS for R&D notification of the investigator that the approvals have been obtained.

(5) The R&D Committee does not perform a continuing review.

b. The required subcommittees of the R&D Committee are:

(1) **Institutional Review Board.** 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 1200.05.

(2) **Institutional Animal Care and Use Committee (IACUC).** Every VA facility conducting research involving the use of live vertebrate animals must establish an IACUC, or secure the services of an IACUC as described in VHA Handbook 1200.7.

(3) **Subcommittee on Research Safety (SRS), or an Institutional Biosafety Committee (IBC).** Every VA facility conducting research must establish either a Subcommittee on Research Safety (SRS), an Institutional Biosafety Committee (IBC), or secure the services of an analogous

committee at another VA or university affiliate. These alternative committees must deal 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. If biosecurity issues are retained by the R&D Committee, a separate subcommittee for biosecurity may not be required.*

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 VA 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 and applicable statutory and regulatory authority.

(2) Be established through a Memorandum of Understanding (MOU) or other written agreement which defines definitions for all roles and responsibilities of each party.

(a) 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.

(b) 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 or obtain the services of another "in lieu of" subcommittee as required by this Handbook.

d. Each subcommittee must maintain adequate records, and retain such records according to VHA Directive 6300. These records must include the following:

(1) Copies of all research proposals and their amendments reviewed by the R&D Committee subcommittees 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 subcommittee's responsibilities;

(7) Standard Operating Procedures (SOPs); and

(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 program's SOPs must indicate this so that documentation can be retrieved.

e. Each subcommittee must make available to the R&D Committee a complete, unredacted, final set of minutes.

NOTE: 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 Department of Health and Human Services (HHS), Office of Human Research Protection, the Food and Drug Administration (FDA), and any other relevant requirements.

15. 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 and its Veterans. 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. 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 comply with VA requirements 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 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.

NOTE: To obtain assistance in any matter concerning government ethics, individual researchers and R&D Committee members should contact the local Regional Counsel.

16. REFERENCES

- a. Title 38 CFR §16.
- b. VHA Handbook 1200.05.
- c. VHA Handbook 1200.06.
- d. VHA Handbook 1200.7.
- e. VHA Handbook 1200.8.
- f. VA Directive 6500 and its implementing handbooks in the 6500 series.
- g. VHA Handbook 1605.1.
- h. VA Directive and Handbook 6102.
- i. VA Directive 6502.
- j. VA Handbook 6502.1.
- k. VA Handbook 6502.2.
- l. VHA Directive 6300.
- m. VHA policy concerning Research Financial Conflict of Interest Statement.
- n. VHA Handbook 1200.13.
- o. VHA Handbook 1100.19.
- p. VHA policies concerning Credentialing of Health Care Professionals.