

Department of Veterans Affairs
Harry S. Truman Memorial Veterans' Hospital
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RESEARCH AND DEVELOPMENT COMMITTEE AND SUBCOMMITTEES

1. **PURPOSE:** To describe the structure, responsibilities, and functions of the Research and Development (R&D) Committee and Subcommittees.
2. **POLICY:** The Veterans' Health Administration (VHA) national regulations concerning the R&D Committee are found in VHA Handbook 1200.1 "The Research and Development (R&D) Committee Handbook." Research in which the Harry S. Truman Memorial Veterans' Hospital (HSTMVH) is to be engaged may not be undertaken without review and approval of the R&D Committee and its appropriate subcommittees.
3. **DEFINITIONS:**
 - a. VA Research. Research conducted by Department of Veterans Affairs (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.
 - b. VA Data or 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.
 - c. 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.
 - d. 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. This 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 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. **RESPONSIBILITY:**

a. The Medical Center Director is responsible for:

(1) The Medical Center Director serves as the Institutional Official responsible for all aspects of the facility's Research and Development (R&D) Program.

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

(3) 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.

(4) Providing appropriate educational and training opportunities for members of the R&D Committee, the research administration staff, and other staff involved in research.

b. The R&D Committee assists the Medical Center Director in fulfilling the responsibilities for the facility's research program. The Committee is responsible for ensuring the scientific and ethical quality of all VA research and development 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.

The R&D Committee is assisted by the Associate Chief of Staff for Research and Development (ACOS/R&D) and the Administrative Officer (AO) for Research in carrying out its duties. The Committee accomplishes its responsibilities through the following activities or procedures:

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

(2) Determining the extent to which the R&D Program has met its objectives.

(3) Annually Reviewing the budgetary and other resource needs of the R&D Program and making appropriate recommendations regarding these needs. This review includes: personnel, materials and supplies, space, capital equipment, training, and education.

(4) Overseeing all research activities for which it serves as the R&D Committee of record.

(5) 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.

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

(6) Reviewing and evaluating all subcommittees or committees both within the VA facility and at external entities that function in lieu of subcommittee, such as Institutional Review Board (IRB), Institutional Animal Care Use Committee (IACUC), or biosafety committees. A summary of these reviews will be sent to the Medical Center Director.

c. Investigators are responsible for:

(1) Holding specific credentials and privileges awarded by the HSTMVH to conduct research at the VA. Investigators must be qualified through education and experience.

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

(3) Obtaining the R&D Committee and its appropriate subcommittees approvals prior to initiating research.

(4) 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.

(5) Developing and implementing plans for data use, storage, and security that is consistent with VA, VHA, and other Federal statutes, regulations, and policies.

(6) 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.

5. **MEMBERSHIP:**

a. The members of the R&D Committee will be appointed by the Medical Center Director. Nominations for membership may be from current R&D Committee members, subcommittee members, and/or the facility's staff.

b. The R&D Committee will consist of at least five (5) voting members.

R&D Committee members will have diverse backgrounds with consideration as to race, gender, ethnicity, and scientific expertise. The R&D Committee will be comprised of voting members as follows:

(1) At least two (2) members from the VA facility's staff who have major patient care or management responsibilities.

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

(3) At least one (1) 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. Ex-officio members include the (1) Medical Center Director, (2) Chief of Staff, (3) ACOS/R&D, (4) AO/R&D, (5) Radiation Safety Officer (RSO), (6) Information Security Officer (ISO), (7) Privacy Officer (PO), (8) Pharmacy representative, (9) Nursing representative, (10) University of Missouri-Columbia's Health Sciences Institutional Review Board (HS-IRB), and (11) Integrated Ethics Advisory Committee member (all non-voting). The ACOS/R&D functions as Executive Secretary for the Committee.

f. Ex-officio non-voting consultants include the Research Compliance Officer (RCO).

g. Voting members are appointed by the Medical Center Director in writing and serve a term of three (3) years. Members may be reappointed without a pause in time if it is deemed in the Committee's best interest. The terms of members will be staggered to provide partial change in membership annually.

h. Committee members, exclusive of ex-officio members, will elect a Chairperson on an annual basis. The Chairperson will be approved and officially appointed, in writing, by the Medical Center Director for a term of one (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 may elect a Vice-Chair.

i. All members of the R&D Committee must fulfill the educational requirements specified by VHA's Office of Research and Development (ORD) and other applicable Federal regulations found on ORD's website.

j. At least one member from each of the following shall serve on the R&D Committee: the Subcommittee on Animal Safety (SAS), the Subcommittee for Research Safety (SRS), the University of Missouri-Columbia's Health Sciences Institutional Review Board (HS-IRB), and other subcommittees of the R&D Committee.

6. **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 the 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 the R&D Committee avoid actual or perceived financial conflicts of interest in the research conducted or reviewed.

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 an 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.

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.

7. **FUNCTIONS:** 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/R&D, AO/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.

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 (CRADAs) 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.

h. An annual review of the Human Research Protection Program (HRPP) 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.

i. Fulfilling other functions as may be specified by the Medical Center Director.

8. 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 engaged 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.

b. Each research project, including those within the facility research programs and research centers, must be reviewed and approved initially and at least annually thereafter. The period for continuing review will be determined as part of the initial review. The continuing review period for studies reviewed by an IRB or IACUC of record may be

established by those subcommittees. In conducting its review, the R&D Committee must consider the findings of its subcommittees.

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.

9. R&D COMMITTEE OPERATIONS:

a. The R&D Committee will meet on a monthly basis, except for one month during the year, if it appears a quorum cannot be obtained.

b. R&D Committee members should make every effort to be present at Committee meetings. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In this 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 which 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 videoconference 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 will be recorded. The minutes will include the following:

(1) A list of all voting members and non-voting members, including ex-officio members, indicating the category of their membership and whether they were present or absent.

(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/R&D and Chief of Staff (COS) for review and appropriate action.

e. The PI will 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 will 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., SAS, SRS, IRB, Biosafety), will 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. Standard Operating Procedures (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.

10. R&D COMMITTEE RECORDS:

a. Adequate documentation of all activities of the R&D Committee will be maintained, including, but not limited to:

(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 9, and for oversight of the research program as listed in Paragraph 7, if not recorded adequately in the R&D Committee minutes.

b. Records are the property of the VA and will be maintained for a minimum of five (5) years.

11. RESEARCH AND DEVELOPMENT SUBCOMMITTEES: The R&D Committee will

oversee the work of specialized Subcommittees in the following areas: (a) biosafety, (b) animal studies, and (c) human studies. Members of R&D Subcommittees will be appointed by the Medical Center Director for a term of three (3) years. The ACOS/R&D, in concert with the R&D Committee, will nominate candidates for membership to the Medical Center Director. The functions of the R&D Subcommittees are as follows:

a. Subcommittee for Research Safety (SRS): A subcommittee of qualified individuals will be appointed to review and oversee all aspects pertaining to the safety of VA research protocols and laboratory activities.

b. Institutional Review Board (IRB): The Medical Center will maintain a Memorandum of Understanding with the University of Missouri-Columbia for the review of VA protocols by designated University IRBs. In addition, the Medical Center will provide two VA representatives to serve on each IRB which is involved in the review of VA human research protocols. The Medical Center will also maintain a Memorandum of Understanding with the VA Central IRB as an IRB of record for VA protocols designated for review by the VA Central IRB.

c. Subcommittee for Animal Studies (SAS): A subcommittee of qualified individuals will provide review and advisement regarding Animal Components of Research Protocols (ACORPs) and the assurance of compliance with VA regulations and those of other national oversight bodies.

d. Biosafety Committee: The Medical Center will maintain a Memorandum of Understanding with the University of Missouri-Columbia Biosafety Committee for the review of VA protocols involving recombinant DNA.

12. **REFERENCES:** VHA Handbook 1200.01, dated June 16, 2009

13. **RECISSION:** B&C 589A4-011, dated February 18, 2009.

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