

IOWA CITY DEPARTMENT OF VETERANS AFFAIRS (VA) HEALTH CARE SYSTEM
Iowa City, Iowa

Medical Center Memorandum
Number 11-65

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RESEARCH AND DEVELOPMENT COMMITTEE

1. PURPOSE. To oversee the local research program, including: risk management, program development, and quality and performance activities.

2. POLICY.

a. All research and development activities within the Iowa City VA Health Care System (ICVAHCS) or VA leased space, whether funded or unfunded, are within the purview of the Research and Development (R&D) Committee. The R&D Committee is responsible for advising and assisting the facility Director in providing oversight, planning and execution of the local research program.

b. The R&D Committee is responsible for maintaining high standards throughout the facility's R&D program. The standards include: ethical quality of VA research projects, proper resource availability, protection of human subjects in research, safety of personnel engaged in research, welfare of laboratory animals, security of VA data, security of VHA research laboratories, both on and off-site, and scientific validity. During the scientific validity review, the procedures must be deemed consistent with sound research design, and the research design must be sound enough to yield the expected results.

c. No research study may be initiated at the ICVAHCS prior to R&D Committee approval. 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 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.

3. DEFINITIONS.

a. VA Data/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 – 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, or other sponsors, or be unfunded.

c. VA Sensitive Information – 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.

4. RESPONSIBILITY.

a. ICVAHCS DIRECTOR. The ICVAHCS 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. The Director is also responsible for ensuring that research at the facility is approved by the appropriate R&D Committee subcommittees and that adequate resources including: personnel, space, equipment and training are available for both the R&D Committee and its subcommittees.

b. ACOS FOR R&D. The ACOS for R&D is responsible for 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. The ACOS for R&D is also responsible for the following:

- Functioning as Executive Secretary of the R&D Committee
- Conducting an annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation
- Ensuring WOC employee appointments have been justified and are in compliance with all VA policies
- Provide annual quality assurance reviews of research employees involved in human subject research to ensure they are working within their scopes of practice and their privileges allowed by the facility's by-laws and granted to them by the facility.
- Provide annual quality assurance reviews of Cooperative Research and Development Agreements (CRADAs) and other agreements in support of the research program and an assessment of the impact of these agreements on the research program.
- Ensure that all minutes of R&D Committee and its subcommittees are sent to the facility Director and COS for review and appropriate action.

- c. INVESTIGATOR. The investigator is responsible for the following:
- Confirming that they have been awarded the appropriate credentials and privileges to conduct research at VA prior to initiating any research.
 - Complying with personnel and other VA requirements whether the investigator is compensated, WOC, or IPA.
 - Obtaining the 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.
 - Developing a research plan that is scientifically valid and contains a sufficient description of the research to allow R&D Committee subcommittees to fully review the research project.
 - Developing and implementing plans for data use, storage, and security that comply with VA Handbook 6500, Information Security Program.
 - Preparing and submitting information, at least annually or as required, on their research programs and on each project to the appropriate R&D Committee subcommittee for continuing review as required by the subcommittees.
 - 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.

d. R&D COMMITTEE. The R&D Committee is responsible for recommending the distribution of R&D funds, space, personnel, equipment, and supplies; the use of animal facilities; and the use of other common resources. In order to ensure the effective oversight of the research program and make appropriate recommendations to the Director of the Iowa City VA Health Care System, the R&D Committee needs to rely on a variety of information sources including 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. The R&D Committee also reviews subcommittee activities including:

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

- The Animal Care and Use Program (including inspection reports, IACUC composition, IACUC arrangements, budgets, space, support staff, training quality improvement activities, compliance issues, and goals for the next year)
- IRB composition or IRB arrangements, credentialing and training status report, budgets, space support staff, quality improvement activities, compliance issues and goals for the next year
- Planning and developing broad objectives for the research program so that it supports VA's mission
- Determining the extent to which the research program has met its objectives

It must also be noted that the R&D Committee does not have the capacity to overturn a disapproval by the Institutional Review Board (IRB-03) but it can disapprove a previously IRB approved study.

5. MEMBERSHIP.

a. The R&D Committee will nominate members with approval by the ICVAHCS Director.

b. The committee will have the following permanent members:

- Health Care System Director (ex officio member)
- Chief of Staff (COS) or designee (ex officio member)
- Associate Chief of Staff for Research who will serve as Executive Secretary (ex officio member)
- Administrative Officer for Research (ex officio member)
- University of Iowa College of Medicine Representative (VA Investigator with academic appointment - voting member)
- Chief, Pharmacy Service or designee (voting member)
- 2 patient care services representatives (voting members)
- Regional Counsel (non-voting member)
- 2 Active VA Investigators (voting members)

c. Nonpermanent membership shall include both clinician and non-clinician scientists and represent a variety of clinical and research disciplines. Members shall serve three-year terms and will elect a new chairperson annually that is officially appointed by the facility Director.

6. PROCEDURES. The R&D Committee will meet monthly and record attendance and minutes. It is allowable for the R&D Committee to miss one meeting per calendar year, due to a lack of a quorum. The R&D Committee may develop procedures that allow unscheduled meetings in response to emergent issues. A quorum must be obtained at both monthly and unscheduled meetings and must be present to conduct business and for each vote.

a. Minutes are to include the following elements:

- List of all voting and non-voting members, including ex officio members, and whether they are present or absent
- Presence of a quorum
- Actions taken by the Committee, including the type of action
- The vote on the action, including number voting for, against and abstaining
- Any excused member from the vote must be named and their presence noted

b. All minutes of the R&D Committee and subcommittees must be sent to the ICVAHCS Director through the ACOS for R&D and COS for review and appropriate action.

c. CONFLICT OF INTEREST. VHA must 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.

d. VA investigators and R&D Committee members must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal criminal code. Complying with laws and regulations also applies to WOC employees and IPAs conducting research or participating on a R&D Committee.

8. SUBCOMMITTEES OF THE R&D COMMITTEE: Each subcommittee must maintain adequate records, which must include the following:

- Copies of all research protocols and their amendments reviewed by the subcommittees and any accompanying materials
- All continuing or final reports
- Minutes of the meetings
- Copies of all written correspondence

- A membership list of all voting, non-voting, and ex-officio members including their appointed roles
- Written records documenting actions taken to carry out subcommittee responsibilities.
- Standard Operating Procedures (SOPs)
- All communication to and from investigators, other committees, and other entities or individuals

The subcommittees of the R&D Committee include:

a. Research Animal Care and Use Committee: To oversee animal use and care to ensure it is humane and that the facilities and programs comply with the American Association for Accreditation of Laboratory Animal Care (AAALAC), Public Health Service (PHS), United States Department of Agriculture (USDA), and other regulatory bodies.

b. Research Biohazard and Safety Committee: To provide oversight of lab safety and safety training needs. Also serves as subcommittee to Iowa City VA Health Care System Safety Management Committee.

c. University of Iowa Institutional Review Board (IRB-03): The IRB is charged with reviewing proposed research involving human subjects to ensure the protection of those subjects and compliance with VA and federal human subjects regulations.

8. REFERENCES. VHA Handbook 1200.01, Research and Development (R&D) Committee.

9. RESCISSIONS. Medical Center Memorandum 08-65, Research and Development Committee, dated July 16, 2008.

BARRY D. SHARP
Director

ATTACHMENT A

SUBCOMMITTEES OF THE R&D COMMITTEE

RESEARCH ANIMAL CARE AND USE COMMITTEE

RESPONSIBILITY: To oversee animal use and care to ensure it is humane and that the facilities and programs comply with the American Association for Accreditation of Laboratory Animal Care (AAALAC), Public Health Service (PHS), United States Department of Agriculture (USDA), and other regulatory bodies.

RESEARCH BIOHAZARD AND SAFETY SUBCOMMITTEE

RESPONSIBILITY: To provide oversight of lab safety and safety training needs. Also serves as subcommittee to Iowa City VA Health Care System Safety Management Committee.

SUBCOMMITTEE ON RESEARCH ENRICHMENT (SCORE)

RESPONSIBILITY: To evaluate ways to improve and enrich the research program at the Iowa City VA Health Care System.

UNIVERSITY OF IOWA INSTITUTIONAL REVIEW BOARD (IRB-03)

RESPONSIBILITY: The IRB is charged with reviewing proposed research involving human subjects to ensure the protection of those subjects and compliance with VA and federal human subjects regulations.