

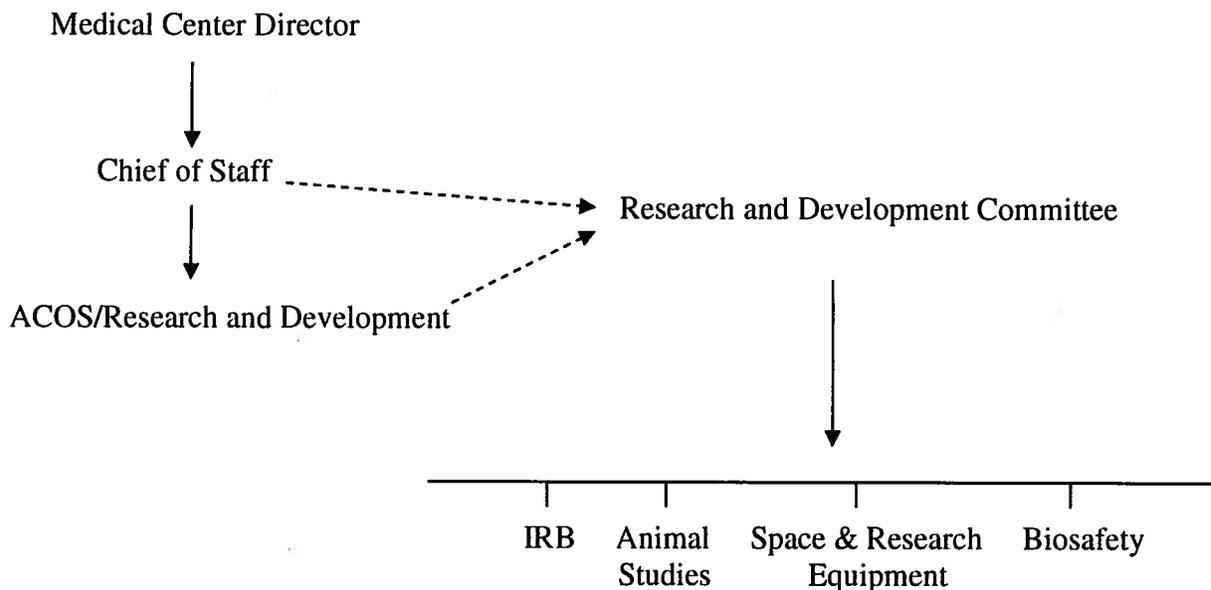
HUMAN RESEARCH PROTECTION PROGRAM

FOR THE

RALPH H. JOHNSON DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER CHARLESTON, SOUTH CAROLINA

- I. DEFINITION. A Human Research Protection Program (HRPP) is a systematic and comprehensive approach for conducting research to ensure human subject protection. This HRPP ensures the rights, safety and well being of human research subjects is protected.
- II. STATEMENT OF PRINCIPLES CONCERNING PROTECTION OF HUMAN RESEARCH SUBJECTS. The Department of Veterans Affairs is one of 16 Department and Agencies that have agreed to follow the Federal Policy For The Protection of Human Subjects (The Common Rule). The Ralph H. Johnson Veterans Affairs (VA) Medical Center (VAMC) implements the use of the requirements specified in 38 Code of Federal Regulations (CFR) 16, Protection of Human Subjects.
- III. IDENTIFICATION OF THE INSTITUTIONAL OFFICER ACCOUNTABLE FOR THE HRPP. The Medical Center Director is accountable for the implementation and performance of the HRPP.
- IV. THE ORGANIZATIONAL STRUCTURE, PROCESS, ROLES AND RESPONSIBILITIES FOR MAKING POLICY TO PROTECT HUMAN RESEARCH SUBJECTS.

A. Organizational Structure:



B. The Medical Center Director is responsible for:

- The R&D program of the institution, advised and assisted by an R&D Committee.
- Implementing the R&D program, policies and procedures, including establishing and appointing members to the R&D Committee and any appropriate subcommittees.
- Ensuring that R&D funds are used appropriately and that adequate resources, including funds and space, are provided for research and administrative functions.
- The ethical conduct of research and for human and animal subjects research protection.

C. The Associate Chief of Staff for Research (ACOS/R&D) is responsible for management of the research program. The ACOS/R&D is responsible for:

- Administration of the facility's R&D program, including the operations of the R&D Committee and subcommittees.
- Participation with the Medical Center Director in the management of the facility's health care programs, particularly in those areas where integration of the R&D programs can have a beneficial effect on patient care.
- Maintenance of liaison with the Dean's Committee or Medical Advisory Committee.
- Assisting investigators by providing advice and guidance in administration and technical matters, aid in the recruitment, appointment, and employment of R&D personnel; progress review of the investigators' R&D programs; and review of publications, scientific exhibits, and public information releases of R&D activities.
- Dissemination of educational materials to all investigators with active or planned research programs, IRB members, IACUC members, and R&D Committee members.
- Preparation, submission, and maintenance of communications, reports, and correspondence required for the administration of the facility's R&D program.
- Financial management of the facility's R&D program.
- Supervision of contracts when requested.
- The ethical conduct of research and for human and animal subjects research protection.

D. The Administrative Officer for Research (AO/R&D) is responsible for:

- Preparing and revising long-range plans for personnel, equipment, space, and construction requirements.
- Planning construction and minor alterations.
- Systematically reviewing and reporting on such administrative functions as manpower utilization, personnel, training, space utilization, publications, supply procedures, and reports.
- Developing and implementing control procedures for fiscal matters, supplies, equipment, and services such as common resources, and animal facilities.
- Maintaining inventory records of non-expendable equipment.
- Assembling, organizing, and presenting information for budget preparation.

- Assisting such administrative functions as recruitment of staff, personnel actions, preparation of reports by investigators, provisions of facilities for the R&D Committee and its subcommittees, and preparation of reports by the ACOS/R&D.
- Supervising nonprofessional staff members when requested by the ACOS/R&D.
- Performing other related functions as assigned by the ACOS/R&D.

V. ROLES AND RESPONSIBILITIES OF THE RESEARCH & DEVELOPMENT (R&D) COMMITTEE IN PROTECTING HUMAN SUBJECTS.

The R&D Committee is responsible through the Chief of Staff to the Medical Center Director for maintaining high standards throughout the facility's R&D Program. These standards include those assuring the scientific quality of the R&D projects, human rights, laboratory safety, and welfare of animal subjects in R&D. It advises the Director on professional and administrative aspects of the R&D Program. All R&D activities within the facility, whether funded or unfunded, are within its purview. Scientific review of research and development is a prime responsibility of the committee. Other responsibilities include:

- Assuring the continuing high quality of the facility's R&D program.
- Planning/developing broad objectives of the R&D program so that it supports the patient care mission of the facility.
- Determining the extent to which the R&D program has met its objectives.
- Evaluating critically the quality, design, desirability, and feasibility of each new R&D proposal, continuing R&D project, application for funding, manuscript to be submitted for publication, or other reporting activity to assure maintenance of high scientific standards, protection of human subjects, adequate safety measures, and proper use of animal subjects.
- Recommending, on the basis of such evaluations and after consideration of other needs, the distribution of R&D funds, space, personnel, equipment and supplies, and use of animal facilities outside the facility.
- Reviewing and approving the R&D budgetary requests of the facility.
- Recommending policies for the recruitment and development of personnel supported by R&D funds.
- Advising the Director on the recommendation to the Chief Research and Development Officer of candidates for the position of Associate Chief of Staff for Research and Development.
- Reviewing and evaluating research performance reports, including compliance audits and Quarterly Quality Assurance reports and implementing performance action plans as appropriate.
- Monitoring changes in regulations and policies relating to research and implement, as required.
- Fulfilling such other functions as may be specified by the Medical Center Director.
- To follow the principles, objectives, and functions outlined in VHA Handbook 1200.01 (June 16, 2009). They will establish subcommittees on Human Studies [Institutional Review Board (IRB)], Animal Studies, Space and Research Equipment, and Biosafety. These subcommittees will advise the R&D Committee on matters relating to each subcommittee. No research may be undertaken without R&D Committee and appropriate subcommittee(s) review and approval.

- The ethical conduct of research and for human and animal subjects research protection.

VI. ARRANGEMENTS FOR AN INSTITUTIONAL REVIEW BOARD (IRB). The Ralph H. Johnson VAMC established a Memorandum Of Understanding (MOU) with the Medical University of South Carolina (MUSC) to use the services of MUSC's IRB(s), except for protocols reviewed by the VA CIRB. For the purposes of the Federal-Wide Assurance (FWA), The Ralph H. Johnson VAMC has designated the MUSC IRB(s) and the VA CIRB as the "IRB (s) of record." The research activities of the Ralph H. Johnson VAMC are supported through MUSC's IRB(s) and the VA CIRB. The MOU will be reviewed at least annually as part of the R&D Committee's annual review of the functioning of the IRB, in accordance with VHA Handbook 1200.05 (June 16, 2009). Under this arrangement, the Ralph H. Johnson VAMC will follow MUSC Policies and Procedures unless otherwise noted in the VA Research Service Quality Manual.



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