

CHAPTER 3. FUNCTIONS**3.01 FUNCTIONS OF THE RESEARCH AND DEVELOPMENT COMMITTEE**

a. The R&D (Research and Development) Committee is responsible through the Chief of Staff to the facility Director for maintaining high standards throughout the facility's R&D program. These standards include those concerning the scientific quality of research and development projects, human rights, laboratory safety, and welfare of animals used in research. 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. The functions of the R&D Committee include:

- (1) Assuring the continuing high quality of the facility's R&D program;
- (2) Planning and developing broad objectives of the R&D program so that it supports the patient care mission of the facility;
- (3) Determining the extent to which the R&D program has met its objectives;
- (4) 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;
- (5) 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 and other common resources;
- (6) Recommending approval of the receipt and use of non-VA financial support for research and development to be conducted in the facility or by members of the VA staff even if conducted outside the facility;
- (7) Reviewing and approving the R&D budgetary requests of the facility;
- (8) Recommending policies for the recruitment and development of personnel supported by R&D funds;
- (9) Advising the Director on the recommendation to the ACMD/R&D (Assistant Chief Medical Director for Research and Development) of candidates for the position of ACOS/R&D (Associate Chief of Staff For Research and Development);
- (10) Fulfilling such other functions as may be specified by the facility Director.

b. Scientific review of research and development is a prime responsibility of the committee.

(1) The R&D Committee is responsible for the scientific quality and appropriateness of all research and development conducted at the facility regardless of funding source and including programs that do not receive VA funding. Each program is to be reviewed formally at least once a year. In addition to the assessment of scientific progress, the review evaluates the budget, requirements for space, personnel, equipment and supplies, the relationship of the program to the total R&D activity of the facility, and the role of the investigator at the health care facility.

(2) The R&D Committee establishes a schedule for local review and devises necessary procedures and forms. Investigators may be asked to discuss the progress and plans for their programs with the committee or a subcommittee thereof.

(3) The committee may accomplish local review by the following mechanisms:

(a) The R&D Committee may establish a Research Review Subcommittee. Its members should be knowledgeable about the VA R&D program and the local facility's environment and it may use ad hoc experts when necessary. Its findings and recommendations are recorded and forwarded to the committee.

(b) The R&D Committee as a whole may evaluate research or development programs and may employ ad hoc consultants for this purpose. Such consultants may be asked to submit written evaluations of the programs or, when necessary, to present their recommendations to the committee in person. R&D funds may be used to pay for the services of consultants who are not employed by the Federal Government.

(c) The committee may use the information generated by the VA Central Office review to complement the local review process.

c. The R&D Committee meets at least monthly, except for 1 month during the summer if it appears that a quorum cannot be obtained.

d. minutes are recorded and maintained for each meeting of the R&D Committee.

(1) The minutes document attendance or absence of members and provide a complete record of all items of business or information brought before the committee.

(2) Motions presented to the committee are recorded verbatim to include the action taken by the committee. Votes on motions are reported to indicate whether the action is unanimous or by divided vote with a statement of the number of members voting for and against the motion.

(3) Minutes of the meeting are signed by both the chairperson and the executive secretary. Copies are submitted to the facility Director, the Chief of Staff, and the Clinical Executive Board for review and signature.

(4) Within 3 weeks after the meeting, copies of the minutes, together with any comments the Director may care to make, will be distributed to all members of the committee and made available upon request to any investigator.

(5) Within 5 weeks after the meeting, two copies of the approved minutes for the meeting, [with medical center identification appearing in upper right corner,] shall be forwarded through appropriate channels to the [Chief, Eastern Research and Development Office (15R), VA Medical Center, Perry Point, MD 21902.]

e. Subcommittees of the R&D Committee are established by that committee, the members being nominated by the committee and appointed by the facility Director. Each subcommittee must have at least one member from the parent committee. Each subcommittee keeps minutes of its meetings and reports to the R&D Committee, which accepts or rejects its recommendations, except that the parent committee cannot alter an adverse report or recommendation, e.g., disapproval for ethical or legal reasons by the Subcommittee on Human Studies or the Animal Research Subcommittee. Minutes of subcommittees are appended to the monthly minutes of the R&D Committee. The subcommittees include:

(1) Subcommittee on Human Studies, members of which serve terms not to exceed 3 years on staggered appointments.

(a) All members of the subcommittee will be VA appointees and a contract will not be used to procure their services. Appointments, as determined appropriate (e.g., consultant, on station fee-basis, or WOC), under the provisions of DM&S Supplement MP-5, part 11, chapter 2, are available for this purpose. Membership must include:

1. A chairperson who currently holds a VA appointment, compensated or WOC.

2. Two or more members who are not already VA appointees nor directly connected with research and development within the VA facility. These members appropriately should include a member of the clergy, an attorney, a representative of a legally recognized veterans organization, and/or a practicing physician from the community.

3. Such additional members as will enable the subcommittee to consider the ethical and legal issues involved in the participation of human subjects in research and development.

(b) The membership must fulfill relevant legal and regulatory requirements of the Department of Health and Human Services, and of other Federal agencies.

(c) The facility may use a comparable "human rights committee" in lieu of the Subcommittee on Human Studies, providing the committee includes among its membership appropriate representation from a significant number of VA-staff salaried more than half time by the VA. Generally, this committee will be constituted by an affiliated medical or dental school or by another VA facility. The R&D Committee of a facility must assure the Director in writing that the outside committee in structure and function conforms to or exceeds the requirements for a Subcommittee on Human Studies. This assurance must be reaffirmed annually after review of the committee's structure and performance. The committee shall submit minutes on its consideration of VA proposals to the R&D Committee.

(d) Functions of the Subcommittee on Human Studies are discussed in paragraph 9.02 g through k.

(2) Subcommittee on Animal Studies in any facility that has animal activities.

(a) Its membership should include no more than **five** persons as follows:

1. At least one member of the parent R&D Committee.

2. A staff or consultant Veterinary Medical Officer who is a VA employee, with or without compensation, and who serves ex officio with a vote.

3. Two to four investigators who are involved significantly in studies using animal subjects.

(b) Members other than those who are ex officio serve terms not to exceed 3 years, on staggered appointments.

(c) The Subcommittee on Animal Studies is responsible for reviewing all use of animal subjects, including proposed and ongoing studies, as they relate to animal welfare laws, regulations, and policies. Review includes the appropriateness, quality, and availability of the selected animals; the humaneness and appropriateness of procedures and conditions surrounding animal subjects before and throughout the study; as well as the adequacy and availability of essential animal research facilities support.

(d) The subcommittee evaluates the animal facility at least annually to identify deficiencies relevant to animal welfare laws, regulations, or policies, recommends appropriate corrective actions, and reports on corrective measures taken.

(3) Research Equipment Subcommittee in any health care facility with a large or complex R&D program.

(a) Membership should include a biomedical engineer if available to the facility, a basic scientist, the AA/ACOS/R&D, and one or more investigators having a broad knowledge of R&D instrumentation.

(b) The subcommittee is responsible for evaluating all equipment requests and for recommending to the R&D Committee whether each is justified and documented. For each request, the subcommittee determines whether alternative equipment is or could be made available, and whether the equipment requested is optimal for the purpose.

(c) The subcommittee reports periodically to the R&D Committee on equipment utilization at the health care facility, specifically, the current actual utilization, potential for sharing, and the need for disposal of equipment.

(4) Subcommittee on Safety.

(5) Such other subcommittees as are deemed necessary by the R&D Committee. Each subcommittee will have at least one member from the parent committee.

3.02 FUNCTIONS OF THE ASSOCIATE CHIEF OF STAFF FOR RESEARCH AND DEVELOPMENT

The functions of the ACOS/R&D (Associate Chief of Staff for Research and Development) are:

- a. Administration of the facility's R&D programs, including the operations of the R&D Committee and its subcommittees.
- b. Participation with the Director and Chief of Staff in the management of the hospital's health care programs, particularly in those areas where integration of the R&D programs can have a beneficial effect either directly or indirectly on patient care. It is suggested that the ACOS/R&D be made a member of the health care facility's Executive Management Committee in order to effect this.
- c. Maintenance of liaison with the Deans Committee or Medical Advisory Committee. This can be brought about by inviting the ACOS to participate in the committee meetings as a nonvoting attendee.
- d. Assistance to the facility's investigators by:
 - (1) Advice and guidance in administration and, when applicable, technical matters.
 - (2) Aid in the recruitment, appointment, and employment of R&D personnel, including scientific and technical personnel.
 - (3) Following the progress of the investigators' R&D programs.
 - (4) Arranging for review of publications, scientific exhibits, and public information releases of R&D activities.
- e. Preparation and submission of communications, reports, and correspondence required for the administration of the facility's R&D program, including such reports as requested by authorized personnel in VA Central Office.
- f. Maintenance of communication with the Office of the ACMD/R&D in VA Central Office and the services therein regarding matters pertaining to research and development.
- g. Financial management of the facility's R&D program by:
 - (1) Preparing estimates of budgetary requirements.
 - (2) Administering R&D funds as recommended by R&D Committee and allocated by the Director.
 - (3) Administration of non-VA monies, as delegated by the medical center Director, for support of research and development held in special VA funds, such as the General Post Fund.
 - (4) Soliciting, receiving, and reviewing annually the financial statement from any non-VA fund, foundation, corporation, etc., that receives or purports to receive and distribute funds for support of research and/or development in the VA facility.
- h. Contract supervision when requested to do so by the Director of an R&D service in VA Central Office. Such requests shall be in writing but need not be renewed annually. This supervision includes:
 - (1) Arranging for and assisting in advertising and negotiating contracts related to research and development. These contracts usually arise from the facility's program or involve contractors geographically near the facility.
 - (2) Monitoring performance under each contract by:
 - (a) Obtaining periodic reports from the contractor as stipulated in the contract, evaluating these reports, and forwarding them through administrative channels to the appropriate Director of an R&D service.

(b) Making or arranging to have made visits to the contractor as necessary to evaluate performance and reporting the results to the Director of the R&D service involved.

(c) Recommending annually to that Director whether the contract should be renewed, modified, or terminated. (See also par. 5.Olc.)

3.03 FUNCTIONS OF THE COORDINATOR FOR RESEARCH AND DEVELOPMENT

The functions of the Coordinator for Research and Development are:

a. Administration of the health care facility's R&D program.

b. Maintenance, where appropriate, of liaison with the Regional R&D Office and the R&D Committee advising the facility Director. This includes submission of necessary R&D proposals, reports, manuscripts, etc., to the committee and the appropriate distribution of its reports, recommendations, etc., to the concerned personnel in the facility.

c. Assistance to the investigators within the facility by:

(1) Providing advice and guidance directly, through the Regional R&D Office, or through the office of the ACOS/R&D of an associated facility, in the preparation and submission of R&D proposals, reports, publications, etc.

(2) Securing, reviewing for completeness, and forwarding all required reports.

d. Financial management of the facility's R&D program by:

(1) Preparing and submitting estimates of budgetary requirements.

(2) Administering funds allocated to each project and any non-VA monies available for research and development in the facility's General Post Fund as delegated by the facility Director.

3.04 FUNCTIONS OF THE ADMINISTRATIVE ASSISTANT TO THE ASSOCIATE CHIEF OF STAFF FOR RESEARCH AND DEVELOPMENT

The administrative assistant is responsible to the ACOS/R&D (Associate Chief of Staff for Research and Development) for the administrative functions of the R&D program. The functions are:

a. Preparing and revising long-range plans for personnel, equipment, space, and construction requirements.

b. Planning construction and minor alterations in coordination with Engineering Service.

c. Systematically reviewing and reporting on such administrative functions as manpower utilization, personnel, training, space utilization, publications, supply procedures, and reports.

d. Developing and implementing control procedures for fiscal matters, supplies, equipment, and services such as common resources, animal facilities and stenographic assistance.

e. Maintaining inventory records of nonexpendable equipment.

f. Assembling, organizing, and presenting information for budget preparation.

g. Assisting such administrative functions as recruitment of staff, personnel actions, preparation of reports by investigators, provision of facilities for the R&D Committee and its subcommittees, and preparation of reports by the ACOS/R&D on the facility's program.

- h. Supervising nonprofessional staff members when requested to do so by the ACOS/R&D.
- i. Such other related functions as may be assigned by the ACOS/R&D.

3.05 FUNCTIONS OF THE VETERINARY MEDICAL OFFICER

The Veterinary Medical Officer is responsible to the ACOS/R&D for operation of the animal facility. A consultant veterinarian shall fulfill the appropriate functions in a smaller program. The functions are:

- a. Directing the design and operation of the animal facility to provide support for R&D programs using animal subjects and to insure compliance with all relevant animal welfare laws, regulations, and policies.
- b. Providing professional and technical support to the health care facility's investigators in planning, executing, and reporting R&D programs using animal subjects.
- c. Participating as a member of the Subcommittee on Animal Studies.
- d. Assisting in promoting favorable community relations and in increasing public understanding of the importance of animal studies in improving patient care.