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CHAPTER 1. GENERAL

1.01 DEFINITIONS

The Rehab R&D (Rehabilitation Research and Development) program consists of a broad range of investigations into the rehabilitation and support of disabled, handicapped, infirm or aged veterans in order to improve the quality of their lives and to enhance their functional independence. The Rehab R&D program expands the VA's historical role in prosthetics research into investigation of any device, technique, or concept for rehabilitation. Projects may relate to techniques for improving function after spinal cord injury, implants to improve locomotor functions, correction of sensory deprivation, means to increase the short distance mobility and long range transportation of the handicapped, physiological control systems, prosthetics, orthotics, cosmesis, and environmental, behavioral, and socioeconomic factors affecting rehabilitation. Rehab R&D projects tend to emphasize devices and prototype development. Such development and evaluation requires compliance with the medical device laws and regulations including those of the Food and Drug Administration and other Federal agencies concerned with other aspects of patient protection and safety.

1.02 PRINCIPLES AND OBJECTIVES

a. The goal of the Rehab R&D program is to improve the quality of life and permit optimal functional independence of disabled, handicapped, and infirm or aged veterans through research and development.

b. The Rehab R&D Service supports primarily intramural and, in some cases, extramural projects. To maintain the high quality of research and development, there is scientific and technical review by experts of all projects.

c. The evaluation of new devices and concepts is effected by means of independent and objective preclinical and clinical trials, including cooperative and collaborative studies, preferably within VA health care facilities.

d. To insure that veterans ' and other patients effectively utilize technological advances, the Rehab R&D Service sponsors publication to disseminate research and development information; collaborates with the Offices of the Assistant Chief Medical Directors for Clinical Affairs and Academic Affairs in the VA, and with other Federal agencies in patient and staff education; and encourages private industry to introduce new devices.

1.03 POLICIES

a. VA professional and technical staff conduct Rehab R&D studies, preferably within VA facilities. When this is not feasible, the VA, through contracts and interagency agreements, supports research and development by individuals, educational and other nonprofit institutions, Federa1, State or local government agencies, and/or commercial organizations. Administrative and technical direction of these extramural activities usually is assigned to the staff of a VA health care facility. (See pt. 1, par. 3.02h.) When this is not feasible, they are directed from VA Central Office.

b. Programs are planned to provide systematic progression through research, development, evaluation, procurement, and introduction into clinical use. The last step implies that a device becomes readily available; this generally requires commercial production by private enterprise. (See pt. I, par. 1.03m.)

c. Rehab R&D patentable ideas and inventions by VA staff members must be reported to Central Office (See pt. 1, par. 1.03n.) The rights to patents developed under.a Rehab R&D contract are stipulated in the agreement.

d. Each Rehab R&D program must be submitted for approval of its scientific and technical merit by peer review, and must comply with existing laws, policies, and regulations concerning safety, research methods, and participation of human subjects. (See pt. 1, par. 9.02.)

e. Evaluation of new products developed by the VA and by other includes suitable laboratory testing and determination of safety and efficacy in clinical use. Independent objective evaluations of new devices and concepts are conducted in VA health care facilities when practical.

f. Routine distribution of new and improved devices and techniques to eligible beneficiaries should occur only after the products have been tested, sources established, and personnel trained in their use. Once commercially available or approved to be marketed by the FDA, they cease to be the responsibility of the Rehab R&D Service.

g. The Rehab R&D staff, both in VA Central Office and in health care facilities, maintains close coordination and cooperation with other research, clinical, and education programs. This facilitates prompt, effective responses to clinical needs; improves clinical trials; ensures timely, informed decisions as to general distribution of new or improved devices and techniques; expedites their availability to patients; and educates and trains VA personnel in areas of rehabilitation R&D.

h. Increased emphasis will be given'in the rehabilitation research and development program to the prevention of disabling conditions, and the restoration of function rather than compensation by adaptive devices and mobility aids. In some areas, development of compensatory devices is the chief goal, as in those cases involving sensory deprivation- of blind and minimally sighted patients, and individuals having hearing impairment or loss of peripheral sensation.

i. Reporting requirements for Rehab R&D programs are given in part 1, chapter 4, and guidance on publications in part 1, chapter 8; where a contract is involved, the requirements for part I, paragraph 5.02a(2)(e) also apply.

CHAPTER 2. ORGANIZATIONAL STRUCTURE

2.01 CENTRAL OFFICE REHABILITATION RESEARCH AND DEVELOPMENT SERVICE

The Director, Rehab R&D (Rehabilitation Research and Development) Service, reports directly to the DACMD (Deputy Assistant Chief Medical Director) for Prosthetics Services, Research and Development for all aspects of Rehab R&D operations. All budget actions relating to the Rehab R&D program are forwarded through the DACMD for Prosthetics Services, R&D for concurrence prior to being forwarded to the ACMD for Clinical Affairs and to the ACMD for Research and Development for review and implementation.

2.02 HEALTH CARE FACILITIES

a. The ACOS/R&D or the C/R&D at the investigator's health care facility coordinates Rehab R&D proposal submissions and administers approved Rehab R&D projects.

b. The R&D Committee and its subcommittees, such as the Subcommittee on Human Studies, perform the same function for Rehab R&D projects as for other research and development. Ad hoc reviewers may be needed to evaluate the scientific and technical aspects of Rehab R&D proposals. The committee reviews the proposals for relevance to the VA health care services and the feasibility of conducting the projects at the health care facility. Human rights issues are addressed by the Human Studies Subcommittee.

c. Professional personnel, including biomedical engineers, in VA health care facilities may initiate and conduct Rehab R&D projects. R&D resources made available by the Rehab R&D Service for approved projects or to provide scientific and technical assistance are not to be used for routine patient care.

2.03 REHABILITATION RESEARCH AND DEVELOPMENT CENTERS

a. Rehab R&D Centers are established in VA health care facilities to conduct research and development in areas of special interest. Research and Development activities at a center may include many programs or be more restricted in scope. The centers must be responsive to agencywide needs, but remain the responsibility of the health care facility Director with the usual relationship to the R&D Committee and the ACOS/R&D.

b. Each Rehab R&D center is administered by a Director and an Assistant Director, one of whom shall be a physician, the other a rehabilitation engineer. The center is staffed to discharge its professional and technical responsibilities but obtains administrative support and services from the health care facility with which it is associated. Any remuneration for the administrative support provided by the R&D office of the parent facility will be determined by the Rehab R&D Service based on services provided.

c. Rehab R&D Centers conduct intensive and extensive research and development within their assigned programs, including fabrication, laboratory testing, preclinical testing, and evaluation, and, when appropriate, clinical evaluation. Rehab R&D Center programs are chiefly intramural but a center Director may recommend and administer approved contracts in furtherance of the approved research and development programs.

d. Rehab R&D Centers must develop a Rehab R&D affiliation by a memorandums of understanding with local academic engineering institutions. Such memorandums shall be approved by the local facility Director and the Director, Rehab R&D Service. Rehab R&D Center personnel are encouraged to conduct classes in biomedical engineering at the centers and to stimulate involvement of students and faculty in research and development projects at the centers. As appropriate the Rehab R&D Center Director coordinates programs under the Rehab R&D affiliation with other VA components, including the ACOS/R&D, the Associate Chief of Staff for Education, Chief of Staff, and the facility Director. Educational programs for students require a Memoradum of Affiliation in accordance with M-8, part 1, appendix 2B.

2.04 REHABILIATION RESEARCH AND DEVELOPMENT UNITS

A Rehab R&D Unit is an organizational designation for a rehabilitation R&D activity with a limited, specific, centrally directed mission. Based on growth and progression in the scope and the number of merit approved projects

developed by the unit, such a unit could evolve into a Rehab R&D Center. A unit would be expected to affiliate with an engineering school(s) and other academic institutions as appropriate. Liaison with other R&D facilities will be promoted.

2.05 ASSOCIATION WITH ENGINEERING SCHOOLS

a. A VA health care facility that does not have a Rehab R&D Center may enter into an agreement for Rehab R&D collaboration with an engineering school. A memorandum of understanding provides the basis for cooperation between the two institutions but arrangements differ significantly from those in medical school affiliations.

b. While it is preferred that they serve as VA employees, faculty members and research assistants (who may also be graduate students) may work in VA facilities as a WOC (without compensation) employee under a contract or IPA (Intergovernmental Personnel Act) agreement. Under such agreements an engineering school assigns its personnel to accomplish specific objectives stipulated in the contract or IPA agreement. University students employed as research assistants are considered temporary employees and are not eligible for assignment under the IPA program (FPM, ch. 334, par. 1-3e(3).)

CHAPTER 3. PROGRAMS AND PROGRAM REVIEW

3.01 PROGRAM ORIENTATION

a. The Rehab R&D Service encourages investigators to explore problems of interest to them but certain areas of endeavor are of special interest to the VA. The VA Central Office identifies these high priority areas and notifies the health care facilities and Rehab R&D Centers when additional support is available for projects so identified. Proposals within these special areas are submitted and evaluated for scientific and technical quality as are other Rehab R&D proposals.

b. Rehab R&D projects that are developmental, device-oriented, or that deal with evaluation must be scientifically as well as technically meritorious. All projects must follow approved protocols and be consistent with VA Regulations and policies and other pertinent laws and regulations. The Food and Drug Administration has requirements for experimental devices similar to those for experimental drugs (see 21, CFR 812.) The VA requires aherence to these regulations and requires the local R&D Committee and Human Studies Subcommittee to review Rehab R&D programs for compliance with them.

c. Well-controlled evaluation projects are critical to the success of the Rehab R&D programs. They should be objective, well-documented clinical studies with adequate controls for comparison even when they cannot be classical double-blind, random-application experiments. An evaluation protocol will be established, reviewed, and approved before the testing and must be adhered'to in the same manner as are other research protocols.

d. Clinical Rehab R&D investigations, including cooperative and collaborative studies, are encouraged. Their initiation and conduct follow the procedures used for other types of research and development. (See pt. 1, chs. 3 through 5, 8 and 9, and pt. 11, par. 3.05.)

3.02 PROGRAM REVIEW

a. In VA health care facilities with R&D Committees, professional staff members in prosthetics treatment centers, orthotics laboratories, clinics, medical centers, and similar facilities submit Rehab R&D research proposals to the local R&D Committee through the ACOS/R&D. The principal investigator prepares a detailed research proposal that the local research office reviews for format and completeness. The R&D Committee and its Human Studies Subcommittee evaluate the proposal as they do other R&D proposals and rec ommend action to the facility Director. The latter forwards any approved proposals with the R&D Committee's recommendation to the Director, Rehab R&D Service, for scientific review and consideration for funding.

b. Rehab R&D proposals submitted to VA Central Office for merit review are evaluated by the Scientific Review and Evaluation Board for Rehab R&D. The Board makes recommendations to the Director, Rehab R&D Service regarding the scientific quality, level of support and relevance to the Rehab R&D Service's mission and priorities. In addition to scientists and experts chosen for their experience, Knowledge and research involvement in the various rehabilitation areas, membership of the Board includes consumer representatives from various veterans service organizations. The decision of the Director, Rehab R&D Service regarding the Board's recommendations is transmitted to the health care facilities along with review results and supporting documentation.

c. A Rehab R&D Center submits a proposal for each new program in the same manner as other proposals; i.e, through the ACOS/R&D, R&D Committee and the facility Director to the Director, Rehab R&D Service.

3.03 RESEARCH ADVISORY GROUP REVIEW

Requests for Rehab R&D funding submitted to VA Central Office for RAG (Research Advisory Group) review must be routed through the Director, Rehab R&D Service, the R&D Committee, and the facility Director before consideration by the RAG. If all concur that the request is appropriate for RAG review, the RAG will process the request and provide its recommendations to the Director, Rehab R&D Service for consideration. (See pt. 11, par. 3.02.)

3.04 CAREER DEVELOPMENT PROGRAM

Rehab R&D Service may participate in the R&D Career Development program as described in part 11, paragraph 3.04. Any requests for Rehab R&D participation will be submitted to the Director, Rehab R&D Service for review and approval prior to processing by the Career Development Program of Medical Research Service as described in part 11, paragraph 3.04.

3.05 COOPERATIVE STUDIES PROGRAM

If funding support will be requested from Rehab R&D Service, any cooperative study proposed in rehabilitation R&D shall be submitted to the Director, Rehab **R&D** Service for review and approval prior to processing by the Director, Cooperative Studies Program in accordance with procedures described in part 11, paragraph 3.05.

3.06 RESEARCH CAREER SCIENTISTS

Any requests for research career scientist appointments of Rehab R&D investigators shall be routed through the Director, Rehab R&D Service for concurrence prior to submission to the Medical Research Service for processing in a manner analogous to that for biomedical researchcar-eer scientists. (See pt. II, par. 3.06.)

CHAPTER 4. REHABILITATION RESEARCH AND DEVELOPMENT BUDGET POLICIES

4.01 REHABILITATION PROJECT SUPPORT

Budgetary control of Rehab R&D projects is centralized. Individual projects are funded annually, by fiscal year, based on approved project budgets.

4.02 FACILITY SUPPORT

a. Financial support to health care facilities research administration for Rehab R&D projects includes research administrative support, an amount separate from the project's direct costs, to defray the cost of maintaining an administrative office, animal research facilities, and common research resources. (See pt. 11, par. 401.) Proposals should include in their budgets only project direct costs.

b. The amount of "administrative" funding to be provided by Rehab R&D Service will be determined for each facility based on assessment of need.

CHAPTER 5. EXTRA-AGENCY ACTIVITIES

5.01 EXTRAMURAL RESEARCH AND DEVELOPMENT BY CONTRACT

a. The varied needs for specific development programs may require extramural or contractual support. All Contracts and consulting arrangements with non-VA personnel must follow Federal and VA Acquisition Regulations. This applies whether the agreement is for a prime contractor or is essentially a subcontract to support an intramural program (See also pt. 1, par. 5.02.)

b. All noncompetitively negotiated research contracts require a justification and approval signed by designated officials and processed in accordance with Federal Acquisition Regulation 6.302-3 and VA implementing and supplementing VA Acquisition Regulation.

c. The Rehab R&D program does not award grants. Projects may be funded through contracts initiated by a contractor, VA Central Office Rehab R&D Service, or personnel in the health care facility. Each proposal must be reviewed and approved as all other Rehab R&D projects. When the initiative for the contract arises within the VA, careful attention must be given to compliance with restrictions on sole-source contracts; use of a RFP (Request for Proposals) is advisable where feasible. The Rehab R&D Service annually issues an RFP as a general program announcement in the *Commerce Business Daily*. The Supply Service should be consulted for guidance as soon as it becomes likely that a contract will be used.

5.02 INTERAGENCY COOPERATION

a. The VA cooperates closely with Federal, State and local governmental and nongovernmental organizations by jointly funding projects in Rehab R&D. Rehab R&D merit reviewed approved projects have been jointly funded by such agencies as the Department of Health and Human Services, Department of Education, State universities and veterans' service organizations.

b. The Rehab R&D Service advocates the use of an IPA to secure the services of personnel and specialized expertise for short periods where recruitment is not likely to occur. For example, the services of faculty and staff at state supported schools could be obtained through an IPA. Many not-for-profit R&D facilities and private educational facilities may qualify for an IPA. For further information, refer to the Federal Personnel Manual, chapter 334, or 5 U.S.C. 334.