

CHAPTER 1. INTRODUCTION

1.01 DEFINITIONS

- a. "R&D (Research and Development)" in the Department of Medicine and Surgery includes the investigation and refinement of biomedical problems and hypotheses related to human health, diseases, defects, and handicaps as well as the systematic study and refinement of problems and hypotheses related to the delivery of health care.
- b. "Research" is the testing of concepts by the scientific method of hypothesis formulation, systematic and recorded collection of relevant data, and interpretation of the results in terms of the hypothesis.
- c. "Development" is the application of research to practical ends with the intent of producing useful devices or techniques rather than the testing of concepts. It can involve nonroutine evaluation of new or existing devices and techniques and may employ the scientific method. The output includes the initial formulation of products, whether devices or techniques, correction of defective products, and improvement of existing products.
- d. "Principal investigator" is the individual who is accountable for the proposal, performance, and continuation of a research or development project.
- e. "Co-principal investigator" is one of two or more principal investigators who share equally in the accountability for a project.
- f. "Cooperating investigator" is the person at any one VA facility who is accountable for the facility's participation in a study that involves two or more facilities.
- g. "Collaborating investigator" is any other investigator who participates in a project; generally persons are considered as "collaborating" if they will be included as joint authors of the final presentation of the project.
- h. "Project" is a coherent unit of research or development that is proposed, pursued, and reported as a separate activity. Its scope is larger than that of a single experiment but may be smaller than that of an individual's scientific activity over a long period. As a unit, the project can be considered the work that will produce one or more published papers, formal reports, or completed devices or techniques.
- i. "Program" includes one or more projects clearly related to one another. Thus, there is the program of an investigator or of a medical center as well as the program of cardiovascular research and the cooperative research program. A single project may be included in more than one program.
- j. "Intramural research or development" is that performed by VA employees or appointees (including those serving without compensation), generally within VA facilities.
- k. "Extramural research or development" is that performed by investigators not in the employ of the VA but financed by the VA.
- l. "Cooperative study" is a project or program of research or development conducted at two or more health care facilities using common protocol so that data obtained at all participating facilities can be treated as though from a single source.
- m. "Collaborative study" is a project or program of research or development conducted at two or more health care facilities; it does not require a common protocol.
- n. "Affiliated institution" generally refers to an academic institution that has a relationship with a VA medical center documented by a Memorandum of Affiliation in conformance with M-8, "Academic Affairs" I Part 1, Chapter 2, Appendix 2A. In addition, special purpose affiliations documented by a memorandum of understanding approved by the Director of the appropriate R&D service, VA Central Office, may be developed in R&D areas such as health services or rehabilitation research and

development. Such special affiliations will be designated as "HSR&D Field Programs" or "Rehab R&D affiliations" and the specially affiliated institution will be termed "HSR&D-affiliated" or "Rehab R&D-affiliated" institution, as appropriate.

1.02 PRINCIPLES AND OBJECTIVES OF THE RESEARCH AND DEVELOPMENT PROGRAM

a. The primary mission of the Department of Medicine and Surgery-to provide high quality medical care to veteran-patients served by the R&D program in three ways:

(1) The production of new knowledge, techniques, or products leading to improved prevention, diagnosis, treatment, and control of disease, as well as correction of, or compensation for, defects. These R&D products benefit veteran-patients and humanity in general.

(2) The attraction and retention of a high quality professional staff that improves the care of the VA's patients,

(3) The provision of a stimulating intellectual environment necessary for the educational programs in VA health care facilities as well as serving in support of subparagraphs (1) and (2) above.

b. These objectives can be attained only through research and development of high quality. The program, therefore, constantly strives to achieve excellence.

c. The results of development and of directly applied research, including clinical studies, can have an immediate effect on patient care. Such applications, however, depend upon research commonly called basic. Scientists performing basic studies also advise and assist other staff members in pursuing their research.

1.03 POLICIES

a. Staff members of health care facilities are encouraged to engage in R&D programs consistent with the best interests of patient care.

b. Research and development are conducted as intramural activities when this is feasible. Extramural research may be supported through contracts when this is the best or only means to achieve the program's objectives and when such support is allowed by law and VA policy. The VA does not make grants for extramural research and development.

c. The VA R&D program encourages free exchange of scientific, technical, and medical information both within and outside the VA. (See M-1, pt. 1, par. 9.66a.) In keeping with this policy, VA investigators are encouraged to report their work at professional meetings and in scientific, technical, and medical publications, and to participate in the activities of their professional organizations. While the importance of the free exchange of information is acknowledged, one must understand that presentations and publications identified with the VA reflect upon the agency. Accordingly, presentations or publications that are to enjoy the support of and identification with the agency must be, and are, subject to appropriate review for quality prior to dissemination. In reporting research, the law and agency policies regarding patient information disclosures must be observed.

d. VA funds may be used to support the exchange of technical information. Such means of exchange include, but are not limited to publications, conferences, and other professional meetings.

e. The VA recognizes the important role of research in the basic biomedical and related sciences and of basic scientists in advancing health care. Scientists, whether clinicians or not, whose work is of high quality and relevant to the VA's mission and who contribute to related functions of the health care facilities, may be supported in their research.

f. Physicians, dentists, and nurses cannot receive salaries or special pay, where applicable, from R&D funds except with the express prior approval of the Chief Medical Director. Written request(s) for exception, with justification for it, shall be submitted by the facility Director through the ACMD/R&D (Assistant Chief Medical Director for Research and Development).

g. The VA and/or its investigators can accept financial support from governmental and nongovernmental organizations for research and/or development in accordance with VA policies and programs. Such funding must use fiscal mechanisms

prescribed by law and VA procedures, must be accounted for in an appropriate and currently prescribed manner, and must not violate Federal conflict of interest regulations and law. (See ch. 5 of this part.)

h. When justifiable under the definition of research and/or development, R&D funds may be used to establish and operate facilities, manage systems, or to provide reimbursement for the care of patients but only insofar as such activities are clearly identifiable as bona fide research and/or development.

i. R&D funds may not be used for services that should be provided as administrative support by the VA health care facility. Among services that may not be supported are: radiation safety, infection control, library, supply, personnel management, fiscal, facility engineering, or building management (excluding building management for animal research facilities). All utilities and normal telephone services are provided by the health care facility without charge to R&D project/program budgets.

j. The VA R&D program supports efforts in all fields where health problems of veterans occur. It may, however, emphasize the importance of some fields to veterans by establishing special priorities for investigations in these fields, by creating specialized Research Centers, or by other devices to stimulate increased efforts.

k. Nonveterans can participate as subjects in intramural VA research, but only when a sufficient number of veteran-patients suitable for the project is not available. In this situation, research funds must reimburse the Medical Care appropriation for any hospitalization and for every outpatient visit. The budget for the project shall reflect this expense.

l. Communication, written or oral, on administrative matters between VA Central Office and R&D personnel in health care facilities is through proper channels, to include, where appropriate, the ACOS/R&D (Associate Chief of Staff for Research and Development), the C/R&D (Coordinator for Research and Development), and the Regional Research and Development Office. Direct contact between investigators and Central Office R&D personnel is appropriate only when concerned with professional or scientific matters relating to investigations and only after authorization from the ACOS/R&D, C/R&D, or another person designated to do so.

m. The VA seeks to foster desirable commercial production and distribution of useful devices, techniques or systems perfected in R&D programs so that these advances are widely available. VA Central Office utilizes all legal means to bring this about, and encourages use of mechanisms available under the patent laws, under the auspices and supervision of VA Central Office.

n. In keeping with VA policy, any new and potentially patentable or copyrightable idea or device devised by a VA employee must be reported to VA Central Office. A letter briefly describing the innovation shall be sent to the General Counsel in Central Office as soon as possible after patentability is suspected.

o. The requirements of any regulations formulated in conjunction with this manual apply to all VA Research and Development including but not limited to investigational drugs, investigational devices, rehabilitation research and development, and health services research and development.