Replaces M-3, Part I, Chapter 1

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1200
Transmittal Sheet
November 1, 2001

VETERANS HEALTH ADMINISTRATION RESEARCH AND DEVELOPMENT

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Directive provides an overview of Research and Development policies and procedures.

2. SUMMARY OF CONTENTS: The Office of Research and Development (ORD) and its four research services (Medical Research Service (MRS), Rehabilitation Research and Development Service (RR&D), Health Services Research and Development Service (HSR&D), and the Cooperative Studies Program (CSP)) address a common mission and adhere to common policies. In addition, shared principles, including prioritization of research proposals on the basis of scientific merit, fiscal responsibility, and high standards of scientific integrity, govern all Department of Veterans Affairs (VA) research activity.

3. RELATED DIRECTIVE: VHA Handbook 1200.1, etc., to be published.

4. RESPONSIBLE OFFICE: The VHA Office of Research and Development (12) is responsible for the contents of this Directive. Questions may be referred to ORD at (202) 273-8284, or by facsimile at (202) 273-6526.

5. RESCISSIONS: M-3, Part I, Chapter 1 is rescinded.

6. RECERTIFICATION: This document is scheduled for recertification on or before the last working day of November 2006.

S/ Tom Sanders for
Thomas L. Garthwaite, M.D.
Under Secretary for Health

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VETERANS HEALTH ADMINISTRATION
RESEARCH AND DEVELOPMENT

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy and guidance related to the Medical and Prosthetic Research and Development (R&D) Program in the Department of Veterans Affairs (VA).

2. BACKGROUND

a. Medical and Prosthetics Research in VHA is an intramural program administered by the VHA Central Office, Office of Research and Development (ORD) and conducted at VA medical facilities nationwide. (Authority: Title 38 United states Code (U.S.C.) Chapter 73, Section 7303.) The mission of the R&D program is to discover knowledge and create innovations that advance health care for our veterans and the nation. In support of this mission, the ORD strives to:

(1) Sustain a superior environment of inquiry conducive to the highest quality research, education and patient care.

(2) Effectively integrate fundamental, clinical, and applied research to best meet veterans' health care needs.

(3) Effectively transfer research results to advance veterans' health care.

(4) Maximize VHA's value as a national research asset.

(5) Lead and manage an effective and efficient research enterprise.

(6) Increase awareness and understanding of the value of VHA's research contributions.

b. The VA R&D program is an intramural program. ORD allocates appropriated Medical and Prosthetic Research funds to VA medical facilities for scientifically meritorious research related to the high priority health care needs of veterans to be conducted by VA employees. VA investigators may also obtain funding support for their research from extramural sources such as other Federal agencies, private voluntary health organizations and foundations, and commercial entities. Unlike agencies such as the National Institutes of Health (NIH) and the Department of Defense (DOD), VA does not have the statutory authority to make research grants to colleges and universities, cities and states, or any other non-VA entity. Contracts may be utilized to obtain special services not available in VA (see VHA Handbook 1200.2, (to be published) "Research Business Operations") for detailed information regarding contracts).

c. Professional staff members of VA medical centers are encouraged to engage in R&D activities.

d. Research proposals received by a VHA Central Office R&D Service (Medical Research Service (MRS), Rehabilitation R&D Service (RR&D), Health Services R&D Service (HSR&D), and the Cooperative Studies Program (CSP)) that are determined to be more appropriate for review by another R&D Service, may be transferred to ensure adequate peer review. The R&D Service accepting review responsibility will notify the applicant. The proposal will be reviewed in accordance with procedures applicable to the reviewing Service.

e. The requirements of any policies and operational procedures formulated in conjunction with this VHA Directive apply to all R&D activities conducted completely or partially in VA facilities, conducted in approved off-site locations and/or facilities and/or conducted by VA investigators while on official VA duty time, whether funded by VA or by other sources, or unfunded.

f. Values guiding all R&D efforts include: scientific excellence; the ethical conduct of research; protection of human subjects; and animal welfare. The R&D program spans the continuum from basic biomedical research through the translation of research into practice, emphasizing health concerns of veterans.

g. The R&D program supports and rigorously abides by the Federal Policy for Protection of Human Subjects of Research (the Common Rule) and the principles outlined in the Belmont Report and the Nuremberg Code. The rights and welfare of all persons participating in research must be vigorously protected. All research involving human subjects must comply with all Federal regulations and VA requirements that address the protection of human subjects, including Title 38 Code of Federal Regulations (CFR) Part 16 (VA's implementation of the Common Rule, also codified by the Department of Health and Human Services at 45 CFR Part 46, Subpart A), and all related policy and procedural documents issued by ORD. These regulations and requirements must be met before any research involving human subjects is initiated, and adherence must be sustained throughout the conduct of the research.

h. The R&D program supports only those animal studies that are designed and performed with the highest degree of attention to the welfare of research animals and that fully comply with Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International guidelines.

i. The R&D program maintains a research safety program consistent with policies, statutes, and regulations issued by the Occupational Safety & Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Centers for Disease Control and Prevention (CDC), and NIH. The R&D program supports only those studies with the highest standards of protecting personnel against biohazards, chemical hazards, and physical hazards in research laboratory settings.

3. POLICY: It is VHA policy that:

a. All research sponsored by ORD and its four research services (MRS, RR&D, HSR&D, and CSP) address a common mission and adhere to common policies.

b. Shared principles, including prioritization of research proposals on the basis of scientific merit, fiscal responsibility, and high standards of scientific integrity, govern all VA research activity.

c. All VA research activities involving human subjects or human specimens and/or tissues must comply with ORD requirements regarding the inclusion of women and minorities in research (refer to VHA Handbook 1200.9, "Inclusion of Women and Minorities in Research").

4. ACTION

a. **VHA Central Office.** The Chief Research and Development Officer (CRADO) is responsible for the overall policy, planning, coordination, and direction of R&D activities within VHA. (Authority: Title 38, U.S.C. Chapter 73, Section 7303.) These responsibilities are carried out at VHA Central Office through ORD and its four research services (MRS, RR&D, HSR&D, and CSP).

b. **Veterans Integrated Service Network (VISN) Directors**. VISN Directors are responsible for ensuring that each medical facility conducting research and development under their jurisdiction is in compliance with current policy and procedural guidelines. VISN Directors also will arrange for appropriate scientific and administrative support for R&D Committees and subcommittees, ensure that these groups are accredited by relevant external credentialing organizations, and provide adequate release time for VA staff serving as committee members. Directors will ensure that investigators are allocated appropriate time during their VA tour of duty hours to conduct funded research.

c. **Facility Directors**

(1) The Director or Chief Executive Officer (CEO) of each health care facility is responsible for the R&D program of that institution, advised and assisted by an R&D Committee. All facilities with an active R&D program must have an official responsible for management of the program. Facilities with large, active research programs will establish a position equivalent to Associate Chief of Staff (ACOS) for R&D such as Research Director, or Clinical R&D Executive or equivalent, through the Chief of Staff (COS) and/or the Chief Medical Officer (CMO) and/or the Chief Clinical Executive (CCE), or equivalent. When a facility's R&D program activity does not justify the position of ACOS for R&D, the position of Coordinator for R&D (C for R&D) may be established in the Office of the COS, or CMO, or CCE in lieu of the ACOS for R&D or equivalent. The position of C for R&D may be designated as a collateral function of another administrative position. The medical center Director is responsible for implementing the R&D program, policies, and procedures, including establishing and appointing members to the R&D committee and any appropriate subcommittees.

(2) The medical center Director is responsible for ensuring that R&D funds are not used for routine clinical care or administrative support services that should be provided by the local facility. The services that may not be supported by R&D funds 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 and information technology services are provided by the health care facility without charge to R&D project and/or program budgets.

(a) It is expected that the portion of the medical center's budget attributable to the R&D portion of the Veterans Equitable Resource Allocation (VERA) transferred to the medical center will be used to provide indirect support for research, including but not limited to, services such as appropriate scientific and administrative support for R&D Committees and subcommittees. These funds may not be used for routine clinical and or administrative support services, utilities or normal telephone service that should be provided by the local facility.

(b) It is the responsibility of the medical center Director to provide adequate administrative support for the R&D Committee, Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Subcommittee on Research Safety (SRS), including personnel to support committee review and record-keeping functions and space sufficient to provide privacy for conducting sensitive duties related to biosafety and protection of human and animal subjects involved in research. If the facility utilizes the IRB of an affiliated institution, the medical center Director may contribute to the support of that IRB as appropriate. VA staff time in support of IRB activity will be accounted for and supported. VA-funded R&D project/program budgets will not be charged for administrative or medical staff support of R&D Committee, IRB, IACUC, SRS or other committee/subcommittee activity. Medical center Directors will ensure that investigators are allocated appropriate time during their VA tour of duty hours to conduct funded research.

(3) The medical center Director is responsible for ensuring that the research program reimburses the medical care appropriation when clinical services are provided to:

(a) A study patient who is a non-veteran or a veteran ineligible for VA care; or

(b) An eligible veteran solely for the sake of participation in a research project.

(4) The medical center Director is responsible for ensuring the ethical conduct of research and adequate protection of human participants in research.

5. DEFINITIONS: The following definitions are applicable in the context of this Directive and all supporting VHA Handbooks (1200 series).

a. **Title 38 CFR Part 16.** Title 38 CFR, Part 16, implements the Common Rule for VA.

b. **Ad hoc member.** An ad hoc member is an individual with expertise or competence in a particular area who assists with the review of issues that require expertise beyond that or in addition to that available on a committee or subcommittee. An ad hoc member may not vote with the committee or contribute to the quorum.

c. **Administrative Officer for Research and Development (AO for R&D).** The AO for R&D is the individual responsible for the administrative functions of the research program. The AO for R&D serves as an assistant to the ACOS for R&D.

d. **Affiliated institution.** An affiliated institution is an academic institution that has a relationship with a VA medical center documented by a Memorandum of Affiliation in conformance with VA regulations (also referred to as "academic affiliate"). In addition, special purpose affiliations documented by a memorandum of understanding approved by the CRADO, may be developed in R&D areas such as health services or rehabilitation research and development.

e. **Appeal.** An appeal is a request to reconsider the disapproval or decision to not fund a research proposal. Appeals of Merit Review results should be focused on the actions of the review board and may be made when, in the opinion of the investigator, the board did not understand the research, missed relevant points, and/or exhibited bias.

f. **ACOS for R&D.** The ACOS for R&D is the individual with delegated authority for management of the research program at facilities with large, active programs.

g. **Biomedical research:** the investigation of the etiology, pathogenesis, diagnosis, and treatment of medical and behavioral diseases and conditions.

h. **Center of Excellence.** A Center of Excellence is a team of researchers funded for the purpose of collaborating on a common research agenda and developing expertise in a specific research area. Centers of Excellence are funded for a specified period of time following scientific merit review.

i. **CRADO.** The CRADO is the individual responsible for the overall policy, planning, coordination, and direction of R&D activities within VHA. These responsibilities are carried out at VHA Central Office through programs administered by ORD and four research services (MRS, RR&D, HSR&D, and CSP).

j. **Chief Veterinary Medical Officer (CVMO).** The CVMO is the individual responsible for veterinary medical and animal research concerns and issues. The CVMO reports to the CRADO, or designee.

k. **Collaborating Investigator (or co-investigator).** The Collaborating Investigator (or co-investigator) is an investigator other than the principal 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.

l. **Collaborative study.** A 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.

m. **Conflict of Interest.** A conflict of interest is any financial arrangement, situation or action that affects or is perceived to exert inappropriate influence on the design, review,

conduct, results or reporting of research activities or findings. Policies and procedures to enable all VA investigators to comply with VHA and applicable Federal and state regulations regarding conflict of interest will be described in VHA Handbook 1200.13 (to be published).

n. **Cooperating Investigator.** The 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.

o. **Cooperative Research and Development Agreements (CRADA).** CRADA is an agreement between VA and one or more non-Federal parties under which VA "laboratory directors" (defined herein as medical center Directors) may accept, retain and use funds, personnel, services, facilities, equipment, or other resources from collaborating parties. In exchange for what VA receives from a collaborating party, VA may provide personnel, services, facilities, equipment, or other resources, but not funds toward the conduct of specified research and development efforts which are consistent with VA's mission.

p. **Cooperative Study.** A 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.

q. **C for R&D.** The C for R&D is the individual responsible for coordination of research activities at facilities with insufficient activity to justify the position of ACOS for R&D. The position of C for R&D may be a part-time position and may be designated as a collateral function of another administrative position.

r. **Co-principal Investigator (co-PI).** A co-PI is one of two or more principal investigators who share equally in the accountability for a project.

s. **Copyright.** Copyright is a form of protection provided by the laws of the United States (Title 17, U.S.C.) to the authors of "original works of authorship" including literary, dramatic, musical, artistic, and other intellectual works, for a limited period of time. A copyright protects the form of expression, rather than ideas or the subject matter of the work. The copyright owner controls a number of exclusive divisible rights, the most fundamental one being the right to reproduce the work in copies.

t. **Data Security and Privacy.** Data Security and Privacy is the protection of confidential information, including technical procedures for maintaining the security and integrity of research data. Policies and procedures for protecting the confidentiality of information pertaining to and/or collected from participants in VA research and in VA research protocols, and the technical procedures for maintaining the security and integrity of research data will be addressed in VHA Handbook 1200.6 (to be published).

u. **Development.** Development is the application of research to practical ends with the intent of producing useful devices, products or techniques rather than the testing of concepts. It can involve non-routine evaluation of new or existing devices, products 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.

v. **Eligibility:** Eligibility is the right of an investigator to receive VA research support based on the investigator's VA employment status, physical presence, and professional commitment. The criteria for eligibility to receive research support from the ORD are described in VHA Handbook 1200.15.

w. **Ex officio member:** An ex-officio member is the individual who serves as a member of a committee by virtue of that individual's position. An ex officio member may be a voting or non-voting member.

x. **Extramural Funds.** Extramural funds are funds available to support VA research other than those specifically appropriated to VA by Congress. These funds may be provided by other federal agencies, state or local government agencies, non-profit corporations or foundations, charitable organizations, companies, or individual contributors.

y. **Extramural Research.** Extramural research is research performed by investigators not in the employ of VA, but who may be under contract with VA.

z. **Federal Policy for the Protection of Human Subjects (56 Federal Regulation 28.003 (June 18, 1991)).** This Federal Policy for the Protection of Human Subjects policy (also known as the Common Rule) sets forth the minimal requirements for the protection of human subjects involved in research conducted or funded by Federal Departments. VA has adopted the rule in regulatory form at 38 CFR Part 16.

aa. **Formal Communication.** Formal communication is correspondence or other written documents forwarded through proper channels and bearing approval signatures as appropriate.

bb. **Health services research.** Health services research is a multidisciplinary field concerned with the effects of social factors, financing systems, organizational structures and processes, technology, and human behavior on health care access, quality, costs, and outcomes. In VA, health services research focuses on understanding how to organize, deliver, and finance health care that is effective and cost-effective, in order to meet the needs of veterans and to ensure that their health care system is sound and consistently excellent. It emphasizes research that has practical applications and that can assist patients, health care providers, managers and policymakers.

cc. **Human Subject.** A human subject is an individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information. An intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes. Research involving human biological specimens (e.g., urine, blood, tissue, and other bodily fluids) and research involving identifiable data about living individuals is considered human subjects research (refer to VHA Handbook 1200.5 (to be published)).

dd. **Institutional Animal Care and Use Committee (IACUC).** IACUC is the local committee charged with ensuring compliance with animal research regulations and guidelines. At VA medical centers, the IACUC is a subcommittee of the R&D Committee (refer to VHA Handbook 1200.7 (to be published)).

ee. **Institutional Review Board (IRB).** The IRB is the local committee charged with the oversight of all research activities involving the use of human subjects. At VA medical centers, the IRB is a subcommittee of the R&D Committee (refer to VHA Handbook 1200.5 (to be published)).

ff. **Intellectual Property.** Intellectual property is any art, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States. Policy guidance and instructions regarding intellectual property and the transfer of new scientific discoveries to benefit the public good are contained in VHA Handbook 1200.18.

gg. **Interagency Agreement.** An Interagency Agreement is an agreement which allows a federal agency with authority to conduct a certain activity to contract with another agency or department, which has the capability to perform the required activity.

hh. **Intramural funds.** Intramural funds are funds appropriated by Congress to support VA research. These funds are allocated by ORD to support programs and projects at local facilities.

ii. **Intramural research.** Intramural research is research performed by VA employees or appointees (including those serving without compensation), at VA facilities and approved off-site locations.

jj. **Memorandum of Understanding (MOU).** A MOU is a written agreement entered into by and between two or more parties to set forth the terms, conditions, and understandings of the parties with respect to a specific activity. For example, an MOU may be developed to delineate each party's responsibilities in collaborations between two or more federal agencies, or between a federal agency and a private entity.

kk. **Non-profit Research and Education Corporation.** A Non-profit Research and Education Corporation is a nonprofit corporation created pursuant to Sections 7361 and 7368 of Title 38, United States Code. These corporations exist solely to facilitate research and education at a VA medical center by acting as a flexible funding mechanism. Policies, procedures, and instructions governing nonprofit research and education corporations will be described in VHA Handbook 1200.17 (to be published).

ll. **Off-site research:** Off-site research is research performed in sites other than VA medical centers or VA leased space. Performance sites for off-site research must be approved in advance by the CRADO. Policies regarding off-site research are clarified in VHA Handbook 1200.16.

mm. **Patent.** A patent is an official written document securing to an inventor for a term of years the exclusive right to make, use or sell an invention.

nn. **Principal Investigator (PI).** A PI is an individual who actually conducts an investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

oo. **Program.** A program consists of one or more projects clearly related to one another. There is the program of an investigator or of a medical center as well as the program of cardiovascular research and CSP. A single project may be included in more than one program.

pp. **Project.** A 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.

qq. **Quorum.** A quorum is defined as a majority of the voting members. At meetings of the R&D Committee and its subcommittees, a quorum must be established and maintained throughout the entire meeting in order for business to be conducted. Some committees, such as the IRB, have additional requirements for the establishment of a quorum, such as the presence of a member whose primary concerns are in nonscientific areas. A member with a conflict of interest cannot contribute to a quorum.

rr. **R&D Committee.** The R&D Committee is the local committee charged with oversight of all R&D activities within a facility.

ss. **Rehabilitation Research.** Rehabilitation Research is the investigation of methods to advance optimal rehabilitation health care for veterans with disabilities.

tt. **Research.** Research is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question.

uu. **R&D.** R&D is the investigation and refinement of 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 organization and delivery of health care.

vv. **Research Center Director.** The Research Center Director is the investigator who serves as the Principal Investigator of a Center of Excellence or other recognized VA R&D Center.

ww. **Research Misconduct.** Research misconduct is fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results. Policies and procedures for reporting, investigating, and resolving allegations of research

misconduct by VA employees will be addressed in VHA Handbook 1200.14 (to be published).

xx. **Subcommittee on Research Safety (SRS).** The SRS is the local committee charged with ensuring compliance with all applicable regulations, policies, and guidelines pertinent to biological, chemical, physical, and radiation hazards, and with oversight of all research activities involving safety hazards. At VA medical centers, the SRS is a subcommittee of the R&D Committee (refer to VHA Handbook 1200.8 (to be published)).

yy. **VA Medical center (or VA Health Care Facility).** A VA medical center (or VA health care facility) is a hospital or other health care facility within the VA system.

zz. **Without Compensation (WOC) Appointment.** A WOC appointment is a personnel appointment by which an individual contributes time to VA activities but receives no monetary compensation.