

## RESEARCH AND DEVELOPMENT PROGRAM

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive provides an overview of Research and Development (R&D) policies and procedures.
- 2. SUMMARY OF MAJOR CHANGES:** The major changes in this Directive include: an abbreviated background section to address only the major focus of the research program, aligning responsibilities of the Veterans Integrated Service Network (VISN) Director with actual practice, deleting the section on research scope of practice as this is addressed in other 1200 series Handbooks, and deleting definitions not pertinent to this Directive.
- 3. RELATED ISSUES:** VHA 1200 Series Handbooks.
- 4. RESPONSIBLE OFFICE:** The VHA Office of Research and Development (ORD) (10P9) is responsible for the contents of this Directive. Refer questions to ORD at 202-443-5600.
- 5. RESCISSIONS:** VHA Directive 1200, dated July 9, 2009 is rescinded.
- 6. RECERTIFICATION:** This VHA Directive is scheduled for recertification on or before the last working day of May 2021.

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## RESEARCH AND DEVELOPMENT PROGRAM

### 1. PURPOSE

This Veterans Health Administration (VHA) Directive provides policy related to the Medical and Prosthetic Research and Development (R&D) Program in the Department of Veterans Affairs (VA). **AUTHORITY:** 38 U.S.C. 501, 513, 3119, 3904, 7303, 7314(g), 7331, and 8154.

### 2. BACKGROUND

a. The Medical and Prosthetics R&D program is an intramural program administered by the VHA Central Office, Office of Research and Development (ORD), and conducted at VA medical facilities nationwide. The R&D program is focused on advancing Veterans' health and health care. R&D supports research that spans the continuum from biomedical research through the translation of research into practice in the VA Health Care System.

b. The mission of the R&D program is to discover knowledge and create innovations that advance health care for Veterans and the Nation. ORD accomplishes its mission through a number of mechanisms, including supporting research through funding opportunities; setting research policy; identifying ethical standards for the conduct of research and researchers; consulting with field research programs, their staff, and their investigators; developing and implementing educational programs that support the research mission; and assisting VA medical facilities in complying with applicable requirements, guidance, and educational programs. In support of this mission, ORD strives to:

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

(2) Effectively integrate biomedical, clinical, translational and applied research to best meet Veterans' health care needs.

(3) Focus research efforts towards increasing the evidence base for treatments, directly contributing to the VA being a learning healthcare system.

(4) Effectively disseminate and implement research results to advance Veterans' health care.

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

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

c. Values guiding all R&D efforts include: Scientific excellence; the ethical conduct of research; protection of human subjects; the welfare of laboratory animals; the safety of those involved in the research program; and the security of our research laboratories, other research resources, and research data.

### 3. POLICY

It is VHA policy that ORD serves as the primary VHA office responsible for the allocation of appropriated Medical and Prosthetic Research funds; the development of policies related to the conduct of research and VHA research program; and the development and implementation of educational programs in support of VHA's research mission.

### 4. RESPONSIBILITIES

a. **Chief Research and Development Officer.** The Chief Research and Development Officer (CRADO) is responsible for the overall policy, planning, coordination, and direction of R&D activities within VHA. The R&D program's major responsibilities are:

(1) Development of VHA policy related to the research program and dissemination of appropriate guidance to assist investigators and research administrative persons in complying with VA and VHA regulations.

(2) Development and implementation of educational programs in support of ORD's research mission. These educational programs address unique needs of researchers and research administrative staff and they are in addition to, or supportive of, other VA and VHA required or applicable educational programs.

(3) Allocation of appropriated Medical and Prosthetic Research funds to VA medical facilities for scientifically meritorious research conducted by VA investigators that is related to the high priority health care needs of Veterans.

b. **Veterans Integrated Service Network Director.** The Veterans Integrated Service Network (VISN) Director is responsible for:

(1) Ensuring that each VA medical facility conducting research and development under the VISN jurisdiction is in compliance with current policy and procedural guidelines.

(2) Providing the Veterans Equitable Resource Allocation (VERA) research support allocation to each of its VA medical centers. The VERA research support allocation computation is based on self-reported research expenditures using the Research and Development Information System Part II (RDIS-II) and certified annually by the VA medical facility Director.

(3) Supporting the provision of appropriately designed and supported space to house the VA research program at each VA medical facility in the VISN.

c. **VA Medical Facility Directors.** The VA medical facility Director is responsible for:

(1) The VA medical facility R&D program, assisted by a R&D Committee.

(2) Implementing the R&D program, policies, and procedures, including establishing and appointing members to the R&D Committee and any appropriate subcommittees.

(3) Ensuring that R&D funds are used as authorized for research, and ensuring that the research appropriation is not used for:

(a) Routine clinical care or administrative support services;

(b) Radiation safety, infection control, library, supply, personnel management, fiscal, facility engineering, medical media, research compliance officer, or building management (excluding building management for animal research facilities).

(4) Ensuring that the VA medical facility's budget attributable to the R&D portion of the VERA funds transferred to the VA medical facility will be used to provide indirect support for research, including but not limited to, clinician investigator salary support, and appropriate scientific and administrative support for R&D Committees and subcommittees.

(5) Providing adequate support for the R&D Committee and its subcommittees, such as the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Subcommittee on Research Safety (SRS), as relevant. This support includes personnel to support committee reviews and record-keeping functions and space sufficient to provide privacy for conducting sensitive duties related to biosafety and the protection of human and animal subjects involved in research. If the VA medical facility utilizes the IRB, IACUC, or SRS of an affiliated institution, another Federal agency or another VA medical facility, the VA medical facility Director may contribute to the support of that committee as appropriate. VA-funded R&D project or program budgets are not to be charged for administrative or medical staff support of R&D Committee, IRB, IACUC, SRS, or other committee and subcommittee activity.

(6) Ensuring that investigators are allocated appropriate time during their VA tours of duty to conduct funded research.

(7) Ensuring adequate research space and physical infrastructure to support the facility's research program.

(8) Ensuring that the research program reimburses the medical care appropriation when clinical services are provided to:

(a) A study subject who is a non-Veteran or a Veteran ineligible for VA care; or

(b) An eligible Veteran solely for research purposes not connected to clinical care.

(9) Ensuring the ethical conduct of research and the adequate protection of human participants in research.

(10) Ensuring that all VA employees involved in the R&D program comply with applicable ethics laws, regulations, and principles. See VHA Handbook 1660.03, Conflict of Interest Aspects of Contracting for Scarce Medical Specialist Services,

Enhanced Use Leases, Health Care Resource Sharing, Fee Basis and Intergovernmental Personnel Act Agreements (IPAs).

(11) Ensuring that VA investigators and research team members have been officially appointed as paid employees, without compensation employees (WOC) employees, or either appointed or detailed through the authority of the Intergovernmental Personnel Act (IPA).

(12) Ensuring all individuals working within and supporting the VA medical facility's research program are fully aware of, and implement all required security controls in accordance with VA and VHA policies.

## 5. DEFINITIONS

a. **Chief Research and Development Officer.** The Chief Research and Development Officer (CRADO) is the individual responsible for the overall policy, planning, coordination, and direction of R&D activities within VHA.

b. **Institutional Animal Care and Use Committee.** An Institutional Animal Care Use Committee (IACUC) is the local committee charged with ensuring compliance with animal research regulations and guidelines. At VA medical facilities, the IACUC is a subcommittee of the R&D Committee (refer to VHA Handbook 1200.07).

c. **Institutional Review Board.** An Institutional Review Board (IRB) is a board, committee, or other group formally designated by an institution to review, approve, require modification of, disapprove, and conduct continuing oversight of human subjects research in accordance with 38 CFR part 16 and other applicable regulations.

d. **Intramural Research.** The VA research program is intramural in nature, with funding provided to VA investigators to conduct research at VA medical facilities or VA-approved off-site locations.

e. **Research and Development.** Research and Development (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.

f. **Research & Development Committee.** The R&D Committee is the local committee charged with oversight of all R&D activities within a facility and is responsible for maintaining high standards throughout the R&D program.

g. **Research.** Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

h. **Subcommittee on Research Safety.** The Subcommittee on Research Safety (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 facilities, the SRS is a subcommittee of the R&D Committee.

i. **VA Investigator.** A VA investigator is any individual who conducts research while acting under a VA appointment, including full and part-time employee, Without Compensation (WOC) employee, or employee under the IPA of 1970. Individuals working under a contract with VA cannot conduct research under a WOC appointment.

j. **VA Research.** VA research is research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the R & D Committee before it is considered VA research and before it can be initiated. ***NOTE: VA space cannot be used for non-VA research unless there is appropriate legal authority to do so (e.g., memorandum of understanding, lease, or other agreement).***

k. **Without Compensation.** VA is specifically authorized by Title 38 United States Code (U.S.C.) 513 to accept uncompensated services for the purpose of carrying out all laws administered by VA. Within the VA research program, a person serving as a Without Compensation (WOC) employee must be officially appointed into that position by Human Resources Management (HRM) and must be supervised by a VA compensated employee.