Department of Veterans Affairs **VHA DIRECTIVE 1200**
Veterans Health Administration
Washington, DC 20420 **July 9, 2009**

VETERANS HEALTH ADMINISTRATION
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 CONTENTS. The major changes in this Directive reflect the:

a. Major responsibilities of the Office of Research and Development (ORD), which include the:

(1) Development of VHA policy related to the research program and apply to all VA R&D activities;

(2) Development and implementation of educational programs in support of ORD's research mission; and

(3) Allocation of 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.

b. Specific references to education and training.

c. ORD research security program.

3. RELATED ISSUES. VHA 1200 Series Handbooks.

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) 461-1700.

5. RESCISSIONS. VHA Directive 1200, dated November 1, 2001, and VHA Directive 1201, dated October 11, 2001, are rescinded.

6. RECERTIFICATION. This document is scheduled for recertification on or before the last working day of July 2014.

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VETERANS HEALTH ADMINISTRATION
RESEARCH AND DEVELOPMENT PROGRAM

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 and Development 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 under the authority of Title 38 United States Code (U.S.C.), 7303. The R&D program is an intramural program that spans the continuum from basic biomedical research through the translation of research into practice, emphasizing the health concerns of Veterans.

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 setting policy; identifying ethical standards; developing and presenting educational programs; consulting with field research programs, their staff, and their investigators; supporting research through funding opportunities; and assisting 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 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.

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 both our research laboratories, other research resources, and research data.

(1) **Research Involving Human Subjects.** The R&D program supports and rigorously abides by the Federal Policy for Protection of Human Subjects in Research (the Common Rule)

and the principles outlined in the Belmont Report and the Nuremberg Code. The R&D program vigorously protects the rights and welfare of all persons participating in VA research.

(a) All research involving human subjects must comply with Federal regulations and Department of Veterans Affairs (VA) requirements that address the protection of human subjects. The Common Rule is codified by VA at Title 38 CFR Part 16; by the Department of Health and Human Services (HHS) at 45 CFR Part 46, Subpart A; and VHA Handbook 1200.05.

(b) All applicable 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.

(2) **Research Involving Animal Studies.** The R&D program supports only those animal studies that are:

(a) Designed and performed with the highest-degree of attention to the welfare of research animals, and

(b) Fully comply with Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) guidelines and VHA Handbook 1200.7.

(3) **Research Involving Recombinant (DNA).** The R&D program must comply with the National Institutes of Health (NIH) Guidelines for Research Involving DNA Molecules.

(4) **Research Safety Program.** The R&D program maintains a research safety program consistent with policies, statutes, and regulations issued by the Occupational Safety and 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 settings including VA research laboratories.

(5) **Research Security Program.** The research security program addresses a number of areas including:

(a) Privacy, confidentiality, and security of all VA sensitive information and compliance with all applicable Federal statutes and regulations related to privacy and security including: the Privacy Act of 1974; the Health Insurance Portability and Accountability Act; 38 U.S.C. 5701, 5705, and 7332; the Federal Information Security Management Act of 2002; VA Handbook 6500; VA Handbook 6502; and all other VHA privacy, confidentiality and security policies. ***NOTE:*** *HHS has issued regulations, the Standards for Privacy of Individually Identifiable Health Information, codified at 45 CFR parts 160 and 164.*

(b) Security of all information and other technology systems related to VA's research program (see VA Handbook 6500, and www.research.va.gov/resources).

(c) Research laboratory security including security of all hazardous agents; sources of ionizing radiation; and both select agents and toxins as defined by the Center for Disease Control and the Department of Agriculture.

d. R&D activities conducted by VA investigators may be funded or unfunded. Sources of funding may include:

(1) Intramural Funds. Funds appropriated by Congress specifically for VA research.

(2) Extramural Funds. Funds provided by sources other than Congress. See paragraph 5r. ***NOTE:*** *Unlike Federal agencies such as 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 entities. Contracts may be utilized to obtain special services not available in VA.*

e. All VA research regardless of funding source or sponsor including sponsorship by ORD and its four research services (Biomedical Laboratory Research and Development (BLR&D), Clinical Science Research and Development (CSR&D), Rehabilitation Research and Development (RR&D), and Health Systems Research and Development (HSR&D)) address a common mission and adhere to common policies.

f. All VA research must be and is governed by shared principles, including prioritization of research proposals on the basis of scientific merit, fiscal responsibility, high standards of scientific integrity, and relevance to the health of our Veterans.

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

4. RESPONSIBILITIES

a. **Chief Research and Development Officer (CRADO).** The 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 required guidance to assist investigators and research administrative persons in complying with VA, VHA, and other applicable Federal laws and regulations. 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 or facilities, and/or conducted by VA investigators while on official VA duty, whether funded by VA, by other sources, or unfunded.

(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 and is to be conducted by VA employees.

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

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

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

(2) Arranging for appropriate scientific and administrative support for R&D Committees and subcommittees.

(3) Ensuring that these groups are accredited by relevant external credentialing organizations as required by VHA.

(4) Providing adequate release time for VA staff serving as committee members.

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

(6) Ensuring all security controls are implemented in accordance with VA and VHA policies.

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

(1) The facility R&D program, advised and 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 not used for routine clinical care or administrative support services that are to be provided by the facility.

(a) Ensuring all utilities and normal telephone and information technology services are provided by the health care facility without charge to R&D projects or program.

(b) The services that may not be supported by R&D funds are: 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).

(c) 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. ***NOTE:*** *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.*

(4) Providing 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). This support includes personnel to support committee review 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 facility utilizes the IRB of an affiliated institution, another Federal agency or another VA facility, the medical center Director may contribute to the support of that IRB 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.

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

(6) 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 the sake of participation in a research project.

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

(8) Ensuring that all VA employees involved in the R&D program comply with ethics laws, regulations, and principles. See VHA Handbook 1660.03.

(9) Ensuring that all individuals working within and supporting the research program have been officially appointed as paid employees, without compensation employees (WOC) employees, or either appointed or detailed through the authority of the Intergovernmental Personnel Agreement (IPA).

(a) All individuals must be appropriately credentialed and privileged (if applicable). In any case, a Research Scope of Practice Statement or Functional Statement must be defined for all individuals conducting VA research, including individuals who do not function as health care providers. The Scope of Practice Statement or Functional Statement must be consistent with the position to which the individual is appointed and must define the duties of the individual. The Scope of Practice Statement or Functional Statement must not include any duties or procedures for which the individual is not qualified. If the individual holds clinical privileges at the facility

and the research responsibilities and duties match the clinical privileges, the clinical privileges may be used in lieu of a Scope of Practice Statement. If there are additional responsibilities and duties, these should be included in the Scope of Practice Statement along with a copy of the clinical privileges. ***NOTE:*** *If applicable because of the position the individual holds, a functional statement may used in lieu of the Scope of Practice Statement.*

(b) For contractors, the requirement for the appropriate background investigation, credentialing, and privileging must be specifically defined in the contract, which must clearly define their duties.

(9) Appointing the facility's ISO and Privacy Officer as non-voting members to either its IRB of record or its R&D Committee of record. ***NOTE:*** *Facilities are encouraged to engage the facility ISO and Privacy Officer even before submission of a protocol for IRB review, optimally in the design phase of the research.*

(10) Appointing a Research Compliance Officer that reports directly to the Director and is responsible for developing and implementing a research compliance program.

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

5. DEFINITIONS

The following definitions are applicable in the context of this Directive.

a. **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 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.

b. **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.

c. **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 (MOU) approved by the CRADO, may be developed in R&D areas such as health services or rehabilitation research and development.

d. **Associate Chief of Staff for Research and Development (ACOS for R&D).** The ACOS for R&D is the individual that is responsible for the day-to-day management of the research program at facilities with large, active programs. ***NOTE:*** *Although 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 the position of Associate Chief of Staff (ACOS) for R&D through the Chief of Staff (COS) and the Chief Medical Officer (CMO) and 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. The position of C for R&D may be designated as a collateral function of another administrative position.

e. **Biomedical Research.** The investigation of the etiology, pathogenesis, diagnosis, and treatment of medical and behavioral diseases and conditions.

f. **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.

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

h. **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.

i. **Common Rule.** The phrase "common rule" means the Federal Policy for the Protection of Human Subjects. VA codified it at 38 CFR Part 16.

j. **Conflict of Interest.** A VA employee has a conflict of interest when he or she participates personally and substantially through decision, recommendation, giving advice, or other action, in any contract, case, controversy, or other particular matter knowing that he, his spouse, minor child, outside employer, or certain others to which he or she has a connection, has a financial interest in the matter. In research, such a conflict of interest would affect, potentially affect, or create the appearance that it could affect, the design, review, conduct, results, or the reporting of research activities or findings.

k. **Cooperative Study.** A VA cooperative study is a project or program of research or development conducted at two or more VA health care facilities using common protocol so that data obtained at all participating facilities can be treated as though from a single source.

l. **Coordinator for Research & Development (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.

m. **Co-Principal Investigator (Co-PI).** A Co-PI is one of two or more principal investigators who share equality in the accountability for a study. A Co-PI must meet the same qualifications as a PI.

n. **Cooperative Research and Development Agreements (CRADA).** A CRADA is an agreement under the Federal Technology Transfer Act of 1986, Public Law (Pub. L. 99-502), between VA and one or more non-Federal and Federal parties under which VA may accept, retain and use funds, personnel, services, facilities, equipment, or other resources from the other party. In exchange, VA may provide personnel, services, facilities, equipment, or other resources, but not funds, for research and development efforts that are consistent with VA's mission. VHA Directive 2007-044, dated December 26, 2997, established that it t is VHA policy that a CRADA must be used to establish the terms of new research collaborations involving use of VA resources (including VA personnel whether salaried or serving under a without compensation appointment) and by non-VA organizations when the non-VA partner seeks commitment of ownership and licensing rights in advance of an invention being made.

o. **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.

p. **Eligibility.** Eligibility is the right of an investigator, Principal Investigator, Co-PI, and Site Investigators to receive VA research support based on the investigator's VA employment status, physical presence, and professional commitment to VA. The criteria for eligibility to receive research support from the ORD are described in VHA Handbook 1200.15.

q. **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 is a non-voting member.

r**. Extramural Funds.** Extramural funds are available to support VA research other than those specifically appropriated to VA by Congress for VA research. 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. Such funds include:

(1) Gifts or donations received for approved VA research projects. These include donations of equipment or supplies as well as funding. Gifts or donations of money for VA research must be deposited in the General Post Fund and then they are treated as appropriated funds.

(2) Grants that have been approved by VA and the medical center Director or designee. ***NOTE:*** *Grants may be gifts or contracts, Regional Counsel or the Office of General Counsel should be consulted regarding this determination.*

(3) Amounts paid under cooperative research and development agreements (CRADA). See VHA Handbook 1200.18

(4) Reimbursables provided in support of an interagency agreement of grant from a non-VA government organization.

(5) Support from Non-profit Research and Education Corporations (NPCs). VA accepts support from NPCs under its gift acceptance authority. Funds received from an NPC must be deposited in to the General Post Fund and then treated like appropriated funds.

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

t. **Federal Policy for the Protection of Human Subjects.** This Federal Policy for the Protection of Human Subjects policy is also known as the Common Rule. It sets forth the minimal requirements for the protection of human subjects involved in research conducted or funded by Federal Departments.

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

v. **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 VA's 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.

w. **Human Subject**. A human subject is a living individual about whom an investigator conducting research obtains either:

(1) data through intervention or interaction with the individual, or

(2) identifiable private information (38 CFR 16.102(f)). Interaction includes communication or interpersonal contact between the researchers and the subject. For research covered by Food and Drug Administration (FDA) regulations, human subject means an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. (21 CFR 50.3(g); 21 CFR 66.102(c)).

x. **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).

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

z. **Interagency Agreement.** An Interagency Agreement is an agreement by which a Federal agency with authority to conduct a certain activity contracts with another agency or department, which has the capability to perform the required activity.

aa. **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 VA facilities.

bb. **Intramural Research.** Intramural research is research performed by VA investigators at VA facilities and approved off-site locations.

cc. **Investigator.** An investigator is any individual who conducts research. The investigator must uphold professional and ethical standards and practices, and adhere to all applicable VA and Federal requirements, and to the applicable local VA facility's policies and procedures.

(1) **VA Investigator**. A VA investigator is any individual who conducts research approved by the VA R&D committee while acting under a VA appointment, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the IPA of 1970. In addition, a VA investigator must comply with all applicable VA and VHA regulations and policies.

(2) **Principal Investigator (PI)**. A PI is a qualified person or persons designated by an applicant institution to direct a research project or program and who usually writes the grant application. The PI oversees scientific and technical aspects of a grant or protocol and the day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of that team. (FDA considers Investigator and Principal Investigator to be synonymous.)

(3) **Co-Principal Investigator (Co-PI).** See paragraph 5m.

(4) **Site Investigator.** Investigator at a site participating in a multi-site research project who serves as the PI at that site.

dd. **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, as allowable by law, in collaborations between two or more Federal agencies, or between a Federal agency and a private entity such as a medical center and its affiliated nonprofit research corporation.

ee. **Non-profit Research and Education Corporation.** A Non-profit Research and Education Corporation (NPC) is a nonprofit corporation created pursuant to 38 U.S.C. 7361 through 7368. These corporations exist solely to facilitate approved research and education at a VA medical center by acting as a flexible funding mechanism. Policies, procedures, and instructions governing NPCs are described in VHA Handbook 1200.17.

ff. **Off-site Research.** Off-site research is research performed at sites other than VA medical centers, other VA space, or VA leased space. Policies regarding off-site research are clarified in VHA Handbook 1200.16.

gg. **Principal Investigator (PI).** See the definition for investigator, paragraph 5cc(2).

hh. **Program.** A program consists of one or more projects clearly related to one another. The program may be specific to an investigator, a service, or a specific area. A single project may be included in more than one program.

ii. **Project.** A project is a coherent unit of research or development that is proposed, pursued, and reported as a separate activity. Its scope may be 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.

jj. **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, be present for the discussion of the issue for which they are conflicted, except to answer questions from the committee, or be present for the vote on the issue. They must not be present in the room for the discussion or the vote.

kk. **R&D 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 through out the R&D program.

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

mm. **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. It is a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalized knowledge.

nn. **Research Information Security.** Research information security is the protection of information and information systems that includes management, operational, and technical procedures for maintaining the confidentiality, integrity, and availability of research data and information in accordance with the Federal Information Security Management Act of 2002 (FISMA, 44 U.S.C. 3541, et seq.) and VA Directive and Handbook 6500, Information Security Program. **NOTE**: *The manner of protecting VA sensitive information must comply with requirements of all Federal statues and regulations, Executive Orders, and Government and VA-wide policies, procedures, and guidance, including but not limited to 5 U.S.C. 552a, the Privacy Act of 1974; Public Law 104-191, the Health Insurance Portability and*

Accountability Act; 38 U.S.C. 5701, 5705, and 7332; and VA and VHA privacy and confidentiality policies.

oo. **Research Protocol**. As used in this Directive, "research protocol" means the formal written plan for conducting a research investigation, including but not limited to biomedical, behavioral, social, health service, or educational research investigations, as well as clinical trials.

(1) The research protocol typically includes the background and rationale for conducting the research, the research hypotheses, the objectives or specific aims, and the research methods to be used.

(2) The protocol also must include a discussion of ethical issues, involvement of human subjects, privacy, confidentiality, data storage, and data security.

pp. **Research Scope of Practice Statement**. As used in this Directive, a Research Scope of Practice Statement is a written document that defines the parameters and functions of an employee's duties and responsibilities. These duties and responsibilities must be consistent with the occupational category under which they are hired (appointed by HRM to the position) allowed by the license, registration, or certification they hold, consistent with their qualifications (education and training), and be agreed upon by the person's immediate supervisor and the ACOS/R&D. When the employee is working on specific research protocols, the PI for each protocol must also agree with the Scope of Practice Statement.

qq. **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.

rr. **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.

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

tt. **VA Research**. VA Research is research that is approved by the R&D Committee and conducted by VA investigators including PIs, Co-PIs, and Site Investigators, (serving on compensated, WOC, or IPA appointments) while on VA time, utilizing VA resources, and/or on VA property including space leased to, and used by, VA. The research may be funded by VA, by other sponsors, or be unfunded.

uu. **Without Compensation (WOC) Appointment.** A WOC is an individual that has been officially appointment by the office of Human Resource Management but does not receive any monetary compensation from VA. This appointment may allow the individual to support the VA research program in various capacities including but not limited to investigator, research

coordinator, and administrator while at VA for a defined period of time. WOCs are subject to laws and regulations pertaining to Government personnel including but not limited to VHA's credentialing and privileging policy and standards of conduct.