

RESEARCH BUSINESS OPERATIONS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes standards and requirements for the proper and efficient operation of the VA facility's research service and offices with regard to protocol submission, protocol review, formal communications, financial operations, and personnel.

2. SUMMARY OF MAJOR CHANGES:

a. Major changes include consolidating requirements that are currently found in other 1200 series Handbooks. Other changes include amended responsibilities for VA facility Research Offices, research staff, and the VA medical facility Director. The requirements in this directive must be implemented no later than July 11, 2017.

b. Amendment, dated September 6, 2017, removes the requirement of each VA medical facility conducting research to submit MOUs or other written agreements to the Office of Research and Development and recommends consultation with VA's Office of Real Property for real property agreement use.

3. RELATED ISSUES: VHA Directive 1200 and VHA 1200 series Handbooks.

4. RESPONSIBLE OFFICE: The Office of Research and Development (10P9) is responsible for the content of this VHA Handbook. Questions may be referred to 202-443-5600.

5. RESCISSION: VHA Manual M-3 Part 1 Chapters 4, 5, 6, 7, and 10; VHA Handbook 1200.2 dated May 23, 2002; and VHA Handbook 1202.06 dated July 9, 2008, are rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of March 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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RESEARCH BUSINESS OPERATIONS

1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy and guidance for the successful administration and operational management of Research Offices in VA medical facilities. In addition, it also addresses issues related to research staff and research conducted within VHA. Requirements of this directive must be implemented no later than July 11, 2017. **NOTE:** *All sections of rescinded VHA Handbook 1200.2, dated May 23, 2002, must be followed until the VA medical facility implements the requirements of this new directive.* **AUTHORITY:** Title 38 United States Code (U.S.C.) 7303.

2. BACKGROUND

a. The mission of the VA Research and Development (R&D) program is to discover knowledge and create innovations that advance health care for Veterans and the Nation. The Office of Research and Development (ORD) accomplishes its mission through a number of mechanisms: setting policy; identifying ethical standards; consulting with field research programs, their staff, and their investigators; supporting research through funding opportunities; and assisting facilities in complying with applicable requirements by developing guidance and educational programs.

b. The VA 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. Each research program supports the mission of VA and conducts research that is relevant to the Veteran population. The VA R&D program conducts research and operates its laboratories in compliance with applicable policies, regulations, and statutes.

c. VA research is primarily conducted at VA medical facilities. These VA medical facilities may house research laboratories, research clinical space, and computer systems to support the research. Each VA medical facility that conducts research is required to establish a research service that includes an administrative structure for the research program and the infrastructure that is required to support the program's activities. The R&D office within each VA medical facility conducting research is composed of administrative and support staff whose functions and responsibilities include the operation and management of the research service and the local research program. These functions and responsibilities cannot be delegated to any other entity, or performed by any other entity on behalf of the VA medical facility, without written permission from the Chief Research and Development Officer (CRADO). The facility R&D office also ensures that VA research conducted by the VA medical facility and the programs' research staff complies with all applicable Federal statutes, Federal regulations, VA policies, and VHA policies.

3. DEFINITIONS

a. **Academic Affiliate.** An academic affiliate is an academic institution that has a relationship for the purpose of education, research, or enhanced patient care with a VA medical center documented by a formal Affiliation Agreement in conformance with VA requirements.

b. **Investigator.** An Investigator is any individual who conducts research including, but not limited to, the Principal Investigator (PI), Co-Principal Investigator (co-PI), sub-investigator, and Local Site Investigator (LSI). All investigators on a VA research study or program must hold a VA appointment.

(1) **Co-Principal Investigator.** A Co-principal Investigator (co-PI) is one of two or more PIs who share equally in the accountability for a study.

(2) **Principal Investigator.** The Principal Investigator (PI) is a qualified person who directs a research study or program. The PI oversees scientific, technical, and day-to-day management of the research. If a study is conducted by a team of individuals, the PI is the responsible leader of that team.

(3) **Site Investigator or Local Site Investigator.** A Site Investigator or Local Site Investigator (LSI) is the Investigator at one of the participating sites in a VA multi-site study that is responsible for the conduct of the study at the local site. The LSI serves as the PI at that local site.

(4) **VA Investigator.** A VA Investigator is any individual who conducts research while acting under a VA appointment, including full and part-time employees, Without Compensation (WOC) employees, or individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970. Individuals working under a contract with VA cannot conduct research under a WOC appointment.

c. **Research Protocol.** A Research Protocol details the aims and objectives of a research study, the scientific rationale, the methods used to carry out the research, and how data will be analyzed. For human subject research, it also entails how subjects will be identified, accessed, and recruited; any foreseeable risks; and how these risks will be mitigated. ***NOTE: The protocol for social or behavioral research is sometimes referred to as the "Research Plan" or "Research Purpose and Methodology."***

d. **Scope of Practice.** The scope of practice is the procedures, actions, and processes that a VA Investigator and research team members are permitted to undertake in a VA medical facility based on education, training, licensure, certification and experience, and specific demonstrated competency.

e. **Stewardship Investment.** Stewardship investments are items recognized as expenses in calculating net cost, but meriting special treatment to highlight the substantial investment and long-term benefit of the expenses. This would include non-Federal physical property, human capital (e.g., Veterans' and dependents' education and health professions' education) and research and development.

f. **VA Information.** VA Information is information on any storage media or in any form or format, owned or in the possession of VA, or under control of VA or any entity acting for or on behalf of VA. The information may be identifiable, de-identified, sensitive, or non-sensitive.

g. **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 by a VA Investigator or other third party for non-VA research unless there is appropriate legal authority to do so, and the parties enter into an appropriate real property agreement that complies with applicable law and VA policy, such as a Revocable License or lease. Questions involving proposed use of VA space should be directed to VA's Office of Real Property.***

h. **VA Sensitive Personal Information and Data.** VA sensitive information is all VA Information which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, and records about individuals requiring protection under applicable confidentiality provisions (see Title 38 U.S.C. 5727).

i. **Without Compensation.** A WOC employee is an individual that has an official VA appointment, but does not receive any salary or benefits from VA. See 38 U.S.C. §513; 38 U.S.C. §7405(a)(1). This appointment may allow the individual to support VA's research program in various capacities including, but not limited to, Investigator, research coordinator, and administrator while at VA for a defined period of time. WOC employees are subject to all laws and regulations pertaining to government personnel, including, but not limited to, Government ethics laws and Standards of Conduct and VHA Handbook 1100.19, Credentialing and Privileging.

4. POLICY

It is VHA policy that the development and management of research programs at all VA facilities that conduct research including opening new programs, financial management of research programs, and responsibilities of research staff is accomplished in accordance with this directive and applicable federal statutes.

5. THE VA MEDICAL FACILITY RESEARCH PROGRAM

a. Each VA medical facility conducting research must establish a research service to administer and manage the research program. The facility Director is the Institutional Official (IO) responsible for the research program assisted by the Chief of Staff (COS) and the Associate Chief of Staff for Research & Development (ACOS/R&D). ***NOTE: In smaller research programs, the VA medical facility may appoint a Coordinator for R&D***

instead of an ACOS/R&D. There are a number of components comprising the research program and the Research Office that administers the program. These include:

(1) **Research Office.** At minimum, the Research Office must include the ACOS/R&D or Coordinator for Research & Development (C for R&D) and a research administrative officer (AO). Additional staff may be required depending on the size of the research program and the type and complexity of research that is conducted at the VA medical facility, e.g., budget analyst, staff assistants, and committee administrators.

(2) **Research Personnel.** Personnel who may conduct or assist in the conduct of research include Investigators, research coordinators, research assistants, technicians, and support staff.

(3) **Committees.** The research service is assisted by the R&D Committee and its subcommittees. Subcommittees of the R&D Committee may include but are not limited to an Institutional Review Board (IRB), an Institutional Animal Care and Use Committee (IACUC), and a Subcommittee for Review of Safety. VHA Handbook 1200.01, Research and Development (R&D) Committee, addresses requirements for and management of the R&D Committee and its subcommittees.

(4) **Non-Research VA Medical Facility Departments.** The research program is assisted by VA medical facility departments, such as engineering/facility management, pharmacy, laboratory, environmental services, acquisition & materials management, human resources, information technology, financial management service, biomedical engineering, and clinical services (e.g., imaging).

b. The Research Office and its personnel are responsible for ensuring the effectiveness of the research program. These responsibilities include but are not limited to:

(1) **Tracking VA Research Activities.** The Research Office must establish tracking systems that allow for easy retrieval of information to assist in assessing compliance with applicable requirements and the status of each program activity or element, including but not limited to:

(a) Research Studies. The system must indicate the studies' status (e.g., active, closed, suspended), the type of study, the sponsor, the funding source, the PI, required approvals, and other relevant information for each study. It must also allow for timely retrieval of the information.

(b) Committee Actions. The system must document activities of the R&D Committee and its subcommittees, including all initial review and continuing review approvals, to ensure that initial approvals are obtained prior to initiating the research, and continuing review approvals are obtained prior to expiration of the approvals.

(c) Agreements. The system must track all local Cooperative Research and Development Agreements (CRADA), research contracts, research Memorandum Of Understandings (MOUs), and other written research agreements.

(d) Personnel. The system must document all research staff, including Investigators, research coordinators, research assistants, research technicians, and others conducting any aspect of research at the VA medical facility.

(e) Training. The system must document completion of all ORD required training and Annual Government Ethics training (applicable to all Investigators) for research personnel.

(f) Research Data. An inventory must be maintained for all research data that are placed in a research data repository for future use and for all research data that are being stored until the retention requirement has been met per Record Control Schedule 10-1. The inventory at minimum must contain information on the origin of the data, whether the data are identifiable, whether the data are sensitive, where the data are stored, how the data are secured, and whether the protocol, consent, and the authorization required under Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (HIPAA authorization) under which the data were collected allows for reuse of the data.

(2) **Reporting**. All regular R&D reporting is incorporated in the Research and Development Information System (RDIS).

(a) The RDIS database provides information needed by field facilities for managing the R&D program and for responding to inquiries from VHA ORD staff, Congress, Executive Branch offices, the scientific community, and the general public.

(b) The RDIS Report, Part II, provides end-of-fiscal year information on VA and non-VA funded Administrative, Veterinary Medical Unit, Career Scientist, and Cooperative Studies Centers. Part II data must be submitted by November 15th annually. Upon completion of data entry, signed reports that certify accuracy of data input must be submitted electronically to the Director of Finance, ORD. Signed originals must be maintained locally for audit and inspection purposes. The local VA medical facility Chief Financial Officer (CFO) and the VA medical facility Director must certify the report's accuracy. Projects must be coded correctly in ePromise as this can affect the RDIS report and the VA medical facility's Veterans Equitable Resource Allocation (VERA) allocation.

c. Each VA medical facility conducting research is responsible for ensuring that the Research Office receives copies of all Research Protocols, including amendments that are reviewed by the R&D Committee and its subcommittees, and all committee and subcommittee approvals.

6. NEW OR REACTIVATED RESEARCH PROGRAMS

a. VA medical facilities wishing to establish a new research program or reactivate a deactivated program must ensure that there is sufficient support from the VA medical facility Director for the program and that there are sufficient resources available for the research program. Needed resources include, but are not limited to, space, finances, and personnel.

b. Approval from ORD in consultation with the Office of Research Oversight (ORO) must be obtained before implementing the new research program or reactivating a previously deactivated program.

(1) In reviewing the request the following elements will be evaluated:

(a) The number of experienced Investigators,

(b) The type of research that is contemplated (human subjects, animal, basic),

(c) For animal research, the existence of or plans to establish a Veterinary Medical Unit,

(d) For basic/laboratory research, the presence of adequate laboratory space,

(e) The ability to establish a R&D Committee,

(f) The ability to establish or obtain the services of an IRB if human subjects research will be conducted, an IACUC if research involving animals will be conducted, or a Subcommittee on Research Safety, and

(g) The ability to establish and fund positions for a Research Compliance Officer, an ACOS/R&D (or a Coordinator for R&D), and an AO/R&D.

(2) The VA medical facility is encouraged to consult with ORD and ORO very early in the planning process.

7. FORMAL COMMUNICATIONS

a. All communication with ORD on operational and administrative matters must be routed through the VA medical facility Director or Chief Executive Officer (CEO) to the Director of the appropriate ORD office. **NOTE:** *The VA medical facility Director may delegate this responsibility to the ACOS/R&D or the Coordinator for R&D.*

b. Email may be considered formal communication; however, communications requiring signature authority may only use email if the electronic signature meets all VA Officer of Information and Technology (OI&T) requirements. Email communication must be in compliance with all VA policies. (See VA Directive 6500 and 6500 series Handbooks.)

8. FINANCIAL OPERATIONS

a. **Funding Mechanisms.** The Research Office is responsible for managing all facility research funds in coordination with the VA medical facility Finance Officer.

(1) **Intramural Funds.** Research and development stewardship investments are treated as expenses incurred for basic research, applied research, and development programs that are intended to maintain or increase national productive capacity. The

ultimate objective of such investment is to equip the Federal Government in dealing with war-related illnesses and post-deployment health issues on a long term basis (see VA Financial Policies and Procedures, Volume 111 – Chapter 9 – <http://www.va.gov/finance/docs/VA-FinancialPolicyVolumelllChapter09.pdf> and 38 U.S.C. 7303(b)). VA's research and development is comprised of the following funding programs: Biomedical Laboratory Research and Development (821), Rehabilitation Research and Development (822), Health Services Research and Development (824), Cooperative Studies Program (825), Clinical Science Research and Development (829) and Medical Research Support.

(2) **Veterans Equitable Resource Allocation (VERA) Funds.** Additional VERA funds are provided to each Veterans Integrated Service Network (VISN) facility based on the level of research expenditures at that facility. As stated previously, the accuracy and completeness of RDIS II input has a direct bearing on the VERA dollars distributed to a VA medical facility. The Research Support is funded as a separate component of the VERA model because research missions and research support are not directly related to the number of patients served by a given VA medical facility. The VERA methodology for allocating research support dollars is based upon the following two factors: (a) the research support budget, and (b) the volume of research dollars expended that are weighted according to the source of the funding. These funds are meant to support the VA medical facility to include personnel costs for individuals who spend a portion of their VA time working on research. It also includes administrative support provided to the research program, including support for committees and other expenses for research compliance and oversight. Further information regarding VERA can be found at <http://vaww.arc.med.va.gov/reports/>. **NOTE:** *This is an internal VA Web site and is not available to the public.*

(3) **Extramural Funds.** Extramural funds are funds other than those specifically appropriated for VA research by Congress. These funds may be provided by other Federal agencies, state or local government agencies, non-profit corporations or foundations, other charitable organizations, corporations and other private sector business entities, or an individual contributor. Such funds are to be administered through the VA Nonprofit Research and Education Corporation (NPC) or through the General Post Fund when possible.

(4) **Reimbursable Funds.** Reimbursable funds transferred to a VA medical facility by another Federal agency or by VA offices funded by different appropriation accounts retain the period of availability of funds under the source appropriation. For example, one-year appropriated funds will not convert to two-year money when the VA medical facility administers them. The VA medical facility's R&D programs must be careful to accept the reimbursable dollars into the appropriate account, prior year or current year, to prevent an inadvertent extension of the life of an appropriation. Once collected and showing in the General Ledger, a Transfer of Disbursement Authority (TDA) will be processed automatically following the month of collection.

b. Administration of Funds.

(1) **Appropriated Funds.** At the beginning of the fiscal year, ORD finance sends an Initial Target Allowance (ITA) to each local VA medical facility conducting research. The amount allocated depends on the level of funding approved by Congress, to include Continuing Resolution (CR) limitations and the number of Research Protocols for the medical facility that have been approved for funding and have not received all applicable funds up to that point in time. The ITA will also contain the CC101 distribution. CC101 refers to the cost center for funds allocated to support the administration of the Research Office at the VA facility. Throughout the year, TDAs are used to add or remove money from the VA medical facility. The research appropriation is a two-year appropriation. First year funds are called “current” year funds while second year funds are called “prior” year funds.

(2) **General Post Funds.** General Post Funds earmarked for Research must be managed according to VHA Handbook 4721. The VA medical facility’s R&D program must have standard operating procedures on how to accept and expend General Post Funds. General Post Funds do not expire but may be restricted by the donor.

(3) **NPC Funds.** The VA NPC facilitates the conduct of VA approved research and education by accepting, administering, retaining, and spending funds in accordance with VHA Handbook 1200.17. A special no-year fund, 0161X2, has been established for the sole purpose of capturing reimbursements from the VA NPC. Funds appropriated by Congress to the Department of Veterans Affairs cannot be managed by the NPC.

(4) **Contracts.** Contracts may be awarded for R&D purposes when the VA medical facility’s R&D program cannot provide the services needed in order to accomplish specific R&D goals and objectives. All contracts must be negotiated by a VA medical facility, VISN, or Regional Office of Acquisitions in compliance with Federal Acquisition Regulations and VA Acquisition Regulation . By law, only a Contracting Officer may execute a contract on behalf of VA. A VA Investigator or personnel in the Research Office cannot commit or appear to commit VA funds. The Investigator may provide technical or scientific assistance in the development of a statement of work or review of proposals. The ORD Contracting Standard Operating Procedures can be found on the ORD SharePoint site at

<https://vaww.vha.vaco.portal.va.gov/sites/comm/admin/contracts/default.aspx>. **NOTE:** *This is an internal VA Web site and is not available to the public.*

(5) **Letter Agreements.** A written agreement may be used for consultant services subject to VA medical facility policies and controls according to current VA regulations.

(6) **Interagency Agreements.** VA may enter into Interagency Agreements (IAA) with other Federal agencies under the provisions of 31 U.S.C. 1535. Such agreements provide a means by which one Federal agency needing supplies or services (the requesting agency) obtains them for another Federal agency (the servicing agency). Pursuant to this authority, VA may purchase R&D performed by other Federal agencies or perform R&D paid for by another Federal agency. The funding for an IAA is provided

through a reimbursable mechanism. VA will use the Treasury Financial Management System (FMS) Form 7600, IAA, for reimbursable agreements (see VA Financial Policies and Procedures, Volume 1, Chapter 11 at <http://www.va.gov/finance/policy/pubs/volumel.asp>). IAAs must be approved by the CRADO or designee prior to any collection of funds from the requesting agency. A representative from the ORD Office of Finance will sign all agreements to signify coordination and authorization for local collection of reimbursable funds. The ORD IAA Standard Operating Procedure (SOP) can be found on the ORD SharePoint site at: <https://vawww.vha.vaco.portal.va.gov/sites/comm/admin/contracts/default.aspx>. **NOTE:** *This is an internal VA Web site and is not available to the public. Also, see 38 U.S.C. 8111; Sharing of Department of Veterans Affairs and Department of Defense Health Care Resource*

c. **Just-In-Time Process to Release Funds.** When a project is selected for possible funding by the VA, it must be entered into the Just-in-Time (JIT) document management website for processing of the documents that must be submitted to ORD. Designated local research administrators must submit all documents into JIT because the website currently does not allow direct access by Investigators. Investigators are notified by ORD that JIT documents are needed and the Investigator must work with the local research administrator to prepare the relevant documents for submission to the local oversight committees (e.g., R&D Committee, IRB, IACUC, etc.). Local administrators with questions about using the JIT document management website should contact the individual indicated on the JIT website.

9. CREDENTIALING AND PRIVILEGING OF RESEARCH STAFF

a. **VA Appointments.** VA Investigators and research team members must hold a VA appointment prior to conducting any aspect of VA research. All VA research staff (clinical and non-clinical) conducting VA research must be credentialed and privileged (if applicable) as required by current local, VA, and VHA requirements (see VHA Handbook 1100.19, VHA Directive 2012-030 and VA Handbook 5005). Research staff may only perform those activities in a research study that are allowed by the job series to which they were appointed, have the relevant credentials and privileges, and are allowed by their research scope of practice.

(1) **Credentials.** All research staff who are licensed health care professionals permitted by the VA medical facility to provide patient care services independently must be credentialed and privileged as defined in VHA Handbook 1100.19. The credentialing but not privileging, requirements of VHA Handbook 1100.19 and VA Handbook 5005 apply to those Advanced Practice Registered Nurses, Physician Assistants, and clinical pharmacy specialists who do not practice as licensed independent practitioners, as well as physicians, dentists, and other practitioners assigned to research or administrative positions not involved in patient care.

(2) **Privileges.** Only practitioners who are licensed and permitted by the VA medical facility to practice independently may be granted clinical privileges (See VHA Handbook

1100.19, Credentialing and Privileging). The following apply to those conducting research:

(a) If the local VA medical facility where the research is to be performed requires privileging to perform a given duty (e.g., a procedure) in the clinical setting, the individual must be privileged at that VA medical facility to perform the duty before the individual can perform that duty in the research setting.

(b) If the local VA medical facility requires privileging for its staff to perform a given procedure, the staff person performing the procedure must have privileges that would allow it. The staff person cannot rely on the privileges of some other staff person including the individual's supervisors.

(3) Human Resources Management Service (HRMS) is responsible for credentialing all research employees prior to offering these individuals a VA appointment per VA Handbook 5005. In addition, the following lists must be checked by HRMS or the Research Office staff to see if the individual's activities are restricted:

(a) The Health and Human Services' (HHS) List of Excluded Individuals and Entities (LEIE) (see https://oig.hhs.gov/exclusions/exclusions_list.asp). This is the sanctions list or the exclusionary list of persons or entities that have been excluded from participation in Federal health care programs.

(b) The Debarment List maintained by the Food and Drug Administration (FDA) and the FDA Disqualified/Restricted/Assurances List for Clinical Investigators at The Debarment List (see <http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm>).

(c) The Public Health Service (PHS) Administrative Actions list. The PHS list indicates researchers who have had administrative actions imposed against them by the Office of Research Integrity. This list can be accessed from the Debarment List Web site or at <https://ori.hhs.gov/phs-admin-action-bulletin-board>.

(d) The System for Award Management (SAM): <https://www.sam.gov/portal/SAM/#1>. This site lists individuals who have been suspended and/or debarred from engaging in procurement and non-procurement transactions Government wide. This database should include researchers debarred for research misconduct and/or other research improprieties by any federal agency.

(e) Research Misconduct List information on ORO's Web site (http://www.va.gov/ORO/Research_Misconduct_Findings.asp). This includes links that provide access to notices of corrective actions imposed on VA researchers based on final findings of research misconduct made and upheld under VHA Directive 1058 (February 7, 2014).

b. **HRMS Responsibilities.** HRMS must review applications from non-United States citizens for their current residency status in the United States prior to employment that may involve the conduct of research or granting access to VA research laboratory

areas. The residency status must be reviewed to ensure the status is in compliance with all applicable laws and regulations.

(1) HRMS is responsible for reviewing, verifying, and tracking citizenship and visa status. Follow-up with appropriate external agencies such as the Immigration and Naturalization Service may be necessary to clarify or validate a non-citizen's credentials, e.g., graduation from educational institutions and licenses. The Research Office must verify that this has been done.

(2) The non-U.S. citizen R&D employee's residency status must be verified annually.

10. TRAINEE RESEARCH

a. Trainees are defined as a subset of employees who are:

(1) Appointed under trainee authority (38 U.S.C. 7405 or 7406), and

(2) Enrolled in one of two types of training programs:

(a) Enrolled in an accredited training program sponsored by an affiliated educational institution under a current and existing academic affiliation agreement (e.g. VA Form 10-0094A-J), or

(b) Enrolled in a VA sponsored training program (either accredited or non-accredited). Examples of these VA sponsored training programs include Office of Academic Affiliation (OAA)-funded advanced fellowship programs, OAA-funded Chief Residents in Quality and Safety, or OAA-funded and VA-sponsored accredited training programs.

b. Trainees as defined above may conduct research at a VA medical facility and serve as a co- or sub-investigator, use VA data, or use human biological specimens that have been collected within VA for clinical, administrative, or research purposes. Trainees who do not fulfill the requirements specified above cannot participate in VA research unless the VA medical facility Designated Education Officer seeks a waiver from the Chief Academic Affiliations Officer or designee, and the CRADO.

c. Trainees must have a VA Investigator sufficiently experienced in the area of the trainee's research interest to serve as the PI. The PI is responsible for ensuring that the trainee:

(1) Complies with all applicable local VA medical facility, VA, and other Federal requirements including those related to human subjects or animal safety, use of radioactive substances, information security, privacy, and other research processes;

(2) Completes or terminates the study in an orderly fashion prior to leaving VA in accordance with all applicable local, VA, and other Federal requirements;

(3) Provides the VA Research Office with an inventory of all research records to be retained at VA in accordance with the Record Control Schedule 10-1.

d. Students from unaffiliated academic institutions in the community may not be permitted to conduct student projects in VA or be given a WOC appointment for the sole purpose of conducting student research.

11. RESPONSIBILITIES OF THE VA MEDICAL FACILITY DIRECTOR

a. **The VA Medical Facility Director.** The VA Medical Facility Director is responsible for all aspects of the research program including but not limited to: human subjects protection; the welfare of research animals; privacy and security of VA data; and the safety and security of research laboratories and laboratory staff. **NOTE:** *The term VA medical facility Director includes medical center Director and Chief Executive Officer or other equivalent titles.*

b. The VA medical facility Director is responsible for establishing the position of and appointing an ACOS/ R&D. Each VA medical facility with a research program must fill the position of ACOS/R&D unless the VA medical facility determines that its research program is too small (based on the amount of funding and number of protocols) to justify such a position, in which case a C for R&D must be appointed. The position of ACOS/ R&D is established in the Office of the COS. **NOTE:** *The ACOS/R&D position is a five-eighths to eight-eighths FTEE position. Within 24 months of publication of this directive all persons holding the ACOS/R&D position that are less than five-eighths VA-compensated, must become at least five-eighths VA-compensated employee.*

(1) The ACOS for R&D must be a physician unless the CRADO has granted an exception. The ACOS for R&D needs to have credible research and academic experience. **NOTE:** *A national search is recommended.*

(2) The nominee must receive concurrence from the CRADO. The nomination package includes the nominee's credentials, curriculum vitae, and letter of recommendation from the VA medical facility Director. The concurrence process includes interviews with the CRADO and ORD staff.

(3) The VISN Director approves the appointment of the ACOS/R&D after receiving notification of concurrence from the CRADO. **NOTE:** *Disagreements between the CRADO and the appointing authority that cannot be resolved should consider input from the VISN Director and the Office of the Deputy Under Secretary for Health for Operations and Management (10N), with the final decision to be made by the Under Secretary for Health or designee.*

(4) When there is a vacancy, the VA medical facility Director must appoint an Acting ACOS/R&D within 1 month of the position being vacant. Use of the "acting" designation for longer than 6 months must be authorized by the CRADO.

c. When the R&D program lacks sufficient funding or number of research studies to justify the ACOS/R&D position, the position of C for R&D, in lieu of that of ACOS for R&D, may be established in the Office of the COS.

(1) The C for R&D needs to be a professional member of the VA medical facility or clinical staff who has research experience.

(2) The VA medical facility Director appoints the C for R&D and notifies the CRADO of the appointment. Supporting documents, including the curriculum vitae of the appointee, should accompany the notification.

d. An AO/R&D must be appointed for all research programs. If the VA medical facility Director appoints a C for R&D instead of an ACOS/R&D, the AO/R&D may be a part-time position, otherwise, the AO/R&D must be a full time position. The exact title for this position may vary depending on the needs of the VA medical facility. Some titles that have been used include Deputy ACOS/R&D or Assistant ACOS/R&D, Director of Research Operations, or Business Manager.

e. Other responsibilities of the VA medical facility Director include:

(1) Ensuring that research in which the VA medical facility is engaged is approved by the R&D Committee, after approval by all its applicable subcommittees.

(2) Ensuring there are adequate resources and administrative support, including personnel, space, and equipment for the R&D Committee and its subcommittees to fulfill their responsibilities.

(3) Ensuring appropriate education and training for members of the R&D Committee and its subcommittees, the research administration staff, and other staff involved in research. **NOTE:** *The type of training for other staff involved in research, such as the COS and the VA medical facility Director, may differ from the training required for committee members and members of a research team.*

(4) Ensuring that Investigators meet the requirements of paragraph 14 in this directive.

(5) Ensuring that research in which the VA medical facility is engaged is conducted in compliance with all applicable regulations and policies.

(6) Suspending research when there are real or perceived safety issues related to the research subjects, research staff, the welfare of research animals, or other serious concerns. This responsibility may be delegated to the COS or to the ACOS/R&D.

(7) Ensuring that VA research space is not used for non-VA research unless there is appropriate legal authority to do so *and the parties enter into a valid real property agreement that complies with applicable law and VA policy. Questions involving proposed use of VA space should be directed to VA's Real property Service, which will engage OGC's Real Property Law Group as necessary.*

12. RESPONSIBILITIES OF THE ACOS/R&D

a. The ACOS/R&D is responsible for the day-to-day activities of the research program and reports through the COS to the VA medical facility Director. The ACOS/R&D also serves as the Executive Secretary of the R&D Committee. **NOTE:** *In small programs lacking an ACOS/R&D, the C for R&D assumes these responsibilities.*

(1) The ACOS/R&D is expected to maintain his or her own research activities. At least five-eighths of the ACOS/R&D time must be used to administer the VA medical facility's research program. **NOTE:** *Activities related to his or her own research activities are not to be included in the five-eighths time used to administer the program.*

(2) The ACOS/R&D appoints an AO/R&D and notifies the Director of Operations in ORD of the appointment.

(3) The ACOS/R&D establishes a Veterinary Medical Unit prior to authorizing any research involving animals. A Veterinary Medical Officer (VMO) must be appointed in order to meet requirements for proper animal care and welfare and to ensure a satisfactory research environment. **NOTE:** *See VHA Handbook 1200.07 for detailed information regarding the qualifications and responsibilities of the VMO or equivalent.*

(4) Other specific responsibilities of the ACOS/R&D include but are not limited to:

(a) Ensuring that all research personnel hold an official VA appointment from HRMS (as a compensated, full-time or part time employee, a WOC, or under an IPA) prior to conducting or being involved in any way in VA research activities, and that the individuals maintain their appointment while conducting or being involved in any way in any VA research activities.

(b) Ensuring that all requests for WOC appointments for research have been appropriately justified and the appointments are in compliance with all applicable research, HRMS, and other VA policies. Such services cannot be used in lieu of the regular employment of employees under the competitive or excepted service procedures. When such services are used, they must be supplementary to the employment of essential personnel (VA Handbook 5005 Part II Chapter 2). **NOTE:** *Individuals working under a contract with VA or on a fee-for-service basis cannot conduct research under a WOC appointment.*

1. A VA supervisor must be officially appointed for each WOC employee.

2. The supervisor may be a PI on whose study the WOC employee is working, a section Chief, or the ACOS/ R&D.

(c) Ensuring that a copy (paper or electronic) of all approved Research Protocols, amendments, consent document templates, and other documents submitted to a research review committee/subcommittee, and documents related to the actions of the research review committees are maintained in and controlled by the VA Research.

NOTE: *The PI should retain the protocol files. If the PI leaves the VA medical facility, the Research Office must ensure that all protocol files are stored securely per VA policy.*

13. RESPONSIBILITIES OF THE AO/R&D

a. The AO/R&D supports the VA medical facility's research program by administering and managing the business operations of the program. Responsibilities of this position are dependent on the VA medical facility's needs and the scope and complexity of the research program.

(1) The AO/R&D reports to either the ACOS/R&D or C for R&D.

(2) Training and experience in health care administration and/or laboratory and/or health sciences are desirable. Prior familiarity with VA fiscal, supply, and personnel procedures and regulations is helpful.

b. Responsibilities of this position may be delegated to another qualified staff person within the Research Office. These responsibilities include but are not limited to:

(1) Reporting required fiscal and research project information in RDIS or the information system superseding RDIS and ensuring its accuracy.

(2) Tracking of all required activities or elements of the research program such as research personnel, research activities, and educational requirements (see paragraph 5.b.).

(3) Maintaining the research service's Equipment Inventory List or ensuring it is maintained correctly by other Research Office staff or other office designated by the VA medical facility's local SOP.

(4) Ensuring that all VA travel is in compliance with VA policy including the completion of travel authorizations, travel arrangements, and the use of travel cards.

(5) Coordinating personnel issues with HRMS.

(6) Overseeing Research Laboratory Areas along with the subcommittee on Research Safety, the Biosafety Officer, the Industrial Hygiene Officer, and/or the Chemical Safety Officer.

(7) Assisting with issues related to the Veterinary Medical Unit.

(8) Coordinating any required site visits from VA and other agencies or organizations and ensuring all activities related to accreditation are completed appropriately.

(9) Assisting with developing and implementing the Emergency Preparedness Plan.

(10) Ensuring that all safety and security issues are addressed and that the research program is in compliance with all applicable policies and regulations.

(11) Working with the VA medical facility's Chief Information Officer, the VA medical facility's Information Security Officer, and others as needed so that the Information Technology needs of the program are met.

(12) Coordinating or facilitating development of VA medical facility research policies.

14. RESPONSIBILITIES OF VA INVESTIGATORS

a. VA Investigators must hold an official appointment (compensated, WOC, or IPA) from HRMS prior to conducting VA research or holding any role in the research service. Specific responsibilities include but are not limited to:

(1) Conducting VA research only within their area of expertise/experience that is consistent with their job description, and where applicable, holding all required credentials and privileges prior to initiating any VA research or research activities.

NOTE: *Certain procedures can only be performed by practitioners with specific privileges to do so. If specific privileges are required in the clinical setting, then specific privileges are also required in the research setting.*

(2) Complying with all applicable personnel, applicable law, and VA requirements whether the Investigator is compensated, WOC, or IPA.

(3) Developing a protocol that:

(a) Is scientifically valid and uses methodology that is appropriate for addressing the goals of the protocol,

(b) Minimizes risk to human subjects, animals used in research, and research personnel,

(c) Contains a sufficient description of the research to allow the R&D Committee and/or its subcommittees to fully review the Research Protocol, including all procedures, plans for statistical analysis of the data, plans for the confidentiality and security of the data, and plans for maintaining confidentiality of the information, where appropriate, and

(d) Is congruent with the funding application/grant for which the Investigator was funded.

(4) Developing and implementing plans for data use, storage, and security that are consistent with the Federal Information Security Management Act, HIPAA, Office of Management and Budget Guidance, National Institute of Standards and Technology Standards, VA Directive and Handbook 6500, and other applicable legal requirements and agency policy.

(5) Ensuring that all research proposals, from any source, support VHA's mission.

(6) Sending the protocol and/or proposal to the Research Office to ensure the Research Office is aware of the submission. This allows the Research Office to act upon

the submission as needed, enter the protocol/proposal into the Research Office tracking system, and forward the protocol/proposal to the funding institution, if applicable.

(7) Ensuring that, when serving as the PI, all research staff are qualified (including but not limited to appropriate training, education, expertise, and credentials) to perform procedures assigned to them during the course of the research.

(8) Initiating research, including collecting data, only after receiving notification that the protocol has been approved by all required committees and subcommittees.

(9) Assuming full responsibility for all aspects in conducting the research. If responsibility for all aspects of the research cannot be fulfilled the research may need to be amended, suspended, or terminated. These responsibilities include ensuring:

(a) The research is ethical and scientifically meritorious,

(b) That sufficient resources (personnel, funding, space, etc.) are available to conduct the research,

(c) The rights, safety, and welfare of VA research subjects,

(d) The humane care and use of animals used in research,

(e) The appropriate biosafety/biosecurity practices and laboratory techniques are used for the research, and

(f) The integrity of the data.

b. In addition, the following apply to VA Investigators:

(1) All research data and biological specimens generated during the conduct of a VA-approved Research Protocol are the property of VA and are not owned by the Investigator, unless there is a valid agreement (e.g. CRADA or other equivalent) that establishes that data collected by VA belong to the sponsor with a copy retained by VA. The original research data, unless collected under a CRADA, are part of the Federal record for the study and must be maintained by VA.

(a) All data developed, used, or shared must comply with all VA and Federal regulations.

(b) Research data collected for VA approved research must comply with all applicable Federal regulations and VA policies.

(2) VA Investigators must only conduct VA research in VHA medical facility space and/or in third party space that VA has the legal authority to use for the intended purpose, and for which the parties have entered into an appropriate agreement such as a real property agreement that complies with applicable law and VA policy. VHA should

contact VA's Office of Real property (ORP) for consultation regarding the proper real property agreement that should be used. ORP will consult OGC as needed.

(3) VA resources must not be used for non-VA research unless there is specific authority allowing such use. If the Investigator holds a compensated appointment at the university affiliate or other entity, the Investigator must ensure that the Investigator's protocols submitted for review do not specifically require that any contract or the scientific integrity of the protocol involve the academic affiliate or the other entity in a way that would violate any financial conflict of interests statutes, including those violations that can be criminal, such as 18 U.S.C. 208.

(4) All publications and presentations resulting from an Investigator's research at VA must appropriately acknowledge VA support and VA employment as required by VHA Handbook 1200.19. They must also include the disclaimer stating that the contents do not represent the views of VA or the United States Government.

(5) When the research is conducted at another VA medical facility or other institution, permission must be obtained from the VA medical facility/institution's Director or equivalent individual.

15. REFERENCES

- a. 31 U.S.C. 1535; Agency agreements (Subtitle II, Chapter 15, Subchapter III of Money and Finance Act).
- b. 38 U.S.C. 7303; Functions of Veterans Health Administration: Research Programs.
- c. 38 U.S.C. 8111; Sharing of Department of Veterans Affairs and Department of Defense Health Care Resource.
- d. 42 U.S.C. Section 289d; Animals in Research.
- e. 38 CFR Part 16, Protection of Human Subjects.
- f. VA Financial Policies and Procedures, Volume 1, Chapter 11.
- g. VA Handbook 5005, Staffing
- h. VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3; VA Information Security Program.
- i. VHA Directive 2012-030, Credentialing of Healthcare Professionals, or subsequent policy issue.
- j. VHA Handbook 1100.19, Credentialing and Privileging.
- k. VHA Handbook 1200.01, Research and Development (R&D) Committee.

l. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.

m. VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories.

n. VHA Handbook 1200.07, Use of Animals in Research.

o. VHA Handbook 1200.08, Safety of Personnel Engaged in Research, Research and Development Service.

p. VHA Handbook 1200.16, Off-site Research

q. VHA Handbook, 1200.17, VA Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C. Sections 7361-7366.

r. VHA Handbook 1200.18, Intellectual Property.

s. VHA Handbook 1200.19, Presentation of Research Results.

t. VHA Handbook 4721, VHA General Post Fund Procedures.

u. VHA Directive 1058, Office of Research Oversight.

v. PHS Policy on Humane Care and Use of Laboratory Animals. Office of Laboratory Animal Welfare, National Institutes of Health, Revised August, 2002, (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>). **NOTE:** *This linked document is outside of VA control and may or may not be conformant with Section 508 of the Rehabilitation Act of 1973.*