



VHA Directive 1200.02: Research Business Operations Summary of Major Changes

VHA Office of Research & Development
June 12 & 14, 2017

Purpose of Presentation

- To describe key policy revisions and changes related to the VHA Office of Research and Development's policy issued on March 10, 2017: VHA Directive 1200.02: Research Business Operations
- Presentation will be conducted on July 12, 2017 and repeated on July 14, 2017.
- Questions can be sent to vhacoordregulatory@va.gov.

Background

- **Why has VHA Handbook 1200.02 (May 23, 2002) been revised into VHA Directive 1200.02 (March 10, 2017)?**
 - National VA and VHA policy format change to convert Handbooks to Directive
 - VHA Directive 1200.02 consolidates requirements found in
 - VHA Manual M-3 Part 1 (Chapters 4,5,6,7, and 10);
 - VHA Handbook 1200.2 (dated 5/23/02); and
 - VHA Handbook 1202.06 (dated 7/9/08).
- **What is the date by which all VA facilities must implement the requirements outlined in this new Directive?**
 - All VA Facilities are required to implement the requirements outlined in this Directive no later than July 11, 2017.
 - All sections of rescinded VHA Handbook 1200.02 (May 23, 2002) must be followed until the VA Medical Facility implements the requirements of VHA Directive 1200.02.

Organization of VHA Directive 1200.02

- **Pages:**

- VHA Handbook 1200.02: 12 pages
- VHA Directive 1200.02: 19 pages

- **Paragraphs:**

- VHA Handbook 1200.02: 4 primary paragraphs
- VHA Directive 1200.02: 14 primary paragraphs

Definitions – VA Investigator (Paragraph 3(b)(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.

This definition is almost identical to the definition of **VA Investigator** in VHA Directive 1200 (May 13, 2016): Research and Development Program.

- **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.

VHA Directive 1200; Paragraph 5(i)

Definitions – VA Investigator (Paragraph 3(b)(4))

- **Why does ORD have a policy stating that a contractor cannot be a VA Investigator?**
 - The contractor is an agent of the institution or agency for whom he/she is a contractor.
 - One cannot simultaneously be an agent of the contracting institution and the Federal Government. This creates a significant conflict of interest.
 - The contract governs the work one is allowed to do as a contractor. Most clinical contracts do not include language about doing research under the contract.
 - The contractor can provide clinical services under a research project if those clinical services are covered by the contract.

Definitions – VA Research (Paragraph 3(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.

Tracking VA Research Activities (Paragraph 5(b)(1))

- The Research Office must establish tracking systems that allow for easy retrieval of information to assist in assessing compliance, including information on:
 - Research Studies,
 - Committee Actions,
 - Agreements,
 - Personnel,
 - Annual Government Ethics training and ORD-required training,
 - The Annual Government Ethics training refers to the training requirement that has already been in place.
 - Research Data.
- There is no mandate that a specific tool be used.

Reporting (Paragraph 5(b)(2))

- RDIS Report, Part II must be submitted annually to ORD by November 15th (current practice).
- Research Office must ensure that it receives copies of all protocols, amendments, and committee approvals.
- Written agreements that must be submitted to ORD prior to signature by VA:
 - MOUs for use of committees (e.g., use of University: IRB, IACUC, Safety Committee, Biosafety Committees),
 - Other written agreements that commit the VA medical facility's research program and another entity to specific programmatic responsibilities.

Reporting: Do the Following Agreements Require Submission to ORD by a VA Facility solely based upon the requirements of VHA Directive 1200.02?

- Data Use Agreements/Data Transfer Agreements?
- Material Transfer Agreements?
- CRADAs?
- Shared Space Agreements?

New or Reactivated Research Programs (Paragraph 6)

- Must have sufficient support from the VA Medical Facility Director
- Obtain Approval from ORD and ORO
- Establish a R&D Committee and subcommittees as appropriate
 - May use a R&D Committee of another facility with the approval of the CRADO
- Establish and fund research positions including
 - Research Compliance Officer
 - ACOS/R&D or Coordinator for R&D
 - AO/R&D

Formal Communication (Paragraph 7)

- Directive simplifies ORD requirements in previous VHA Handbook 1200.2.
- The VA Medical Center Director may delegate responsibility to the ACOS/R&D or the Coordinator for R&D for communications with ORD on operational and administrative matters.
- Communications requiring signature authority may only use email if the electronic signature meets all VA OI&T requirements. Email must be in compliance with applicable VA policies.

Financial Operations: Extramural Funds (Paragraph 8(a)(3))

- Previous reference to affiliated schools and universities and nonprofit organizations (other than VA NPCs) being able to administer extramural funds if authorized by the VA medical center director has been deleted.
- New language states that extramural funds are to be administered by the VA NPC or through the general post fund when possible. This does not disallow the affiliate from managing Federal funds that include VA researchers. However:
 - Where funds are managed should not be up to the individual investigator;
 - The VA Facility should have a policy describing how funds should be administered that takes into account the VA effort, for example, some VAs require the VA be prime on the award when more than 50% of the work is conducted at VA.

Financial Operations: Contracts and Just-in-Time (JIT) (Paragraph 8(b)(4) and 8(c))

- **Contracts**
 - New VHA Directive 1200.02 no longer requires that contracts for research purposes be approved by the R&D Committee.
- **Just-in-Time (JIT) Requirements**
 - New VHA Directive 1200.02 contains a description of the JIT process for ORD-funded studies.
 - No changes in JIT are required as a result of VHA Directive 1200.02.

Credentialing and Privileging (Paragraph 9)

- Topic is a new addition to the Directive, however most of the policy covering credentialing and privileging has been in place since VHA Handbook 1200.05 was issued.
- Credentialing and privileging is limited to those personnel who require credentialing and privileging for clinical purposes at the Medical Center (see VHA Handbook 1100.19 and VA Handbook 5005 for a list of categories that require credentialing).
 - The requirement for specific credentialing for research was removed when the Stand-down memos were rescinded years ago.
- Research staff may only perform those activities in a research study that is 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.

Credentialing and Privileging: HRMS Responsibilities: (Paragraph 9(b))

- Human Resources Management Service (HRMS) or the Research Office is required to check for exclusion or debarment restrictions on research investigators.
- For non-U.S. citizens:
 - HRMS must review applications for current residency status in the U.S. prior to employment in the U.S. that may involve the conduct of research or granting access to VA research laboratories. Residency status must be verified on an annual basis.
 - HRMS must review, verify, and track citizenship and visa status.
- The Research Office is responsible for verifying that HRMS has done the necessary reviews clarifying or validating the non-citizen's credentials.

Trainee Research (Paragraph 10)

- Topic is a new addition to the Directive, however most of the policy covering trainee research has been in place since VHA Handbook 1200.05 was issued.
- Trainees are defined as those who are (1) Appointed under trainee authority and (2) Enrolled in one of two types of training programs:
 - Enrolled in an accredited training program sponsored by an affiliated educational institution under a current and existing academic affiliation agreement or
 - Enrolled in a VA sponsored training program (either accredited or non-accredited).

Trainee Research (Paragraph 10)

- Trainees who do not meet the definition of trainees under this Directive cannot participate in VA research unless the VA Medical Facility's Designated Education Officer seeks a waiver both
 - from the Chief Academic Affiliations Officer or designee
 - and the CRADO.
- Students from unaffiliated academic institutions may not be permitted to conduct their student projects in VA or be given a WOC appointment ***for the sole purpose of*** conducting student research.

Responsibilities of the Facility Director (Paragraph 11)

- VHA Directive 1200.02 reinforces VA Medical Facility Director requirements for responsibility of all aspects of the research program.
- Responsible for appointing the ACOS /R and requires that the ACOS/R position be at least a 5/8ths FTE.
 - If the research program is too small to support a ACOS/R at that level, a Coordinator for R&D may be appointed.
 - All persons holding the position of ACOS/R must become at least 5/8ths FTEs within 24 months of the publication of this Directive.
- Can suspend VA research activities when there are real or perceived safety issues related to the research staff, the welfare of research animals, or other serious issues. This responsibility can be delegated to the the Chief of Staff or to the ACOS/R&D.

Responsibilities of the Facility Director (Paragraph 11)

- The VA Medical Facility Director is responsible for ensuring that VA research space is not used for non-VA research unless there is an 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.

Responsibilities of the ACOS/R (Paragraph 12)

- Describes primary responsibilities of the ACOS/R&D for the day-to-day activities of the VA Facility's research program, including:
 - Must use at least 5/8ths time to administer the research program.
 - Ensures that all VA research personnel hold an official VA appointment
 - Ensures that all requests for WOC appointments for research are appropriately justified and the appointments are in compliance with the applicable policies
 - Ensures 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 Office.

Responsibilities of the AO/R&D (Paragraph 13)

- This entire section of AO/R&D responsibilities is new, although most AOs have been doing this work. Note that these responsibilities can be delegated to others in the research office as appropriate. These duties include:
 - RDIS reporting, tracking personnel,
 - maintaining equipment inventory,
 - coordinating personnel issues with HRMS,
 - overseeing research laboratory areas,
 - coordinating site visits, assisting with Emergency Preparedness Plan,
 - ensuring safety and security issues are addressed,
 - working with the Chief Information Officer (CIO) to meet IT needs of the service, and
 - coordinating development of facility research policies.

Responsibilities of VA Investigators (Paragraph 14)

- Most of these responsibilities have been previously covered in 1200.01. New sections include:
 - 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.
 - 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.

Responsibilities of VA Investigators (Paragraph 14)

- 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.
- 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.



Questions?

