VHA HANDBOOK 1200.16 Transmittal Sheet November 18, 2013

#### **OFF-SITE RESEARCH**

- **1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook clarifies the scope of the Office of Research and Development (ORD) on the performance of the Department of Veterans Affairs (VA) funded research at sites other than VA medical facilities and VA-leased space.
- **2. SUMMARY OF CHANGES:** The primary changes are in Section 4, Requirements for Off-Site Waivers, and provide clarification on the considerations for granting an Off-Site waiver.
- **3. RELATED ISSUES:** VHA Directive 1200, Veterans Health Administration Research and Development Program.
- **4. RESPONSIBLE OFFICE:** The Office of Research and Development (10P9) is responsible for the contents of this VHA Handbook. Questions may be addressed to (202) 443-5600.
- **5. RESCISSIONS:** VHA Handbook 1200.16, dated September 20, 2006, is rescinded.
- **6. RECERTIFICATION:** This VHA Handbook is scheduled for recertification on or before the last working day of November 2018.

Robert A. Petzel, M.D. Under Secretary for Health

**DISTRIBUTION:** E-mailed to the VHA Publications Distribution List on 12/02/2013.

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#### **OFF-SITE RESEARCH**

**1. PURPOSE:** This Veterans Health Administration (VHA) Handbook defines policies of the Office of Research and Development (ORD) regarding the performance of Department of Veterans Affairs (VA) funded research at sites other than VA medical facilities and VA-leased space.

### 2. BACKGROUND AND AUTHORITY:

- a. VA research 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 [38 United States Code 7303]. The opportunity to explore research within VA medical facilities provides a strong foundation for this program. However, VA medical facilities may be unable to provide sufficient or appropriate space and facilities for specific components of research projects. To accommodate such programs, ORD reviews and evaluates all VA-funded research proposed to be performed at sites outside VA medical facilities or outside VA-leased space previously approved by ORD for research use.
- b. Research conducted under a partial or full off-site waiver is considered VA-approved research being performed by a VA employee with research duties during VA official time and any invention arising from such research shall be disclosed consistent with title 38 Code of Federal Regulations (CFR) 1.662, 37 CFR Part 501, and Executive Order 10096. The research conducted under a partial or full off-site waiver must comply with all applicable regulations and VA policies.
- **3. SCOPE:** The provisions of this Handbook apply to research funded by VA with appropriated funds and conducted by VA investigators, including individuals under an Intergovernmental Personnel Act agreement or work without compensation appointments while on VA time, utilizing VA resources. Research funded through ORD's Cooperative Studies Program is exempt from the requirements of this Handbook.

#### 4. REQUIREMENTS FOR OFF-SITE WAIVERS:

- a. VA-funded research must be performed in laboratory, clinical, or office space within a VA facility or VA-leased space. If any of the proposed work will be conducted in non-VA space, a waiver to perform the research off-site must be obtained prior to the research being funded. Work performed in an off-site Core facility or non-VA collaborator's laboratory may not require an off-site waiver, as determined by the approving research service.
- b. Each investigator who performs, or seeks permission to perform, VA-funded research outside of a VA facility or VA-leased space must request an off-site waiver. A waiver must be requested even if only a portion of the work will be performed off-site (partial off-site waiver). NOTE: Laboratory or other procedures performed outside VA as a service do not require off-site waivers but may require a contract or Memorandum of Understanding. For example, an investigator may send blood samples to an outside laboratory for a specific test that is not available at a VA laboratory.

- c. Off-site waivers are investigator, project, and funding source-specific. A separate request for an off-site waiver must be submitted for each research program or project. However, an approved off-site waiver is sufficient for the life-cycle of an application. Off-site waivers are granted for research funded by an individual research service within ORD, and are not reciprocal among the other research services.
  - d. Considerations for granting an off-site waiver include:
- (1) The proposed area of research is relevant to VHA's understanding and/or treatment of a particular disease or health problem important to the Veteran population.
- (2) Unique or specialized facilities or equipment include those not available and not easily reproducible at the VA facility. The need for such facilities or equipment to carry out the proposed research should be clearly justified in the waiver request.
- (3) If adequate space for an investigator's research program is not available on-site, the VA medical facility must demonstrate in the waiver request that VA-funded investigators occupy all usable VA laboratory, clinical or office space or explain alternative space assignments.
- (4) If sufficient and/or adequate research space is not available at the VA medical facility to conduct the proposed research, the facility Director is responsible for devising a long- and short-term plan to acquire additional research space. Plans to acquire additional space may include construction of new research space, renovation of current research space, renovation of other (non-research) space within the VA facility, or negotiation with an affiliate institution for leased space. The waiver request should include documentation regarding the plans for obtaining additional space (e.g., construction has been funded or approved with an estimated start date), or details of a lease negotiation.
- (5) Facilities may negotiate formal lease agreements to provide sufficient and adequate research space for VA-funded investigators. If a lease agreement is used, it is preferred that it be for a block of contiguous space rather than for scattered, independent laboratories, clinics, or offices.
- (6) If the investigator relocates to another VA facility during the conduct of the research, the investigator must report the change in station to the appropriate ORD service program manager and a transfer request must be submitted in accordance with VHA Handbook 1200.2. If the new space is not VA space or VA-leased space, the investigator must request a new off-site waiver.

## 5. SUBMISSION OF REQUESTS FOR OFF-SITE WAIVERS:

a. All requests for off-site waivers must be approved by the Associate Chief of Staff for Research and Development and, in addition, requests for a full off-site waiver must be approved by the facility Director prior to submitting the request to ORD.

- b. If a portion of the proposed research needs to be performed off-site, a partial off-site waiver must be requested. Waivers for investigators to be located completely off-site (full off-site waiver) are considered only under extenuating circumstances and must be time limited, (e.g., a facility is being renovated and some of the laboratories are out of service for a period of time).
- c. For deadlines and instructions for submitting partial and full off-site waivers, refer to the guidance document entitled, "Instructions for Preparation and Submission of Requests for Off-Site Waivers," which may be found at: <a href="http://vaww.research.va.gov/resources/policies/default.cfm">http://vaww.research.va.gov/resources/policies/default.cfm</a>.
- **6. EQUIPMENT:** Investigators with approved off-site waivers must have appropriate VA facility approval prior to relocating equipment purchased with VA funds to off-site research space. The VA medical facility must maintain documentation of such approval. VA retains ownership of all such equipment.
- **7. VA-LEASED SPACE:** Investigators working in leased space approved for research use by the local facility do not require off-site waivers. The use of leased space approved for research use must be clearly indicated in the Resources section of any research proposals submitted for funding.
- **8. MENTORED AWARDS:** Career Development awardees may train in mentors' laboratories that are off-site; however, they may not establish new off-site laboratories. At the conclusion of the training period, they are expected to establish a research laboratory within VA space as a condition of the award.