

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 Department of Veterans Affairs (VA)-funded research in sites other than VA medical centers and VA-leased space.

2. SUMMARY OF MAJOR CHANGES. The principal change is in paragraph 3 noting that off-site waivers are approved by ORD Service Directors. In addition, full or partial off-site waiver requests may be submitted electronically using the provided template.

3. RELATED DIRECTIVE. VHA Directive 1200.

4. RESPONSIBLE OFFICE. The Office of Research and Development (12) is responsible for the contents of this VHA Handbook. Questions may be addressed to (202) 254-0183.

5. RESCISSION. VHA Handbook 1200.16 dated April 21, 2001, is rescinded.

6. RECERTIFICATION: This VHA Handbook is scheduled for recertification on or before the last working day of September 2011.

Michael J. Kussman, MD, MS, MACP
Acting Under Secretary for Health

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OFF-SITE RESEARCH

1. PURPOSE

This Veterans Health Administration (VHA) Handbook clarifies the Office of Research and Development (ORD) procedures regarding the performance of Department of Veterans Affairs (VA)-funded research in sites other than VA medical centers and VA-leased space. **NOTE:** *The provisions of this Handbook apply to research funded by VA with appropriated funds and conducted by VA salaried investigators. Research that is funded through ORD's Cooperative Studies Program is exempt from the requirements of this Handbook.*

2. BACKGROUND

VA research is an intramural program derived from clinician observation of the health problems and needs of veterans. The opportunity to explore research based upon these observations in laboratory and other appropriate settings within VA medical centers provides a strong foundation for this program. However, in rare situations, VA medical centers may be unable to provide sufficient or appropriate space and facilities for specific research projects. To accommodate such programs, ORD reviews and evaluates all VA-funded research proposed to be performed at sites outside VA medical centers or outside VA-leased space previously approved by ORD for research use.

3. SCOPE

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.

4. REQUIREMENTS FOR OFF-SITE WAIVERS

a. VHA policy mandates that VA-funded research be performed in laboratory, clinical or office space within VA medical centers or VA-leased space, except when off-site facilities provide unique research opportunities. A waiver to perform all or a portion of VA-funded research in an off-site location, henceforth called an off-site waiver, must be approved by the appropriate ORD Service Director. When approved, the waiver allows part of the research project (partial off-site waiver) or the entire research project (full off-site waiver) to be conducted at a non-VA site.

b. Each investigator who performs, or seeks permission to perform, VA-funded research outside of VA medical center or VA-leased space must request an off-site waiver. Full or partial off-site waivers will not be granted unless the investigator is salaried by the VA as a part-time or full-time employee. A waiver must be requested even if only a portion of the work will be performed off-site (partial off-site waiver). Considerations for granting an off-site waiver include:

(1) **Importance of the Research to the VA Research Portfolio and Patient Care Mission.** The proposed area of research is to be relevant to VHA's understanding and/or treatment of a particular disease or health problem important to the veteran population.

(2) **Need to use Unique or Specialized Facilities or Equipment not Available at VA.** Unique or specialized facilities or equipment include those not available and not easily reproducible at the VA medical center. The need for such facilities or equipment to carry out the proposed research should be clearly justified.

(3) **Lack of a Suitable or Sufficient Performance Site Within VA Space.** If adequate space for an investigator's research program is not available on-site, the VA medical center must demonstrate that VA-funded investigators occupy all usable VA laboratory, clinical or office space or explain alternative space assignments. If a portion of the proposed research needs to be performed off-site, a partial off-site waiver is to be requested.

(4) **Long- and Short-term Plans to Acquire Additional Research Space.** If sufficient and/or adequate research space is not available at the VA medical center, the facility 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 medical center, or negotiation with an affiliate institution for leased space.

(5) **Status of Formal Lease Agreements that Will Be or Have Been Negotiated for Research Space.** Facilities may negotiate formal lease agreements in order 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. In order for leased space to be used for research purposes, prior approval must be granted by the appropriate ORD Service Director.

5. SUBMISSION OF REQUESTS FOR OFF-SITE WAIVERS

NOTE: Proposals for off-site research submitted for funding consideration without an approved off-site waiver will be returned without review.

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 medical center 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 special circumstances.

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: <http://www.va.gov/resdev> .

6. EQUIPMENT

Investigators with approved off-site waivers must have appropriate VA medical center approval prior to relocating equipment purchased with VA funds to off-site research space. The VA medical center must maintain documentation of such approval.

7. VA-LEASED SPACE

Investigators working in leased space approved for research use 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.

9. SPECIFICITY OF OFF-SITE WAIVERS

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. Off-site waivers are granted for research funded by an individual research service within ORD, and are not reciprocal among the other research services.

10. CONTACTING ORD STAFF

Contact information for each ORD Service may found on ORD's Web site at:
<http://www.va.gov/resdev>.