

OFF-SITE RESEARCH HANDBOOK

- 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 2 (and subsequent subparagraphs 3a(5), 3b, Appendix B, and subparagraph 2b(5)) which establishes that ORD approval is required in order to use leased space for research purposes.
- 3. RELATED DIRECTIVE:** VHA Directive 1200, to be issued.
- 4. RESPONSIBLE OFFICE:** The Office of Research and Development (12) is responsible for the contents of this VHA Handbook.
- 5. RESCISSION:** VHA Directive 98-004, dated January 15, 1998, is rescinded.
- 6. RECERTIFICATION:** This document is scheduled for recertification on or before the last working date of April 2006.

S/ by Dennis H. Smith for
Thomas L. Garthwaite, M.D.
Under Secretary for Health

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OFF-SITE RESEARCH HANDBOOK

1. PURPOSE

This Veterans Health Administration (VHA) Handbook clarifies the policy 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. **NOTE:** *The provisions of this Handbook apply to all research services within the ORD (Medical Research Service (MRS), Rehabilitation Research and Development Service (RR&D), Health Services Research and Development Service (HSR&D), and the Cooperative Studies Program (CSP)).*

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, the ORD will review and evaluate 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

a. **Requirements.** VHA policy mandates that VA-funded research be performed in laboratory or office space within VA medical centers or VA-leased space, except when off-site facilities provide unique research opportunities. A waiver to perform VA-funded research in an off-site location, henceforth called an off-site waiver, must be approved by the Chief Research and Development Officer (CRADO). 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. A waiver must be requested even if only a portion of the work will be performed off-site. Considerations for granting an off-site waiver include the following:

(1) **Importance of the Research to the VA Research Portfolio and Patient Care Mission.** The proposed area of research should 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. Such facilities or equipment should be necessary to carry out the proposed research.

(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 medical center must demonstrate that VA-funded investigators occupy all usable VA laboratory space or explain

alternative space assignments. If a portion of the proposed research needs to be performed off-site, a partial off-site waiver should 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. In order for leased space to be used for research purposes, prior approval must be granted by ORD.

b. **Submission of requests for off-site waivers.** Off-site waiver requests must be submitted to the Director of the appropriate research service (MRS, RR&D, HSR&D, or CSP) at least 60 days prior to the due date for receipt of proposals. Proposals for off-site research submitted without an approved off-site waiver will be returned without review.

(1) Off-site investigators who received funding prior to January 15, 1998 (the effective date of VHA Directive 98-004), must request an off-site waiver prior to submission of a renewal of their ongoing research.

(2) Requests for off-site waivers must be approved by the Associate Chief of Staff for Research and Development (ACOS/R&D) and submitted through the medical center Director.

(3) Requests for off-site waivers must be submitted in accordance with procedures outlined in Appendix B.

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

d. If a portion of the proposed research needs to be performed off-site, a partial off-site waiver needs to be requested. Waivers for investigators to be located completely off-site are considered only under special circumstances.

e. 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.

f. Principal investigators on mentored awards such as Career Development awards or Medical Research Merit Review Entry Program (MREP) awards 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.

4. RECIPROCITY

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.

5. INQUIRIES

Information regarding points of contact for issues related to off-site research is contained in Appendix A.

CONTACT INFORMATION

1. Inquiries regarding off-site issues should be directed to:
 - a. **Medical Research Service (121E)**
(202) 408-3611
 - b. **Rehabilitation Research and Development Service (122)**
(202) 408-3678
 - c. **Health Services Research and Development Service (124B)**
(202) 273-8287
 - d. **Cooperative Studies Program (125B)**
(202) 273-8248
2. Contact information may also be found at the following web site:
<http://www.va.gov/resdev>

**INSTRUCTIONS FOR PREPARATION AND SUBMISSION OF
REQUESTS FOR OFF-SITE WAIVERS**

1. **Format.** Applications should consist of single-spaced typed pages. Use only letter-quality print. The font size should be at least eleven point with no more than fifteen characters per inch and no more than six lines per inch.

2. **Content.** Each application should consist of the following materials:

a. A cover sheet listing the following information in the order specified:

(1) Off-Site Waiver Request.

(2) Type of waiver requested (partial or full off-site waiver).

(3) Approving Research Service (Medical Research Service (MRS), Rehabilitation Research and Development Service (RR&D), Health Services Research and Development Service (HSR&D), or the Cooperative Studies Program (CSP)).

(4) VA medical center name and address.

(5) Investigator's name and degree(s).

(6) Investigator's title and VA appointment (in 8ths).

(7) Review cycle or submission deadline for proposed off-site research.

(8) Title of investigator's research proposal (for ongoing programs).

(9) Proposed off-site location.

(10) Name, title, and signature of the Associate Chief of Staff for Research and Development.

(11) Name, title, and signature of the medical center Director.

b. A narrative describing the following:

(1) **Importance of the Research to the VA Research Portfolio and Patient-care Mission.** The importance of the proposed area of research to veterans' health issues and the contribution of the specific research to our understanding or treatment of a particular disease or health problem must be clearly described.

(2) **Need to Use Unique or Specialized Facilities or Equipment not Available at VA.** Describe any specialized equipment or unique facilities that are not available or cannot be

reproduced at VA. Briefly explain why the proposed research cannot be done without access to these facilities or equipment. Explain what portion of the investigator's research effort requires these facilities. Clearly identify what portion of the proposed research, if any, will be performed in on-site research space.

(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 medical center must demonstrate that VA-funded investigators occupy all usable VA laboratory space or explain alternative space assignments. If a portion of the proposed research needs to be performed off-site, a partial off-site waiver should be requested.

(4) **Long- and Short-term Plans to Acquire Additional Research Space.** Clearly describe long- and short-term plans 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. During construction or renovation of additional research facilities, plans for interim use of off-site space prior to relocation of investigators to VA-controlled space will be considered. If interim use of off-site space is requested, a timetable for relocation of off-site investigators to VA-controlled space must be provided.

(5) **Status of Formal Lease Agreements that will be or have been Negotiated for Research Space.** Clearly explain the terms and current status of any lease agreements. Plans for interim use of off-site space during the final stages of lease negotiations will be considered. If a lease agreement is to be negotiated, it is preferred that it be for a block of contiguous space rather than for scattered, independent laboratories. Investigators working in leased space approved for research use do not require off-site waivers. The use of leased space must be clearly indicated in the Resources section of any research proposals submitted for funding.

c. **A Spreadsheet or Table Detailing VA Research Space Utilization.** Any discrepancies from the data contained in the Research and Development Information System (RDIS) Space Utilization report should be explained. The following information must be included for each room:

- (1) Room number,
- (2) Use (Office, laboratory, core facility, etc.),
- (3) Research space in square footage,
- (4) Investigator assigned to that room, and
- (5) Investigator's funding source(s).

3. **Due Dates.** Applications must be submitted at least 60 days prior to the due date for receipt of proposals.

4. **Mailing Addresses.** Applications are to be mailed to the address listed for the appropriate research service:

a. **Medical Research Service**

Medical Research Service (121E)
810 Vermont Ave, NW
Washington, DC 20420

If courier or commercial overnight delivery service is used, send to:

Medical Research Service (121E)
1400 Eye Street, NW
Suite 400
Washington, DC 20005
(202) 408-3611

b. **Rehabilitation Research and Development Service**

Rehabilitation R&D Service (122)
810 Vermont Ave, NW
Washington, DC 20420

If courier or commercial overnight delivery service is used, send to:

Rehabilitation R&D Service (122)
1400 Eye Street, NW
Suite 700
Washington, DC 20005
(202) 408-3678

c. **Health Services Research and Development Service**

Health Services R&D Service (124B)
810 Vermont Ave, NW
Washington, DC 20420
(202) 273-8287

d. **Cooperative Studies Program**

Cooperative Studies Program (125B)
810 Vermont Ave, NW
Washington, DC 20420
(202) 273-8248