



**DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF RESEARCH & DEVELOPMENT
PROGRAM GUIDE 1200.16:
OFF-SITE RESEARCH**

As of August 2, 2018, the Office of Research and Development Handbook Off-site Research (1200.16) has been replaced with this Program Guide. This Program Guide replaces all prior official ORD guidance on Off-site Research.

TABLE OF CONTENTS

OFF-SITE RESEARCH

1. PURPOSE.....	1
2. BACKGROUND.....	1
3. SCOPE.....	1
4. REQUIREMENTS FOR OFF-SITE WAIVERS	2
5. WORK IN AN OFFSITE BSL-3 LABORATORY	3
6. DIFFERENCES BETWEEN THE SERVICES	4
7. EQUIPMENT.....	4
8. VA-LEASED SPACE	4
9. MENTORED AWARDS	5
10. SUBMISSION OF REQUESTS FOR OFF-SITE WAIVERS.....	5

1. PURPOSE

This Veterans Health Administration (VHA) Program Guide describes requirements and includes guidance from 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

- 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. The ORD service funding the proposed research must issue a waiver permitting the conduct of the research at sites other than VA medical facilities and VA-leased space prior to the research being funded, unless it meets the specified exceptions. The ORD funding service can issue a partial off-site waiver or a full off-site waiver depending upon whether some or all of the proposed ORD-funded research is being conducted off-site. Approved off-site waivers are good for the lifecycle of a proposal and the duration of the research project if funded.
- b. Research conducted under a partial or full off-site waiver is always VA research and must be approved as VA research. VA-approved research is defined as 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, Executive Order 10096, and VHA Directive 1200.18. The research conducted under a partial or full off-site waiver must comply with all applicable regulations and VA policies and does not replace any agreements that are required for VA use of the space, such as a lease agreement.
- c. All VA research, including off-site research performed with or without waivers, as appropriate, must be managed in compliance with all applicable VHA Policies¹ and should be governed by a Memorandum of Understanding (MOU) or similar agreement, assuring such compliance.

3. SCOPE

The provisions of this Program Guide apply to research funded by ORD with appropriated funds and conducted by VA investigators, including full and part-time employees, individuals appointed or detailed to VA under an Intergovernmental

¹ Including, but not limited to, VHA Handbooks 1200.06, 1200.08, and 1058.01.

Personnel Act (IPA) of 1970, and without compensation (WOC) employees. Research funded through ORD's Cooperative Studies Program is exempt from the waiver requirements of this Program Guide.

4. REQUIREMENTS FOR OFF-SITE WAIVERS

- a. ORD-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.
- b. Each investigator who performs, or seeks permission to perform, ORD-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, Memorandum of Understanding, or other type of agreement. For example, an investigator may send blood samples to an outside laboratory for a specific test that is not available at a VA laboratory using a Material Transfer Agreement as required by the outside 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, or another individual designated by the 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 affiliated 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. The plan should be evaluated and updated at an appropriate interval to document progress and ensure plans for obtaining additional space continue to meet ongoing research needs.

(5) Facilities may negotiate formal lease agreements or other agreements as determined by the Office of General Counsel Real Property Group 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, unless the configuration of the facility under consideration precludes such arrangements.

(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 1200.02. If the new space is not VA space or VA-leased space, the investigator must request a new off-site waiver.

5. WORK IN AN OFFSITE BSL-3 LABORATORY

a. Work in an off-site biosafety level 3 (BSL-3) facility may be allowed, provided that appropriate safeguards and oversight mechanisms have been established and ORD has granted written approval. The approval is investigator, project, and funding source-specific. However, all use of Select Agents and Toxins (defined by the CDC list of select agents and toxins, APHIS biological agents, and the products of such) is restricted to VA owned or leased space. In the event that the VAMC leases an entire BSL-3 facility and no affiliate research is conducted therein, an off-site waiver and MOU shall not be required; however, the lease agreement must include VA expectations for physical security to be provided by the lessee. If the VAMC leases a portion of an affiliate BSL-3 laboratory, such that affiliate research is comingled with VA research, an MOU for shared oversight must be implemented; however, an off-site waiver is not required.

b. A memorandum of understanding (MOU) between the VAMC and the off-site affiliate specific to and permitting the off-site BSL-3 VA research must be approved by the specific ORD research service and signed by the appropriate officials at each institution; this MOU must be submitted to ORD and approved before any off-site waiver will be granted. The MOU must address:

Explicitly what entity has responsibility for safety oversight of the BSL-3 space

Explicitly what entity has responsibility for security oversight of the BSL-3 space

How safety incidents are handled, including reporting expectations

How security incidents are handled, including reporting expectations

How training will be provided for use of the space

c. That use of off-site BSL-3 facilities for VA research will be limited to only those investigator(s) and project(s) that have received written approval from the specific ORD research service.

An example MOU can be found online along with this Program Guide at <https://www.research.va.gov/resources/policies/>

6. DIFFERENCES BETWEEN THE SERVICES

Biomedical Laboratory/ Clinical Sciences Research and Development (BLRD/CSRD): Off-site waiver requests (full or partial) may be submitted to BLRD/CSRD at any time during the lifecycle of an application. As applications are judged, in part, on the facilities available to conduct the research, applicants are encouraged to submit off-site waiver requests in advance of submission of an application. Any facilities described in off-site waiver requests submitted during the Just-in-Time (JIT) process should not differ significantly from what was stated in the application. Work performed in an off-site Core facility or non-VA collaborator's laboratory does not require an off-site waiver unless such locations are within a BSL-3 facility. It is expected that Career Development awardees (CDA-2) will conduct research in a VA mentor's space, and off-site waivers are not needed for these awards. Off-site waivers for non-clinicians who do not have eligibility will not be reviewed until after the eligibility panel meeting has occurred.

Rehabilitation Research and Development (RRD): RRD requires full off-site waiver requests be submitted and approved prior to application submission. Partial off-site waiver requests will be addressed as part of the JIT process. Any facilities described in off-site waiver requests submitted during the JIT process should not differ significantly from what was stated in the application.

Health Services Research and Development (HSRD): Off-site waiver requests (full or partial) may be submitted to HSRD at any time during the lifecycle of an application.

7. 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.

8. VA-LEASED SPACE

Investigators working in VA-leased space approved for research use by the local facility do not require off-site waivers. The use of VA-leased space approved for research use must be clearly indicated in the Resources section of any research proposals submitted for funding.

9. 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.

10. 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. **Partial:** If a portion of the proposed research needs to be performed off-site, a partial off-site waiver must be requested. An electronic template is available at <https://www.research.va.gov/resources/policies/>

c. **Full:** 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).

Any full off-site waiver request must include 1) Administrative support and oversight for off-site investigators should be comparable to on-site support; and 2) Each station requesting an off-site waiver must be able to demonstrate that VA-funded investigators occupy all usable VA lab space.

Content. Each application should consist of the following materials:

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

- (1) TITLE: FULL OFF-SITE WAIVER REQUEST,
- (2) Approving Research Service (BLRD, CSRD, RRD, or HSRD),
- (3) VA medical center name and address,
- (4) Investigator's name and degree(s),
- (5) Investigator's title and VA appointment (in 8ths),
- (6) Review cycle or submission deadline for proposed research to be conducted off-site,
- (7) Title of investigator's research proposal,
- (8) Proposed Off-site location,
- (9) Name, title, and signature of the Associate Chief of Staff for Research and Development, and

(10) 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 the 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.

(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. A spreadsheet or table detailing VA research Space utilization must be submitted. See section c. below.

(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.

c. The completed, signed form(s) should be e-mailed to the appropriate point of contact for each of the ORD Services.

**Biomedical Laboratory Research and Development /Clinical Sciences
Research and Development (BLRD/CSRD) (10P9B)**

Amanda Hunt at (202) 443-5684 or offsite.waiver@va.gov

Rehabilitation Research and Development Service (RRD) (10P9R)

Tiffany Asqueri at (202) 443-5757 or rrdreviews@va.gov

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Liza Catucci at (202) 443-5797 or liza.catucci@va.gov

APPROVED:



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