INSTRUCTIONS FOR PREPARATION AND SUBMISSION OF REQUESTS FOR OFF-SITE WAIVERS TO VA OFFICE OF RESEARCH AND DEVELOPMENT

A. General Waiver Information.

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. Further information on off-site research can be found in VHA Handbook 1200.16

(http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2955).

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. Approved off-site waivers are good for the lifecycle of a proposal and the duration of the research project if funded.

You do not need an off-site waiver if: 1) you are using VA-leased space (with appropriate memorandum of understanding [MOU] and approvals); 2) you have an MOU signed by ORD authorizing use of non-VA space; or 3) you are using laboratory or other services under contract (e.g. sending blood samples out for testing). Additionally, for BLRD/CSRD only, you do not need a waiver if: 1) you are using core facilities, including animal facilities for housing animals ONLY (unless you are the director of the facility); or 2) you are performing work in a non-VA collaborator's lab.

Please note that for BLRD/CSRD, off-site waivers for non-clinicians who do not have eligibility will not be reviewed until after the eligibility panel meeting has occurred.

Due Dates: Requests for off-site waivers must be submitted by the due date listed in the ORD submission calendar (http://www.research.va.gov/funding/process/submission-calendar.cfm). An off-site waiver request for ongoing research may be submitted at any time. 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

Health Services Research and Development Service (HSRD) (10P9H)

Robert Small at (202) 443-5743 or robert.small@va.gov

- **B. Partial Off-site Waiver.** An electronic template is available on the <u>VA Research and</u> Development website (http://www.research.va.gov/resources/policies/default.cfm#off-site).
- **C. Full Off-site Waiver.** It is not customary to grant full off-site waivers. They are considered only under special circumstances.

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.

- **1. Format.** Use standard paper size (8 ½" x 11), at least one-half inch margins (top, bottom, left, and right), single-spaced typed pages with Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. Type density, including characters and spaces, must be no more than 15 characters per horizontal inch. There may be no more than six lines per vertical inch on a page.
- **2. 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
- (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 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. 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).