**Memorandum of Understanding between the (*VAMC*) and**

**(*Affiliate*) concerning Shared Oversight of VHA BSL-3 Research conducted in *(Affiliate)* BSL-3 Laboratory Space**

####

**Effective Date: Upon the date of the last signature by authorized agents to this Memorandum of Understanding**

This Memorandum of Understanding (“MOU”) is entered by the (*VAMC*) and (*AFFILIATE*) and sets forth the terms and conditions in accordance with which (*AFFILIATE*) will permit the conduct of VA research requiring Biosafety Level 3 (BSL-3) containment in (*AFFILIATE*) BSL-3 laboratory space. This MOU does not address the use of Select agents, defined as biological material including the Centers for Disease Control (“CDC”) list of select agents and toxins, APHIS biological agents, and products of such biological material, i.e. toxins. ([www.selectagents.gov](http://www.selectagents.gov)). Use of such defined hazardous agents in VA research is restricted to VA owned or leased space.

Oversight of laboratory safety and security at (*AFFILIATE*) and (*VAMC*) are the responsibility of the (*Affiliate office or committee*) and the (*VAMC office or committee*) respectively. Similarly, the Institutional Biosafety Committee (IBC) of the (*Affiliate*) and the (*VAMC*), which are registered with the National Institutes of Health Office of Science Policy (NIH-OSP), are responsible for the approval and the oversight of all research performed at their respective institutions that is governed by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). Both (AFFILIATE) and (VAMC) will maintain their respective NIH-OSP IBC registrations and will notify the other party, within five business days, of any change or lapse in registration.

All VA research governed by the NIH Guidelines must be approved by the (*VAMC*) IBC, the VA Subcommittee on Research Safety, and the VA Research and Development Committee (R&DC), and the VA Associate Chief of Staff for Research (ACOS/R). VA research includes research that is conducted under the auspices of (VAMC), by (VAMC) investigators during their VA tour of duty, and that uses (VAMC) funding or resources, irrespective of location.

The parties also acknowledge that, for VA research conducted in (*AFFILIATE*) laboratory space, (*Affiliate office or committee*) will ensure compliance with all applicable Federal, state, and local laws that pertain to research safety and security, including Office of Research and Development (ORD) policies. Through this MOU, (*Affiliate office or committee*) agrees to provide post-approval oversight (including managing any safety or security incidents) for VAMC research requiring BSL-3 containment that is conducted in laboratories or facilities located and maintained at (*AFFILIATE*), on the (VAMC)’s behalf. (*Affiliate office or committee*) agrees to meet or exceed the CDC and National Institutes of Health (NIH) Guidelines for BSL-3 research, as incorporated within the (*Affiliate office or committee*) Manual. This agreement does not abrogate the VAMC’s responsibility for oversight of all VA research, but defines and delegates specific aspects of research oversight to the (*AFFILIATE*), as the host facility for off-site BSL-3 VA research and defines communication pathways that facilitate this shared responsibility.

Both (AFFILIATE) and (VAMC) agree to limit use of (AFFILIATE) BSL-3 facilities for VA research to only those investigator(s) and project(s) that have received written approval from the specific ORD research service; both (AFFILIATE) and (VAMC) recognize that off-site waivers are investigator, project, and funding source-specific.

**General Stipulations**

1. All VA research to be conducted using (*AFFILIATE*) BSL-3 laboratory space, must be reviewed and approved by the (*Affiliate office or committee*) and any other applicable (*AFFILIATE*) research oversight committees to ensure it complies with relevant federal regulations, NIH guidelines, and relevant (*Affiliate office or committee*) policies and procedures prior to initiation and at least annually if the study is active. Such required (*AFFILIATE*) approvals are in addition to all VAMC required approvals (*i.e., approvals by the VA IBC, the SRS, the R&DC, IACUC, and the ACOS/R*). (*Affiliate office or committee*) agrees to review the scope and content of VAMC biosafety training and determine whether additional training will be required before VA personnel are permitted to initiate BSL-3 research in (*AFFILIATE*) laboratory space.

2. The (*VAMC office or committee*) and the (*Affiliate office or committee*) are required to perform a comprehensive review of each proposal for BSL-3 research and, when appropriate, grant approval[[1]](#footnote-1). The reviews should include, as appropriate for each committee, consideration of chemical hazards, radiological hazards, physical hazards, and biosafety hazards in accordance with applicable Federal regulations, including any NIH and/or CDC guidelines and policies. The results of these reviews will serve as guidance to the (*Affiliate office or committee*) in determining appropriate safety practices and procedures. When appropriate, the review should include: (1) all identified hazards and risks; (2) recommended risk group or biosafety level determination for the research, when applicable; (3) recommendations for appropriate practices, procedures, personal protective equipment (PPE), and other mitigations to minimize risk to personnel and the environment; and (4) minimum training recommendations for study personnel. The results of the reviews and any supporting documentation shall be made available to both parties.

3. The (*AFFILIATE*) will agree to require appropriate security measures to prevent unauthorized access to the (*AFFILIATE*) BSL-3 laboratories or facilities. Any safety or security incident involving conduct of VA research in the (*AFFILIATE*) BSL-3 laboratory or facility must be reported to the (*Affiliate office or committee*) and the (*VAMC) SRS* within five business days. Any information security incident must be reported to the (*AFFILIATE*) Information Security officer and the (*VAMC*) Information Security officer within five business days.

4. The VAMC will provide copies of all relevant VA approval documents (e.g., documenting, as appropriate, initial and continuing approvals by the VA IBC, the VA SRS, the IACUC, the VA R&DC, and the VA ACOS/R) to (*Affiliate office or committee*). (*Affiliate office or committee*) will provide copies of approval documentation for the (*AFFILIATE*) to the (*VAMC*). Requests for amendment to VA research conducted in (*AFFILIATE*) BSL-3 laboratory space must be reviewed and approved by the (*VAMC office or committee(s)*), and the (*Affiliate office or committee*) (as applicable), in advance of implementation.

5. (*Affiliate office or committee*) agrees to perform regular (i.e., annual, at minimum) inspections of all (*AFFILIATE*) BSL-3 laboratories where (VAMC) research is conducted. When possible, one or more qualified representatives of the (*VAMC office or committee*) will be invited to participate in these inspections. Copies of the inspection reports will be provided to the (VAMC) SRS/IBC for review within 30 business days after the inspection is completed. (*Affiliate office or committee*) will be responsible for satisfactory resolution of any deficiencies identified during these inspections, with VA participation, if and as required. The (*VAMC office or committee*) must be notified of any deficiencies that present a significant risk or hazard to research personnel, human subjects, and/or animals within 5 business days after initial identification by (*Affiliate office or committee*) and informed in writing, on a regular basis (e.g., monthly) of corrective/remedial actions in progress and completed.

6. (*AFFILIATE*) authorizes VA research and/or compliance staff, including personnel from the VHA Office of Research Oversight (ORO) to inspect (*AFFILIATE*) laboratories where VHA BSL-3 research is performed. Per (*AFFILIATE*) policies, these individuals must sign in at the visitor’s log book, comply with entry requirements, and be escorted by (*AFFILIATE*) staff while in the BSL-3 laboratories. If possible, the VA will provide written notice to (*Affiliate office or committee*) at least three business days in advance of the inspection and coordinate such VA inspections with scheduled (*AFFILIATE*) Biosafety inspections*. (AFFILIATE)* acknowledges that VA personnel will comply with all VA requirements for the conduct of off-site VA research (e.g., providing semi-annual chemical inventories, obtaining off-site waivers when required, etc.).

**Reporting**

7. The VAMC complies with reporting requirements established in accordance with VHA policy. To comply, each party to this MOU shall notify the other party, to the best of its knowledge, of any adverse event (including, but not limited to, personnel exposures[[2]](#footnote-2) or accidental release), security incident, serious protocol violations, and/or allegations of noncompliance involving VA research conducted or personnel located at a (*AFFILIATE*) BSL-3 laboratory or facility; any notice of an investigation or inspection by an oversight agency, regulatory body, or other organization of VA research activities or personnel related to research conducted at a (*AFFILIATE*) BSL-3 laboratory or facility; any requests for routine information pertaining to VA research or personnel by an oversight agency, regulatory body, or organization related to research conducted at a (*AFFILIATE*) BSL-3 laboratory or facility; and any notice that a compliance action has been initiated against any VA research activities or personnel by an oversight agency, body or organization related to research conducted at a (*AFFILIATE*) BSL-3 laboratory or facility within five business days. This reporting mechanism is in addition to, and does not replace, the legally effective requirements pertaining to reporting of events by research investigators. In addition, the VAMC and (*AFFILIATE*) will abide by NIH-OSP reporting requirements.

8. In addition, the research compliance staff of each institution under review as described in Paragraph 5 and Paragraph 6 must provide the research compliance staff of the other institution the opportunity to review any reports and/or correspondence to an oversight agency or organization pertaining to issues that concern VA research conducted at and/or personnel located at a (*AFFILIATE*) BSL-3 laboratory or facility and, when timelines permit, to provide clarification and suggested revisions, as needed, provided that the institution under review shall retain final editorial control over any response. Both parties agree that no report or notice will be released by one party to any oversight agency, body, or organization without previous (or, under exigent circumstances, concomitant) written notification to the other party. If possible, written notice will be provided at least three business days in advance to the other party's research compliance staff representative. Both parties acknowledge that under some circumstances it is not possible to provide three days notice, however, every effort will be made to notify the other party within this timeframe or at the earliest feasible opportunity. Either party may decide to independently correspond with oversight agencies after the review and comment period, but must continue to keep the remaining party informed of this ancillary correspondence.

**Documentation**

9. Copies of documents maintained by (*Affiliate office or committee*) which pertain to VAMC research (e.g., approval documents, committee minutes or excerpts thereof, reviewer worksheets, inspection reports, etc.) will be provided to the (*VAMC office or committee*) within 30 days of document approval. The (*VAMC office or committee*) is responsible for maintaining such documentation in compliance with all applicable VHA record retention policies. Similarly, documents maintained by VA which pertain to VAMC research conducted in (*AFFILIATE*) BSL-3 space will be provided to the (*AFFILIATE*) within 30 days of document approval.

10. To the extent permissible by their respective policies, each party shall provide all applicable documentation concerning VA research performed in (*AFFILIATE*) BSL-3 laboratory space to the respective research compliance and research administrative staff when the institutions are cooperating to investigate or review specific allegations or non-compliance issues associated with that research. Applicable documentation includes, but is not limited to, research oversight subcommittee minutes, associated policies and/or Standard Operating Procedures (SOPs), written reports, and research and/or facility records. Such documentation shall be provided at a time and place and in a format agreeable to both parties.

11. In addition, to the extent permitted by their respective policies, each party shall provide all applicable additional documentation concerning VA research activities performed in (*AFFILIATE*) BSL-3 laboratory space to the respective research compliance and/or research administrative staff when the institutions are cooperating to achieve accreditation or ensure the continued accreditation status of a participating research program that is affected by this agreement in any way. Such additional documentation shall be provided at a time and place and in a format agreeable to both parties.

12. The Medical Center Director of the VAMC is ultimately responsible for ensuring that all VA research activities comply with all applicable Federal regulations and VHA‑specific policies and standards.

**Additional Terms and Conditions**

13. This MOU sets forth the entire agreement between the parties that have executed this MOU. No other terms, conditions or agreements, whether oral or written, shall apply between such parties, unless such terms, conditions or agreements are set forth in writing and executed by such parties after the execution of this MOU.

14. All results arising from the VA research performed at (*AFFILIATE*) under this Agreement shall be owned by VAMC, with proper acknowledgement of the (*AFFILIATE*) resources and institutional support included in any resulting publication.

15. Nothing in this Agreement shall act as a grant of any rights under any of (*AFFILIATE*) intellectual property conceived solely by (*AFFILIATE*), its faculty, employees and agents before or independent of this Agreement.

16. During the term of this MOU, (*Affiliate office or committee*) will notify the (*VAMC office or committee*) in writing at least fifteen business days before the implementation of any significant policy and/or procedural changes that pertain to VA research conducted at (*AFFILIATE*), whether that change was requested by the (*VAMC office or committee*). Notification may be made by e-mail. Similarly, during the term of this MOU, the VA SRS will notify (*Affiliate office or committee*) in writing at least fifteen business days before the implementation of any significant policy and/or procedural changes that pertain to VA research conducted at (*AFFILIATE*), whether that change was requested by the (*VAMC office or committee*). Notification may be made by email to (NAME/POSITION).

17. Notices or communications to be provided under this MOU shall be given to the respective parties in writing either by personal delivery, overnight delivery service, confirmed facsimile or registered or certified mail, postage prepaid, as follows:

 To VAMC:

 To Affiliate:

18. If for any reason either party fails to satisfactorily fulfill its obligations under this MOU, or breaches any of the provisions, terms or conditions of this MOU, and having been given reasonable notice of and opportunity to correct any such failure, and not having taken satisfactory corrective action within the time specified by the non-breaching party, the non-breaching party shall have the right to terminate this MOU by giving written notice to the breaching party of such termination at least thirty calendar days before the effective date of such termination. Without cause, either party to this MOU shall have the right to terminate this MOU by giving written notice to the other party of such termination at least sixty calendar days before the effective date of such termination.

19. Effective Date: This MOU will become effective upon the date of the last signature below. The MOU will automatically renew annually for five successive years, in conjunction with this initial date, unless either party provides six months prior written notice in advance of the renewal date. In conjunction with renewal, the parties agree to the conduct of an annual review of the agreement, by an appropriate oversight committee. At the end of the automatic renewal period, the parties will renegotiate and resign the agreement. The agreement may be amended by agreement of both parties.

The undersigned have authority to bind their respective entities to the terms of this MOU and have read and agreed to all the terms stated herein. This MOU shall remain in effect until the authorized agents of VAMC and (*AFFILIATE*) mutually agree to terminate or modify this MOU.

**(Affiliate)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Title Date

### **(VAMC)**

 Date

Director

**Acknowledged by**:

(*ACOS*) Date

*(PI)* Date

VA Merit Review Investigator

1. The review processes for each facility’s IBC (and all other committee(s)/offices with responsibility for the review and approval of BSL-3 VA research) will be described in an SOP and the reviewing bodies will be authorized to approve or disapprove a proposal or to require modifications to secure approval. [↑](#footnote-ref-1)
2. Injuries or exposures affecting personnel will be addressed by the occupational/employee health services of (*AFFILIATE*) and/or VAMC, as appropriate for the nature of the injury/exposure (e.g., treatment for infectious exposures must be provided within hours, whereas treatment for some other classes of injuries may be delayed to allow for transit to VAMC). [↑](#footnote-ref-2)