

**Memorandum of Understanding**  
**VA Boston Healthcare System and Boston University**  
**Interim Use of Boston University Institutional Biosafety Committee**

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**PURPOSE**

This Memorandum of Understanding (MOU) sets forth the agreement between the VA Boston Healthcare System (VABHS) and Boston University (BU) concerning use of the services of BU Institutional

Biosafety Committee (IBC) for approval of studies using recombinant DNA (rDNA). The purpose of this agreement is to enable VABHS to assure adherence to all applicable provision of the applicable National Institute of Health (NIH) guidelines in approved research project utilizing rDNA. The provisions of this MOU are in addition to any requirements imposed by BU with respect to the review of research protocols for individuals holding BU faculty appointments.

**AGREEMENT**

Under this MOU, the BU/IBC shall review and approve or disapprove all requests to perform research using rDNA at VABHS, whether funded or unfunded and without regard to funding agency until such time as this MOU may be rescinded and/or VABHS establishes its own IBC (but notfor more than one year as ofthe date this MOUwas approved). While VABHS reviews research protocols for biosafèty matters beyond biohazards, the scope of the BU/IBC's authority under this agreement will extend only to rDNA proposals which require review by IBC.

The research activities will also be reviewed for approval by the VABHS subcommittee for Research Safety (SRS) and Research and Development Committee (R&DC) and will conform to all regulatory processes of both of those committees. The VA committees retain authority to approve, disapprove or require modifications of all research conducted at VABHS, but may not, under this MOU, override the BU/IBC or by modifying rDNA aspects of research that has already been reviewed by BU/IBC. With respect to protocols involving individuals with joint VABHS appointments, the SRS and R&DC shall coordinate with BU/IBC to ensure that approved protocols meet the biosafety requirements of both VABHS and BU/IBC.

The VA R&D program operates its laboratories in compliance with policies, statues, and regulations of appropriate Federal agencies including VA, Occupational Safety and Health Administration

(OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Department of Transportation (DOT), Department of Health and Human Services (DHHS), United States Department of Agriculture (USDA), and any applicable state and local agencies. All applicable guidelines issued by DHHS, the National Institutes of Health (NIH), the Center for Disease Control and Prevention (CDC), the USDA, the Animal and Plant Health Inspection Service (APHIS), and the Boston Public Health Commission (BPHC) must be followed.

THE VA BOSTON HEALTHCARE SYSTEM AGREES:

1. To be responsible for and have administrative authority over all aspects of research safety for research funded solely by VA and conducted in VABHS except for research safety issues that arise solely due to rDNA aspects of the research.
  - A. That the Subcommittee for Research Safety of VABHS shall review and approve or disapprove research using rDNA after approval by BU/IBC. The SRS may not approve biohazard aspects of research that has been disapproved by BU/IBC. Prior to initiating a project, the VABHS will require the approval of the IBC as the designated oversight body of record for any research involving recombinant DNA, or any study involving the use of transgenic animals or animals whose genome has been altered by the stable introduction of recombinant DNA. To obtain IBC approval VABHS researchers must complete and submit IBC form, 'Boston University Institutional Biosafety Committee Application for work with Recombinant DNA and/or Biohazards'. BU/Biosafety manual can be found at [http://www.bu.edu/orccommittees/files/2010/07/Boston-University-Biosafety-Manual-Revised,,\\_September-2011.pdf](http://www.bu.edu/orccommittees/files/2010/07/Boston-University-Biosafety-Manual-Revised,,_September-2011.pdf). VABHS agrees to pay for the services of Boston University's/IBC and Environmental Health and Safety (EHS).
2. To supply to BU/IBC copies of any new VA directives or policies pertaining to the use of rDNA in VABHS research laboratories and safety of personnel engaged in research using rDNA.
3. To permit BU/EHS staff to inspect VA laboratories in which rDNA research is, or is propose to be, conducted, (VABHS recognizes that BU is authorized to conduct inspections jointly with VABHS Safety Staff of VA laboratories in which BU-funded research is conducted).
4. The VA Boston Healthcare System must promptly report to the BU/IBC any incidents of noncompliance, exposures, or accidents involving rDNA. This is in addition to the requirement

for the VABHS to report all rDNA incidents to the Office of Biotechnology Activities (OBA) as a term of their registration.

5. Training for working with biohazards is the responsibility of the Principal Investigator, but may include online information provided by BU or VA-affiliated training providers (CITI e.g.).

**BOSTON UNIVERSITY AGREES:**

1. To review and approve, disapprove or require modifications to rDNA proposals of VABHS research protocols until such time as this MOU is rescinded.
2. To consider the inclusion of a VABHS SRS representative/liaison on the BU/IBC,
3. To perform assessments of the VABHS laboratory space and laboratory procedures in which rDNA research is proposed to be conducted to assure that it meets NIH standards for the type of work proposed.
4. To provide the VA Research Office copies of all documents pertaining to the review and approval or other action of VABHS research by BU/IBC.
5. To report to the Boston Public Health Commission any incidents of non-compliance, exposures, or accidents involving rDNA use to the appropriate regulatory agencies. It is the responsibility of VABHS to report to OBA under their own registration.
6. Not to disclose any confidential information pertaining to or related to VABHS research activities without written consent of VABHS.

The undersigned have read and agreed to all of the terms outlined above. This agreement will be fully executed by its authorized officers and representatives as of the date of the last signature written below.

3/87/9—

████████████████████

Date

DIRECTOR, VABHS

Address:

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Address:

Boston, MA