BOSTON
PUBLIC
HEALTH
COMMISSION

BOSTON PUBLIC HEALTH COMMISSION
Biological Safety Office
PERMIT APPLICATION FOR USE OF RECOMBINANT DNA IN THE CITY OF BOSTON

Small Scale Permit Application (less than 10 liters): _____X Large Scale Permit Application (> 10 liters):_____

Date: February 27, 2012

Name Of Institution: Boston University (BUMC, NEIDL, Charles River Campus), Boston Medical Center (BMC), VA Address: [redacted], BU Office of Research Compliance, 85 E. Newton Street, [redacted], Boston MA 021 Name, Mailing Address, Telephone Number of:

Chief Executive Officer/lnstitutional Official: [redacted],85 E. Newton Street, Boston, MA, [redacted]

Biosafety/Biohazard Officer: [redacted], 85 E. Newton Street, [redacted], Boston, MA, 02118, [redacted]

Chairperson of IBC/IRC: [redacted], 650 Albany Street, [redacted], Boston, MA, 02118, [redacted]

If Institution is a partnership, give full name and residence of all partners:

If Institution is a corporation, give date and state of incorporation:

Massachusetts, 1869

Full Name, Address and Telephone of:

President: [redacted]., One Silber way, Boston MA 02215

[redacted], 881 Commonwealth Avenue, Boston MA 02215 [redacted]:

If Institution is neither a partnership nor corporation, please state its status:

How is insect/rodent control maintained: Self only:_____by Contractor:X

Type(s) of control used: IPM, baiting and traps, mechanical traps, monitors

If maintained by a contractor, state the name of the exterminator and the frequency of service: Please see attachment for details

Application for permit is submitted with the understanding that this constitutes a written agreement to:

(a) Follow the NIH Guidelines as defined in Sec. 1.03(b)(i) of the Regulations.

(b) Follow all other conditions as set forth in the Regulations including but not limited to:

Sec. 3 Restrictions
Sec. 4 Fees and Expenses
Sec. 5 Penalties

(c) Allow inspections, at reasonable times, of facilities and pertinent records (Sec. l .03b)(iii).

The following documents/requirements must be included as part of this application:

(a) All IBC minutes from July l, 1981 onward, clearly identifying all large scale RDNA use in these minutes (Commission RDNA Regulations, Sec. 1.06). The minutes shall identify present and absent IBC members and the numerical results of all votes taken. Institutional Review Committees (IRC) are not required to keep minutes.

(b) If this is a large scale special permit application, develop and submit IBC approved procedures for monitoring operations for compliance with the NIH Guidelines and Commission RDNA Regulations, for approval consideration by the Commission. Describe all large scale containment facilities and equipment plus the experience and training of the lab staff in using such large scale equipment. Emergency procedures for dealing with accidents or spills of large volumes of RDNA must be developed and explained to the BRAC and the Environmental Health Office staff.
(c) A roster and the resumes of IBC/IRC members.

(d) A description of how the IBC/IRC functions including its RDNA research project review process, its monitoring system, and its reporting mechanism.
A Health and Safety Manual (Commission RDNA Regulations, Section

(f) A description of the RDNA Technology Health and Safety training program of safeguards and procedures for appropriate employees (Commission RDNA Regulations, Sec. 1.03(b)(v)). The BRAC is interested in obtaining the specific guidelines and practices in place to promote lab safety in your institution including provisions for retraining.

(g) Institutions engaged in RDNA uses or projects exempted by the NIH Guidelines but not engaged in any other RDNA uses are exempt from the Commission RDNA Regulations of any requirement to develop an institutional review mechanism or to register RDNA uses. Institutions only engaging in RDNA uses or projects

exempted (Section Ill-F) under the May, 2011 NIH Guidelines but not the November 21, 1980 Guidelines must assign either an IBC or Institutional Review Committee (IRC) to oversee RDNA uses. The composition of an IRC is at the discretion of the institution but the resume(s) of IRC member(s) must be sent to the BRAC for examination. An authorized IRC signature on registration forms signifies institutional review and acceptance of responsibility for the project; the institution's determination that the experiment is (Ill-F) exempt (May, 2011 NIH Guidelines), the appropriateness of the facility for BLI level containment; and the adequacy of personnel training to ensure BLI containment. Institutions who wish to engage in Class Ill-A, B, C, D or E RDNA or Large scale RDNA (May, 2011 NIH Guidelines) uses must appoint an IBC, as defined in the NIH Guidelines and Commission RDNA Regulations.

(h) RDNA uses classed as Ill-A, B, C, & D can only be approved by a vote of an IBC. Register each RDNA project or experiment, not exempt from the NIH Guidelines (Sections Ill-A, B, C, D, & E) (May, 2011 NIH Guidelines) on the Commission RDNA Project Registration Form. Class Ill-A & B project applications must include NIH as well as IBC approval and the applicable RAC & IBC meeting minutes.

Section Ill-E or F RDNA uses (May, 2011 NIH Guidelines) may be administratively approved in a manner authorized by the IBC or by a vote of the IBC. Exempt use registration applications must be signed by either an IBC or Institutional Review Committee (IRC). Either Commission RDNA Registration Forms or equivalent institutional forms containing approximately the same information will be accepted for Class-III-F applications.

Section Ill-A,B, C, D, E, & F Project Registration Forms should be mailed to the Commission.

(i) Medical surveillance program (Commission RDNA Regulations, Sec. 1.07(a) which shall include, but not necessarily be limited to:

(1) a medical examination for all employees prior to their employment in a labor area engaged in RDNA use.

(2) prompt reporting of significant or potentially related employee illness to their IBC.

(3) retention of medical and health records for a period of time to be determined by the Commission.

G) Include reports, applications, recommendations or other communications to the institution from the IBC when relevant to the implementation of the Commission RDNA Regulations.

(k) An Annual Report of RDNA use must be sent to the Commission by each permit holder and received by the Commission no later than November 15 of each year. A listing of active principal investigators/users conducting either exempt or nonexempt RDNA uses, the location of their facilities, and the highest containment level used in the facilities should be included in the report. Inactive registrations should be clearly identified so that they may be deleted from active Commission files.

(l) Documents and written material requested in the permit application that have been previously sent to the Commission by the institutions need not be duplicated for this permit application.

This application will not be acted upon by the Commission until verification of approval for such use is received from the Zoning Division of the Inspectional Services Department.

We, the undersigned, hereby certify that the declarations and answers to the above questions are true and that all use of Recombinant DNA shall conform with the Commission RDNA Regulations, the pertinent NIH Guidelines and any further Regulations enacted by the Commission.

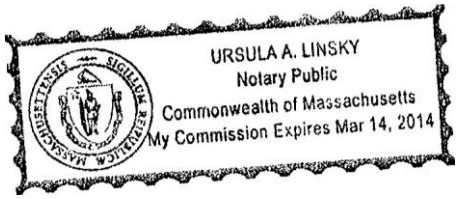
Signed
Institution's Chief Executive Officer:

Chairperson of IBC/IRC:

Biosafety/Biohazards Officer:

Seal of Institution
Notarized

Ursula A. Linsky
URSULA A. LINSKY



BOSTON PUBLIC HEALTH COMMISSION
Biological Safety Office

REGISTRATION FORM FOR IONA PROJECTS

Project Title:
Anticipated Starting Date:
Brief Description or Project:

Institution:

Lab Facility Address(es):
Building(s):
Room(s):

Principal Investigator(s):

Large Scale(> 10 liters): Yes No

Is an RDNA gene product efficiently expressed: Yes No

Containment levels (date and subsection of applicable NIH Guidelines).

Date Reviewed by IBC.

Host-Vector-Donor System:

Lab Personnel to contact in emergency situations requiring immediate remedial action:

Certification:

l. I am familiar with and agree to abide by the provisions of the Boston Public Health Commission Regulations tor Recombinant DNA Use & Technology. The information above is accurate arid complete.

Principal Investigator:_____ Date:

2a. I certify that the Institutional Biosafety Committee (IBC) has reviewed on the proposed project for RDNA and has by a majority vote found it in compliance with the provisionsof the Boston Public Health Commission Regulations for Recombinant DNA Use & Technology. The IBC will monitor the project throughout its duration to ensure its compliance with the Boston Public Health Commission Regulations.

Chairperson, BiosaTety Committee: Date:

OR

2b. I certifv that I have been authorized by the IBC to administrativel review and approve Class Ill-É, and F experiments or by an Institutional Review Body (IRB) to administratively review and approve Class Ill-F experiments. The proposed project has been found to be in compliance With the Boston Public Health Commission Regulations for Recombinant DNA Use & Technology. The institution will monitor the project throughout its duration to ensure its compliance with the Boston Public Health Commission Regulations.

Officer:Date:

Send completed application and registration forms to:

Julien Farland
Director of Biological Safety
1010 Massachusetts Ave,
2nd Floor
Boston, MA 02118
Or
Email: biologicalsafety@bphc.org
or call: (617) 534-2814

Boston University
Institutional Biosafety Committee
February 2012

The Institutional Biosafety Committee (IBC) is a University-wide group Committee responsible for reviewing and approving recombinant DNA research and biohazard research projects. The IBC has overall oversight responsibility for the Biosafety Program at Boston University and Boston Medical Center. Specifically, the IBC evaluates research projects that use recombinant DNA, agents that are infectious to humans, animals and plants, other potentially infectious materials, select agents and biological toxins, human materials including blood, cells, unfixed human tissues and other body fluids, xenotransplant and gene transfer clinical studies. The IBC coordinates its application procedures with two other offices, Research Occupational Health Program (ROHP) and the Environmental Health and Safety Department (EHS), in order to ensure that research personnel have adequate occupational health monitoring, training on safe work practices, exposure control emergencies and use of personal protective equipment. The IBC carries out these functions pursuant to requirements set forth by federal, state, and local agencies as well as Boston University.

The IBC is composed of faculty investigators from both campuses with expertise in recombinant DNA and biohazards research, as well as non-scientist and community members, and a Biosafety Officer. In conjunction with Environmental Health & Safety and the Research Occupational Health Program, the IBC oversees the Biosafety Program for laboratory research with recombinant DNA and biohazards on the Charles River Campus and at the Boston University Medical Campus including NEIDL BSL-2 and Boston Medical Center. At this time IBC oversight will include the Veterans Affairs Boston Health Care System (VA). The IBC Roster was recently updated and submitted through Boston Public Health Commission's on-line permitting system.

IBC rDNA Protocol Review Process and Monitoring System and Reporting Mechanism

Institutional Biosafety Committee (IBC) oversight includes the review and approval of all new research involving recombinant DNA and biohazards; continued review of approved research projects; review of laboratory inspection reports; investigation of complaints and concerns, and review of training and a medical surveillance programs. IBC approval of recombinant DNA and biohazardous research projects is effective for three years. Principal Investigators (PIs) must complete an IBC Annual Renewal each year to continue work for up to three years after the initial approval. After three years, the application must be resubmitted and reviewed by the committee.

In order to complete the renewal, the Investigator must list all proposed deviations from the protocol as initially approved (or since the last renewal notice), including any changes in laboratory location or equipment, changes in laboratory staff working on the project, any project titles to be added, and any agent or experimental changes. If there are significant deviations from the protocol, especially deviations that affect the containment level, the IBC may ask that the investigator seek an additional approval to cover the additional experiments. The PI and all lab staff must complete the annual EHS Lab Safety Training requirement, the annual ROHP clearance update, and any other training requirements

applicable to the project. Amendments must be submitted to the IBC for approval of changes within an approved project. All changes are required to be described in detail, and these must be reviewed and approved by the IBC before any changes in the work can commence.

Reports are submitted to Boston Public Health Commission for an Annual Report of RDNA Use, and for an Annual Report of the BSI-3 Permit in accordance with the Biological Laboratory Regulations. An Annual IBC Membership Report is submitted to the NIH Office of Biotechnology Activities (OBA) for an annual update of the registration for the IBC.

BU/BMC Biosafety Manual

The purpose of the Biosafety Manual is to define the biological safety policies and procedures pertaining to research operations at Boston University and Boston Medical Center and for the Veterans Affairs Boston Health Care System (VA). These policies and procedures are designed to safeguard personnel and the environment from biologically hazardous materials and to comply with federal, state, and local regulatory requirements. All BU and BMC Principal Investigators and laboratory workers must adhere to the biological safety policies and procedures in the conduct of their research and the management of their laboratories. The Biosafety Manual is available on the IBC website at: http://www.bu.edu/orccommittees/ibc/policies/. The same Biosafety Manual and Standard Operating Procedures (SOPs) will apply to BSI-Q in the NEIDL.

Laboratory Safety Training Program

The Institutional Biosafety Committee (IBC) considers the qualifications of all individuals involved in conducting research as part of its protocol review and approval process. Environmental Health & Safety (EHS) and Research Occupational Health Program (ROHP) provide support and are available to provide training or programs to assist Principal Investigators (PIs) to ensure that they and their laboratory staff are appropriately trained and qualified. The Research Safety Division provides training on a frequent basis which encompasses many different topics as they apply to specific laboratory spaces, materials used and the types of work being conducted. Laboratory Safety Training for researchers is offered two ways. In-classroom or online training programs are routinely scheduled and made available for all personnel which they can choose to participate. Both trainings are available to personnel working in or supervising research laboratories. The trainings cover topics including the OSHA Laboratory Standard, hazardous wastes, emergency procedures, general laboratory safety practices, general biological safety practices, general occupational health, and other best practices and guides. The Laboratory Safety Training must be renewed and completed annually by Principal Investigators, Laboratory Safety Coordinators, and all personnel (faculty, staff, students, trainees, visitors) who will work in the laboratory including use of biological agents before starting work. The PI is required to complete annual on-line Recombinant DNA Training to ensure knowledge of the NIH Guidelines and IBC policies and standards. The requirement for training and knowledge of other special conditions is met by the Principal Investigator (PI) and laboratory staff completing training for Biosafety Level Three (BSI--3) Training, Select Agent Training, or Shipping Biologicals Training, if applicable for research proposed in an IBC protocol. The PI provides agent specific training for laboratory staff and assistance is available through EHS and ROHP if needed. Agent Information Sheets and Agent Identification Cards are provided

to all research personnel using biological agents with the potential to cause Laboratory Acquired Infection (LAI).

Description of Medical Surveillance Plan

The Boston University Research Occupational Health Program (ROHP) provides a medical surveillance program to all personnel that enter Boston University research facilities. This includes all research personnel as well as non-research personnel such as IT, facilities, housekeeping and public safety. All employees working in the laboratory with potentially hazardous materials undergo a job risk assessment and are enrolled into a medical surveillance program with ROHP based on those risks. When appropriate, immunizations are offered to all individuals with potential exposure to biological materials in which vaccines are available at no cost to the individual. Additionally, ROHP requires annual health status evaluations for all personnel enrolled in the medical surveillance program. Personnel who support the NEIDL BSI- 2 undergo a more comprehensive medical evaluation which includes a job risk assessment with a mental health screening and urine drug analysis. ROHP is available to perform immediate triage for treatment of exposure to animals, chemicals, toxins and physical or biological agents. Employees are directed to seek appropriate medical care based on the severity of the injury or exposure. ROHP works closely with the IBC and EHS to promote a culture of health and safety at Boston University.

Insect and Rodent Control

At the Boston University Medical Campus (BUMC) and for the Charles River Campus (CRC) insect and rodent control is maintained by a Contractor and the types of control used are Integrated Pest Management OPM), baiting and traps, mechanical traps, and monitors. The name of the exterminator is All Star Pest Services, Salem, NH 03079, and the frequency of service is weekly for BUMC and IPM control is a daily process for the CRC.

For NEIDL BSL-2 insect and rodent control is maintained by a Contractor and the types of control used are monitoring by trap (insect — sticky trap; rodent — metal trap). The name of the contractor is Buono Pest Control, Belmont, MA 02478, and the frequency of service is monthly for the BSI-2 labs.

For Boston Medical Center (BMC) insect and rodent control is maintained by a Contractor and the types of control used are Integrated Pest Management OPM). The name of the contractor is Modern Pest Services, Woburn, MA, and the frequency of service is three times per week.

At the Veterans Affairs Boston Health Care System (VA) insect and rodent control is self-maintained and the types of control used are large traps for rodents (Have a Heart/brand) checked on a daily basis, and sticky traps for insects checked on a weekly basis.

Documents and Written Materials

Documents and written materials requested in the permit application that have been previously sent to the Boston Public Health Commission include the Annual Reports of RDNA Use and RDNA Registration Forms, the Annual Reports for the BSL-3 Permit, and IBC Minutes. An updated IBC Roster and resumes for new members were recently submitted as updates to the BPHC web permitting system.