APPLICATION FOR PERMIT
INSTITUTIONS USE OF REGULATED BIOLOGICAL AGENTS

PERMIT FEE $250.00

In accordance with the provisions of Beverly Board of Health Regulation, Chapter 12 – ***Regulation of Biological Safety*** promulgated under authority of Section 31 of Chapter 111 of the General Laws of the Commonwealth of Massachusetts, the undersigned hereby apply for a permit to use Regulated Biological Agents pursuant to Chapter 12.

This application is for biosafety containment level (circle all that apply):
BL - 1 BL - 2 BL - 3

Name of Institution/Company: _____
State of Incorporation: _____
Mailing Address: _____
Phone No. _____
EMERGENCY (24hr) PHONE # _____

Name and address of chief executive officer of Institution/Company:
Name: _____
Office: _____ Home: _____
_____ _____
_____ _____
Phone No. _____ Phone No. _____

Name and address of officer (biosafety) in charge of Regulated Biological Agent experimentation and use:
Name: _____
Office: _____ Home: _____
_____ _____
_____ _____
Phone No. _____ Phone No. _____

The Institution seeking a permit shall certify and attest to its understanding that it shall:

1. conform with the NIH Guidelines.
2. conform with the biosafety standards established in the BMBL.
3. conform with other conditions set forth in this regulation.
4. conform with any special or specific requirements prescribed by the City as a condition of permit approval.
5. allow access for site inspection of facilities and pertinent records by the Board of Health or its designees upon reasonable notice, should it be deemed necessary by the Board of Health.

6. submit (with permit application and renewal) a copy of all minutes from IBC meetings held during the previous year. These minutes should provide sufficient detail to allow the Board of Health and its staff, members of the BBC, or professional consultants to understand the risk assessment or risk assignment process by which the IBC determined that all work approved by the committee would be conducted safely at the assigned Biosafety Level using corresponding safety practices and any additional special safety practices as specified by the IBC.
7. submit (with permit application and renewal) a detailed table of all protocols reviewed and approved by the IBC within the previous year including, at a minimum, a one to two page summary of each regulated activity and a listing of all biological agents utilized (e.g. host cell lines, biological vectors), any inserted gene sequences that would elevate risk (e.g. oncogenes), the BSLs assigned after IBC review and the rationale or guidance document upon which the selected BSL was based, and the name(s) of the Principal Investigator(s) who shall be responsible for each protocol. If any new regulated activity is added between permit cycles then said information for that new regulated activity would need to be submitted at that time.
8. submit (with permit application and renewal) a protocol for strain verification of all known human pathogens that are considered to be attenuated or non-infectious approved by the IBC within the previous year for use within the permitted facility, if any, or sufficient documentation to demonstrate that such a screening process has been completed by another laboratory, in order to ensure the proper characterization of the virulence, replication competence, and extent of resistance to therapeutic antibiotics.

Laboratories permitted to operate at **BSL-3** containment will additionally be required to submit:

a summary of protocols approved for BSL-3 containment that identifies the specific Regulated Biological Agents and describes the nature of the associated research, manufacturing and/or use to be conducted in the City. This summary may conform to the NIH Project Registration format or may follow any other format that provides sufficient detail to understand the nature and extent of the biological risk associated with that project. Any IBC approval of a protocol or experiment that is deemed to require BSL-3 containment must be reported to the Board of Health within thirty (30) days of that decision.

I, _____ of _____
(chief executive officer) (institution)
_____ do hereby swear and affirm that all of the facts contained in this application and all attachments are true.

Signature of CEO _____ Date _____

The Following supporting documents must be submitted to the Health Department as part of this application:

1. A complete roster of all IBC members, including names, home addresses, phone numbers, email addresses and resumes or *curriculum vitae* (CVs), including institutional and community members shall be maintained and submitted upon initial application or within thirty (30) days after submission of a completed application. An updated roster of IBC members, with resumes or CVs of new members (community or institutional) appointed to the IBC since the previous roster submission, shall be provided with IBC minutes and other required annual documentation.
2. Copy of a completed Biosafety Manual. Copies of updated Biosafety Manual(s) are to be submitted upon annual permit renewal.
3. Floor plans showing laboratory areas. All biosafety containment, Biosafety Levels, and designated waste storage areas should be indicated. Also, Institutions located in multi-tenant buildings will need to submit a hazardous materials/waste transportation plan, i.e. how will these materials enter/leave the building. (should use freight elevators and entrances not used by the general public). Updated floor plans to reflect any changes in assigned Biosafety Level or expansion of laboratory areas to be submitted upon annual permit renewal.
4. An Emergency Response Plan for the purpose of orienting City representatives, including but not limited to, the Board of Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency. This documentation must include a floor plan showing the internal layout of the facility with specific biological containment and non-biological laboratory areas, biological waste storage areas, and biological waste removal routes clearly indicated. Amendments to this plan must be submitted as they are incorporated.
5. Medical Surveillance agreement. This service may be provided through the Institution's internal clinical resources or through an independent third party provider. A letter indicating the completion of a contractual agreement for provision of occupational medicine and medical surveillance services shall be submitted upon application and whenever the clinical provider of these services has changed thereafter. In addition to the aforementioned requirements, each Institution shall provide a written summary of any incidents or adverse event involving Regulated Biological Agents that may have resulted in an exposure to a human pathogen within the facility or in the release of a human pathogen from the facility through wastewater or direct airborne release or through improper disposal of potentially contaminated solid waste. This report shall be sent to the Board of Health as soon as it is feasible but not less than seven (7) days from the date of the incident. Animal bites will be considered to represent potential human exposures, unless the animal was known to be free of infection and this can be documented upon request.
6. A written chemical inventory (per SARA Title III/Right to Know). Applicants need to provide confirmation (via plans and/or a signed inspection report by an appropriate professional) that all exhaust hoods are separate and isolated from the general building ventilation system.
7. A description of procedures and policies related to lab safety including: employee training records, waste disposal, decontamination, pest control plan and termination of work.
8. When any Institution ceases operations it will be required to provide documentation/certification that their facility has been properly closed and decontaminated pursuant to NIH and Massachusetts Department of Public Health Standards.