City of Medford
Board of Health
All Regulated Biological Agents or Toxins

Public Health
Prevent. Promote. Protect.

Registration

GENERAL INFORMATION	
Institution Name:	
Address:	
Telephone number:	
Date:	

	REGISTRATION CHECKLIST
☐	Names of corporate officers and addresses
☐	Name and C.V. of designated person familiar with proposed rDNA work and NIH Guidelines responsible for compliance with this plan
☐	Summary of type of recombinant DNA technology and/or biological agents and the nature of associated research or other use to be conducted
☐	Designation of the appropriate Biosafety Level by the IBC
☐	Copy of completed Biosafety Manual
☐	Copy of Emergency Plan for the facility containing biological activity regulated herein
☐	Names and addresses of Institutional Biosafety Committee (IBC)
☐	Description of planned implementation of an adequate Medical Surveillance Plan
☐	Plan for the systematic monitoring of waste
☐	Plan for systematic pest control management in laboratories, contiguous areas, and food service facilities in the same building
☐	Plan for the security of the premises
☐	Registration fee of $500

BOARD OF HEALTH

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Mary Ann O'Connor
Director
Board of Health

APPLICATION FOR PERMIT
INSTITUTIONS USE OF REGULATED BIOLOGICAL AGENTS

PERMIT FEE $500.00

In accordance with the provisions of Medford Board of Health Regulation, ***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.

Our purpose is to safeguard the health and welfare of the residents of the City of Medford. The Medford Board of Health hereby promulgated this regulation governing the use of all Regulated Biological Agents in the City.

The Board of Health retains all final responsibility for enforcement of this regulation. The Board of Health, whenever the facts and circumstances deem necessary, shall be authorized to retain assistance from a professional consultant with appropriate professional and academic experience and training to support review of applications and required documentation. Costs incurred by the Board of Health in utilizing a professional consultant may be assessed to a permit holder/applicant according to the time required to inspect facilities and to review documentation for said permit holder/applicant. This cost assessment is in addition to any established permit fee(s).

Unless specifically exempted under this regulation, all research or manufacturing involving Regulated Biological Agents in the City of Medford shall be undertaken only in strict conformity with the NIH Guidelines, the current edition of the BMBL, the Massachusetts Minimum Requirements for the Management of Medical or Biological Waste 105 CMR 480.00, and all other health regulations of the Board of Health.

All Institutions proposing to use or continue the use of regulated biological agents at BSL-1 or BSL-2 containment levels must obtain a permit from the Board of Health before commencing or continuing said research, manufacturing, or other use of regulated biological agents and annually thereafter. Institutions receiving such a permit shall conduct research, manufacturing or other sue only as specifically set out in their permit applications, and supporting documents filed with such application. The use of regulated biological agents requiring BSL-3, BSL-4 containment and/or the BMBL, or identified as Select Agents by the CDC and USDA shall not be permitted.

Upon submission of a permit application, the applicants will present an overview of the use of rDNA or regulated biological agents during a regularly scheduled meeting of the Board of Health. The presentation shall include a general introduction of the institution, its mission, its research or production plans, a timeline of the use of rDNA or regulated biological agents, an overview of the applicant's biosecurity risk assessment and program, and a discussion of the facilities. A presentation is not required for permit renewals unless otherwise determined by an Agent of the Board of Health.

Transition Rules: Any Institution currently engaged in the regulated activities hereunder at the time of passage of these Regulations, shall be required to apply for and receive a permit within one from the passage hereof and then annually in accordance with the permit procedures set forth herein.

Permit renewal applications must be submitted by March 31st each year. Permits are valid for one year from May 1st to April 30th. New permits issued after May 1st shall be valid from the date of issue through April 30th. Applications submitted late may be rejected or subject to a late fee.

The fee for a permit granted by the Board of Health, or annual renewal thereof, shall be $500.00 with exemptions for nonprofits and institutions of higher education.

This application is for biosafety containment level (circle all that apply):

BSL - 1 BSL - 2

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

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

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

The Institution seeking a permit shall certify and attest to its understanding that it shall comply with the following requirements and shall:

1. Conform with the latest amendment of the NIH Guidelines.

2. Conform with the biosafety standards established in the BMBL. (Biosafety in Microbiological and Biomedical Laboratories)

3. Conform with other conditions set forth in this regulation.

4. Conform with any special or specific requirements prescribed by the City of Medford, Board of Health 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 annually or more frequent, 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.

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 shall be provided 10-14 days 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. The applicant shall provide proof of Liability of Insurance in an amount t deemed sufficient by the Board of Health, but not less than $50,00, and naming the City of Medford as an additional insured, and shall agree to release, indemnify, defend and hold the City of Medford and its agents harmless as to any claims, assessments, damages or causes of action arising out of or relating to the work.

8. A description of procedures and policies related to lab safety including employee training records, waste disposal, decontamination, pest control plan and termination of work.

9. 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.

Violations of any provisions of this regulation may be subject to penalties as follows:

The Board of Health shall enforce this regulation in any court of competent jurisdiction pursuant to the authority granted. Each day will thereof constitute a separate offense; and /or whoever violates any provision of this by -law may be penalized by indictment or on complaint brought in the district court. The maximum penalty for each violation or offense shall be one thousand dollars ($1,000). Each day or portion thereof shall constitute a separate offense.

In addition to a fine for which continued conduct or recombinant DNA technology or other activity covered under this regulation poses an immediate threat to the public health or environment may be closed by the Board of Health.

The Board of Health may suspend or revoke a permit if it determines that the institution has failed to comply with this regulation, or other applicable permit conditions. Suspension or revocation shall follow written notice and a hearing in accordance with the timeframe set forth. A hearing request shall be in writing and shall be submitted to the office of the Board of Health within ten (10) days after receipt of the Order. After said hearing, the Board may affirm, modify, or rescind said Order or take any other action it deems warranted and appropriate.

The Board of Health reserves the right to report violations to applicable State and Federal regulatory agencies.

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BIOLOGICAL AGENT'S INCIDENT REPORTING FORM

This form is meant to be used by permitted Biological Safety facilities in the event of an adverse event. The Medford Board of Health requires verbal notification within 24 hours of an adverse event. This form is to be completed and submitted to the Medford Board of Health within 5 days of an incident.

Date and time of incident: _____

Employees and biological agents involved:

Employee Name: _____
Biological Agent involved: _____

Employee Name: _____
Biological Agent involved: _____

Employee Name: _____
Biological Agent involved: _____

Employee Name: _____
Biological Agent involved: _____

Narrative of incident (Include all details, including whether or not the biological agent exited the facility, whether directly or indirectly, through wastewater, airborne release, improper disposal of potentially contaminated solid waste, etc.):

_____
_____
_____
_____
_____

Is the released material biologically viable? _____ Does this incident pose a risk to the community? _____

Was/Is medical treatment required? _____
_____

What corrective actions have been initiated to prevent a recurrence?

_____
_____
_____

What other agencies have been notified? _____
_____

*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.