BOARD OF HEALTH
City Hall - Room 311
85 George P Hassett Drive
Medford, Massachusetts 02155

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Mary Ann O'Connor
Director
Board of Health

APPLICTION FOR LOW-RISK FACILITIES REGISTRATION INSTITUTIONS USE OF REGULATED BIOLOGICAL AGENTS

REGISTRATION FEE $100.00

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.

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.

Upon submission of the Low-Risk Facility 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.

The use of biological agents requiring Biosafety Level 3 or 4 (BSL-3 and BSL-4) containment (as defined herein), as well as the use of Select Agents as identified by the CDC and the USDA shall not be permitted in the City of Medford.

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 registration application within one from the passage hereof and then annually in accordance with the registration procedures set forth herein.

Low-Risk Facilities renewal applications shall be submitted to the Board of Health by March 31st each year. Applications submitted late may be rejected or subject to a late fee.

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. _____

Registration of Low-Risk Facilities:

Low Risk Facilities, as defined in Section-2 of these Regulations, may conduct rDNA Work without a permit, provided that they register with the Board of Health. Written registration is required prior to commencement of Work and includes:

1. Name and type of organisms (host/donor [foreign DNA]/vector) being used.
2. Reference to the section of the NIH Guidelines where the Work falls.
3. If Recombinant DNA Molecules containing eukaryotic viruses are propagated in cells, give the approximate percentage of viral genome present.
4. The scale (in liters) on which the organisms will be grown.
5. An assurance that all Work will be carried out following the NIH Guidelines, where applicable.

6. Name of biological waste handler (if any) and written assurance that all waste will be disposed of according to all applicable federal, state, and local codes.

7. Description of annual safety training and refresher training provided to laboratory staff.

A registration fee of $100.00, due upon initial application and upon annual renewals.

Upon receiving and reviewing the submitted information, the Board of Health may require additional information to be submitted, and it may recommend other procedures or safeguards as it deems appropriate up to and including full permit application under the existing Board of Health Regulation.

The release of agents that require reporting to Federal, State or Local agencies shall be reported to the Board of Health.

A registration shall be valid for a period of one year, unless sooner revoked in accordance with these Regulations.

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 _____

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

If a designated agent of the Board determines that a party has violated this regulation, such agent may issue a written order ("Order") to the Institution (registration holder) and its designated agent to correct the offending deficiencies within a reasonable specified time.

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 a 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. If more than one, each condition violated shall constitute a separate offense. The Board of Health may enforce these Regulations or enjoin violations thereof preclude enforcement through any other lawful means.

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 registration if it determines that the institution has failed to comply with this regulation, or other applicable regulations conditioned. 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 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.

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 $100

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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.