



Building a Healthy Boston

BOSTON PUBLIC HEALTH COMMISSION Biosafety Office

1010 Massachusetts Avenue (2nd Floor), Boston, MA 02118
617-534-5965 Fax: 617-534-2372 E-mail: biosafety@bphc.org

APPLICATION FOR RECOMBINANT DNA PERMIT

INSTRUCTIONS:

Send the completed permit application form, all required documents, and fee to:

ATTN: Director of Biological Safety
Environmental Health Office
Boston Public Health Commission
1010 Massachusetts Avenue, 2nd Floor
Boston, MA 02118
Phone: 617-534-5965 E-mail: biosafety@bphc.org

APPLICATION TYPE	TYPE OF rDNA ACTIVITY
<input type="checkbox"/> New	<input type="checkbox"/> Small-Scale (<10 liters of rDNA culture in a single vessel).
<input type="checkbox"/> Renewal	<input type="checkbox"/> Large-Scale (≥10 liters of rDNA culture in a single vessel).

BIOSAFETY LEVEL: BSL-2: ____ Enhanced BSL-2: ____ ABSL-2: ____

INSTITUTION / COMPANY INFORMATION:

Name: _____

Mailing Address: _____

Mailing Address: (if different): _____

Phone Number: _____

Institutional Official / Responsible Official / Chief Executive Officer (CEO):

Name: _____

Work Address: _____ City _____ State _____ ZIP _____

Phone Number (Office): _____ Email Address: _____

Biosafety Officer:

Name: _____

Work Address: _____

Phone Number (Office): _____ Phone Number (Mobile): _____

Email Address: _____

AGREEMENT AND SIGNATURE

1. We, the undersigned, do hereby certify and affirm that all the information provided in this application, including all attached documents, is true and accurate to the best of our knowledge and belief.
2. We certify that we shall conduct work specified in this Permit Application in compliance with the Boston Public Health Commission’s Biological Laboratory Regulations and Disease Surveillance and Reporting Regulations.
3. We agree to adhere to any other conditions outlined in the BPHC regulations and guidelines, the NIH Guidelines, and the Recombinant DNA Permit.
4. We agree and consent to allow inspections, at reasonable times, of the Entity’s laboratory facility or facilities and relevant documents and records by the BPHC or its designees.

Institutional Official / Responsible Official / CEO

Date

Institutional Official / Responsible Official / CEO (Printed)

Biosafety Officer Signature

Date

Biosafety Officer Name (printed)

PERMIT APPLICATION FEES

1. Calculate the total permit application fee for a single rDNA Permit by adding the total area (square feet) of the Regulated Laboratory Space in all the institution's buildings in Boston where rDNA materials are used or stored.
2. **TOTAL AREA OF REGULATED LAB SPACE = _____ Square Feet**
3. Select the applicable permit fees from the table below:

Total Area of Regulated Laboratory Space	Permit Fee
1-5,000 square feet	\$500
5,001-10,000 square feet	\$1,000
10,001 or more square feet	\$1,500

4. Send a check or money order made payable to the Boston Public Health Commission, with the permit application.

RENEWAL APPLICATION ONLY - Please submit the following documents:

- Completed and signed Recombinant DNA Permit Application Form.
- Check or money order for permit annual renewal fees, made payable to the Boston Public Health Commission.
- List of the required documents specified in Section 4.1(f) through 4.1(l) of the Guidelines under New BSL-2/ABSL-2 (Recombinant DNA) Permit application. The list should include the document title, any changes that have been made to the document since it was last submitted to BPHC, and a brief description of those changes. The listed documents should be those that are currently used in the BSL-2/ABSL-2 (rDNA) labs in the institution. The BPHC may ask the institution to provide more information during permit application review.
- IBC Annual Report (Refer to Section 7.3 of the Guidelines).

NEW APPLICATION ONLY - Please submit the following documents:

- Completed and signed Recombinant DNA Permit Application Form.
- Check or money order for new permit application fees, made payable to the Boston Public Health Commission.
- List of all physical locations (street addresses and building names), including animal care and core research facilities, where rDNA materials are used or stored.
- List of all current research protocols using rDNA, including the assigned biosafety levels and the category of non-exempt experiments (Section III of the NIH Guidelines). The BPHC may ask the Entity to provide copies of any research protocols.
- Description of large-scale rDNA activities, containment facilities, and equipment (Appendix K of the NIH Guidelines), if applicable.
- Biosafety Manual describing the institutional policies and procedures based on risk assessment. The Biosafety Manual must establish minimum standards and guidelines for the research activities and facility operations in BSL-2/ABSL-2 laboratories. The biosafety policies and procedures must protect laboratory personnel, public, and the environment from biohazardous materials, and ensure compliance with federal, state, and local regulations.
- OSHA Bloodborne Pathogens Standard Exposure Control Plan (29 CFR 1910.1030) and Chemical Hygiene Plan (29 CFR 1910.1450).
- Biological Waste Management Plan for disposal of infectious waste generated at the laboratory facility, in compliance with 105 CMR 480.000 (*Minimum Requirements for the Management of Medical or Biological Waste; State Sanitary Code Chapter VIII*) and other applicable federal, state, and local regulations.
- A brief description of the institution's Occupational Health Services Program approved by the Institutional Biosafety Committee (IBC) for all persons working with rDNA materials at the laboratory facility.
- Laboratory Safety Training Program for all employees, students and visitors working with recombinant DNA and biohazardous materials at the laboratory facility. The training modules must include information specific to recombinant DNA technology use and BPHC incident reporting requirements.
- Emergency Response Plan covering accidental spills, personnel contamination, or environmental release resulting from recombinant DNA materials.
- Brief description of the insect/rodent control program used at the facility.
- List of all IBC members (name and title), clearly showing the Chair, contact person, Biosafety Officer (if applicable), recombinant DNA expert, community members, and ad hoc consultant (if applicable).
- Biographical sketches of all IBC members, including community members.
- Copy of IBC minutes (if the IBC has already held its first meeting).
- Copy of Laboratory Registration Permit (Boston Fire Department).
- Copy of Certificate of Occupancy (Boston Inspectional Services Department).