

Cambridge Biosafety Committee POLICIES AND PROCEDURES

Section 1.00 Introduction

Pursuant to Cambridge Municipal Code Recombinant DNA Technology Chapter 8.20.040(A) (the “rDNA Technology Ordinance”) and the Cambridge Public Health Department’s Biosafety Regulation (the “Biosafety Regulation”), Section 3.00(A), the Cambridge Biosafety Committee (“CBC”) herein promulgates the following policies and procedures applicable to the application for and/or amendment to and administration of permits issued pursuant to the rDNA Technology Ordinance and the Biosafety Regulation.

All communications and submissions shall be sent to Cambridge Biosafety Committee (“CBC”) to the attention of the Director of Environmental Health, Cambridge Public Health Department, 119 Windsor Street, Cambridge, MA 02139. More specific contact information and supporting materials are available at: <http://www.cambridgebiosafety.org> (also accessible through <http://www.cambridgepublichealth.org> under Services and Information/Regulatory Activities)..

Applicants are responsible for obtaining copies of the NIH Guidelines and the BMBL. The most recent versions of these documents with amendments are available through the Biosafety section of the CPHD website under “Useful Links.” Information pertaining to training materials and other background material are also available at that location or by contacting CBC staff as indicated above.

Section 2.00 Definitions

All terms used herein shall have the same meaning as set forth in the rDNA Technology Ordinance and the Biosafety Regulation.

Section 3.00 Overview of the CBC’s Permit Application and Review Process

Any Person seeking to use recombinant DNA (“rDNA”) or Biological Agents, (as defined by the rDNA Technology Ordinance and the Biosafety Regulation), shall first obtain a permit pursuant to the rDNA Technology Ordinance (an “rDNA Permit”) or the Biosafety Regulation (a “Biological Agent Permit”) (hereinafter collectively referred to as a “Permit”) from the CBC prior to any such contemplated use. Any Person applying for a Permit, or any Person seeking to amend a Permit, shall appear before a regularly scheduled meeting of the CBC to present that Person’s application. Thereafter, the CBC may conduct a site visit of the Person’s facilities in conjunction with the CBC’s review of the Person’s application.

Section 4.00 Required Documentation for an Application

Any Person applying for a Permit shall submit the following materials **electronically** (except the notarized application and check for permit fee, which shall be submitted in hard copy):

- A. Notarized application form and check to cover initial annual fee.
- B. Name of one employee at permitted company or institution who will be the point of contact for all matters related to permit compliance and renewal. The assignment of this individual must be kept current and a different employee must be identified so that time-sensitive information and renewal materials can be delivered without interruption;

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- C. Summary of proposed work with a brief explanation of biosafety level (BSL) to which that work will be assigned;
- D. Labeled floor plan of the facility including BSL areas and access routes and an estimate of the laboratory and waste storage floor area (sq. ft.).
- E. Health and safety (“biosafety”) manual with procedures relevant to the safe operation of the facility, a protocol for response to accidental employee or community exposure and/or illness, and relevant sections of the NIH Guidelines pertaining to the biocontainment level permitted;
- F. Employee biosafety training program summary;
- G. Documentation of pest control program to be employed at the facility in conformance with Chapter 8.20.100 of the rDNA Technology Ordinance and/or Section 8.00 of the Biosafety Regulation;
- H. Description of protocol for disposal or decontamination of infectious waste (in accordance with 105 CMR 480 - Storage and Disposal of Infectious Biological or Medical Waste);
- I. Documentation of a medical surveillance agreement with a qualified provide
- J. Documentation pertaining to Institutional Biosafety Committee (“IBC”) membership (names, home addresses, phone, e-mail) and a resume or *curriculum vitae* for each community member; and;
- K. **For BSL-3 facilities only:** Documentation establishing the retention of a third-party laboratory commissioning agent with the appropriate experience in the evaluation of facilities employing BSL-3 containment. The third-party commissioning agent shall be identified to the CBC prior to the construction of any facility proposing to employ BSL-3 containment. The CBC may request selection of another commissioning agent at its discretion if the third-party agent does not appear to possess sufficient experience and expertise in commissioning BSL-3 laboratories.

Section 5.00 Protected Documentation Submitted with Application

A Person applying for or seeking to amend a Permit may redact specific information required by Section 4.00 above which the Person believes should be confidential and unavailable for inspection by members of the public. If the CBC is unable to evaluate the application for or amendment to a Permit without the redacted information, the CBC shall go into executive session to discuss the redacted information.

Section 6.00 Prior Notification to the CBC of the Use of Biological Agents and rDNA Requiring BSL-3 Containment

A Person holding a Permit shall notify the CBC of the Person’s intention to use Biological Agents and/or rDNA which require BSL-3 containment at least thirty (30) days prior to such use. Such Person shall submit an executive summary of the proposed work with sufficient detail to demonstrate that the work shall be done in full compliance with the rDNA Technology Ordinance and/or the Biosafety Regulation and to allow the CBC to assess the nature of the biological hazard that requires BSL-3 containment. The CBC may request further clarification or assurance that such use may be conducted safely and in compliance with the Guidelines by the Person. If a Person subject to this section believes that the thirty (30) day prior notification will impede its ability to effectively respond to a specific public health emergency, then the Person may contact the CBC to request a waiver of the thirty (30) day prior notification period. A

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Person making such a request shall identify 1) the circumstances of the public health emergency; 2) the necessity for the use prior to the thirty (30) day advance notification required by this Regulation; and 3) the identity of the Biological Agents and/or rDNA to be employed. After the Person has notified the CBC, as set forth herein, the Person may engage in such use but the Person shall comply with the remaining requirements of this Regulation within thirty (30) days of such notification to the CBC.

Section 7.00 Prior Notification to the CBC of the Use of Select Agents

A Person holding a Permit shall notify the CBC of the Person's intention to employ a Select Agent at least thirty (30) days prior to such use. Such Person shall submit an executive summary of the proposed work with sufficient detail to demonstrate that the work shall be done in full compliance with the rDNA Technology Ordinance and/or the Biosafety Regulation and to allow the CBC to assess the nature of the biological hazard posed by the contemplated use of a Select Agent. The CBC may request further clarification or assurance that this use may be conducted safely and in compliance with the Guidelines by the Person. If a Person subject to this section believes that the thirty (30) day prior notification will impede its ability to effectively respond to a specific public health emergency, then the Person may contact the CBC to request a waiver of the thirty (30) day prior notification period. A Person making such a request shall identify 1) the circumstances of the public health emergency; 2) the necessity for the use prior to the thirty (30) day advance notification required by this Regulation; and 3) the identity of the Select Agent to be employed. After the Person has notified the CBC, as set forth herein, the Person may engage in such use but the Person shall comply with the remaining requirements of this Regulation within thirty (30) days of such notification to the CBC. All documentation regarding the use of Select Agents shall be kept confidential to the extent permitted by law.

Section 8.00 Other Applicable Permits and Approvals

Persons applying for a Permit shall be responsible for obtaining all required federal, state, and local permits and regulatory approvals for the use of the Person's facility. An illustrative list of the most commonly required permits and approvals is included at the end of this document. A Permit will not be withheld in the event that other permits are still being sought, but the CBC may request documentation that these Persons have applied for such other permits. The Person applying for a Permit shall be under a continuing obligation to notify the CBC of the refusal of any governmental or regulatory agency to issue such permit or approval. Failure to obtain any such required permit or approval may be grounds for the denial or revocation of a Permit.

Section 9.00 Presentation to the Cambridge Biosafety Committee

Upon submission of an application, the CBC will schedule applicants to present an overview of the use of rDNA or Biological Agents by the permit-holding entity. This presentation shall be given during a regularly scheduled CBC meeting and shall include a general introduction of the company or institution, its mission, its research or production plans, a timeline of the use of rDNA or a Biological Agent and a discussion of the facilities. Any applicant or permit-holder required to present to the CBC shall contact the CBC staff to be placed on the agenda for a subsequent meeting of the CBC. A template for this presentation is available at <http://www.cambridgebiosafety.org>. An electronic copy of the presentation should be submitted two days before the meeting; 10-15 printed copies should be brought for meeting participants.

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Section 10.00 Site Visits

Prior to the commencement of the use of rDNA or Biological Agents, any Person applying for or seeking to amend a Permit shall submit to and arrange for a visit to the Person's facility by the CBC. All maintenance and laboratory safety records shall be made available to the CBC members at the time of the site visit. Areas of particular interest to the CBC include:

- A. General housekeeping and biological hygiene;
- B. Physical separation and access control (BSL-2 and BSL-3 laboratories);
- C. Proper signage indicating biosafety level and emergency contact information;
- D. Proper equipment such as appropriate biosafety cabinets for meeting the biosafety level containment standards with performance ratings clearly indicated;
- E. Proper general ventilation and hygiene facilities (e.g. sink) for the biosafety level
- F. Proper personal protective equipment in use by personnel (e.g. lab coat, gloves, eye protection).
- G. Possession of all required federal, state, and local permits and approvals; and
- H. Establishment of an appropriate medical surveillance program for all employees coming into contact with regulated materials.

Section 11.00 Administrative Approval and Formal Approval

Administrative approval may be granted at the conclusion of the site visit provided that there are no significant deficiencies. Administrative approval may be appropriate when there are minor deficiencies identified by the CBC and the CBC determines that a subsequent site visit is unnecessary. Formal approval shall be contingent upon the Person providing documentation to the CBC that such minor deficiencies have been resolved. Such documentation may be made in the form of a letter or e-mail indicating that the necessary steps shall have been taken to resolve such deficiencies. However, if significant deficiencies are discovered during the site visit, the CBC may conduct subsequent site visits to confirm that such deficiencies have been resolved to the satisfaction of the CBC. Formal approval may be granted at a subsequent CBC meeting, once any deficiencies are resolved.

Section 12.00 Permit Amendments and the "Three-Year Rule"

Any move to a new location, physical expansion of lab space within current facilities, creation of additional lab space at another location within Cambridge, increase in the containment level (BSL) for existing lab space, significant change of protocol (e.g. new work involving a Risk Group 3 or 4 agent, or addition of large scale activities, as defined by the Guidelines, requires an amendment to a Permit.

If a Person seeks to amend a Permit it shall contact the CBC and request to be placed on the agenda for a subsequent CBC meeting. If that Person has already appeared before the CBC within the past three (3) years and the CBC determines that the proposed amendment represents a minor change under the permit (e.g. simple expansion at BSL-1), this requirement to appear may be waived. These minor amendments may or may not require a site visit, and may be handled administratively.

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Section 13.00 Designation of Community Representatives to the IBC

Two members of the surrounding community shall be designated for membership in any IBC. Community Representatives can have no professional or financial relationship to the host company/institution and no immediate family relationship with anyone who has a professional or financial relationship with the host company. At least one members of the surrounding community shall be a resident of the City of Cambridge and shall be identified as a member of the IBC before an application for use of rDNA or Biological Agents is submitted to the CBC.

Section 14.00 Fees

Any Person who holds a Permit shall pay a fee which shall be paid at the time of application when any Person applies for a Permit and then such fee shall be paid annually for renewal. As set forth below, the amount of the Permit fee is based on the amount of the Regulated Space as defined herein. Regulated Space shall mean the amount of the total area of biological laboratory and biological waste storage used by any Person in connection with a permitted use under the Biosafety Regulation or the rDNA Technology Ordinance. The fee structure is organized into three (3) tiers according to the amount of Regulated Space. The smallest tier (1) is designated for laboratories that contain less than 10,000 square feet of Regulated Space and shall be assessed **\$325** annually. The middle tier (2) will be designated for laboratories that contain between 10,000 square feet and 40,000 square feet of Regulated Space and shall be assessed **\$650** annually. The largest tier (3) shall be designated for laboratories that contain more than 40,000 square feet of Regulated Space and shall be assessed **\$1,300** annually. All payments should be made to the order of the **Cambridge Public Health Department**.

Section 15.00 Reporting Requirements

All Permit holders shall **electronically** submit to the CBC an annual Biosafety Report. This report, which must be submitted before the time of permit renewal, shall include: **1)** minutes from all IBC meetings held since the last annual report, **2)** protocol summaries of all work approved or reviewed by the IBC since the last report, **3)** an updated IBC membership roster with e-mail, home phone numbers, and home addresses for all members, and **4)** any major changes to the biosafety manual or floor plans originally submitted during the initial application.. **IBC minutes** will have sufficient detail in order to demonstrate the risk assessment undertaken by the IBC during the review of the proposed work (e.g. assigned Risk Group and any other mitigating factors such as infectivity, insertion of oncogenes, or tumor-suppressor functionality).

Section 16.00 Decommissioning Procedures

Should a Person using rDNA or a Biological Agent seek to cease said use, all laboratory areas employed in said use shall be decontaminated before a Person's Permit is terminated. Such measures will include, but shall not be restricted to, surface decontamination of all floors, laboratory equipment including Biosafety cabinets and hoods and bench-top surfaces with an effective anti-microbial agent,. Permit holders operating a BSL-3 laboratory shall complete laboratory decontamination using a method known to be effective against the biohazardous materials in use in the laboratory, and which is in compliance with the Guidelines set forth in the Regulation. This decommissioning process will be documented and such documentation shall be submitted to the CBC upon completion.

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Common Permits, Licenses and Regulations**

| CAMBRIDGE | | | |
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| <u>Jurisdiction</u> | <u>Permit or Regulation</u> | <u>Contact</u> | <u>Phone / email</u> |
| Cambridge Public Health Department | Recombinant DNA | Sam Lipson, Director of Envl Health | 617-665-3838 slipson@challiance.org |
| Cambridge Public Health Department | Care & Use of Research Animals | Dr Julie Medley, Dir. of Lab Animals | 617-665-3853 jmedley@challiance.org |
| Cambridge Water Department | Cross connection & Backflow Prevention | Backflow Prevention Program | 617-349-4770 |
| Cambridge Fire Department | Flammables Storage (flammable solvent inventory required) | Fire Prevention Office | 617-349-4918 |
| Local Emergency Planning Committee, Cambridge Fire Dept | Risk Management Plan & Site Inspection | Deputy Chief Brian Gover, LEPC Chair | 617-349-4944 bgover@cambridgefire.org |
| Cambridge Inspectional Services Department | Electrical; Plumbing, HVAC; Occupancy | ISD building, plumbing, and electrical inspectors | 617-349-6100 |
| Cambridge Dept of Public Works | Wastewater Discharge Must mail a copy of MWRA application | Jim Wilcox, Director Engineering Services | 617-349-6426 jwilcox@cambridgema.gov |
| MASSACHUSETTS | | | |
| <u>Jurisdiction</u> | <u>Permit or Regulation</u> | <u>Contact</u> | <u>Phone</u> |
| Massachusetts Water Resource Authority | Wastewater Discharge Application, fee, inspection, Chemical Hygiene Plan | Alix Pierre-Louis or Tom Coffey | 617-305-5660 617-305-5624 |
| Massachusetts Department of Envl Protection | Wastewater: pH neut. (Category I Operator, facility grading report) | Tom Bienkiewicz, Wastewater Specialist | 508-767-2781 |
| Massachusetts Department of Public Health, Envl Health | Medical or Biological Waste (Compliance with 105 CMR 480) | Steven Hughes, Director Division of Community Sanitation | 617-624-5757 |
| Massachusetts Department of Envl Protection | Hazardous Waste Generator | Staff MA DEP, Div. of Solid & Hazardous Waste | 508-792-7470 www.mass.gov/dep/cero |
| Massachusetts Department of Envl Protection | Release/Spills of Oil or hazardous materials Call to get EPA ID # | staff | 617-292-5858 |
| Massachusetts Department of Public Health, Rad. Control | Radiation Control Permit (fee for use of any radionuclides) | Robert Walker, Director 90 Washington St 2 nd Fl Dorchester, MA 02121 | 617-427-2944 |