

Cambridge Biosafety Committee POLICIES AND PROCEDURES

Section 1.00 Introduction

Pursuant to Cambridge Municipal Code Chapter 8.20.040(A) (“rDNA Technology Ordinance”) and the Cambridge Public Health Department’s Laboratory Biosafety Regulation (“Cambridge 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, 2nd Floor, Cambridge, MA 02139. More specific contact information and supporting materials are available at: <http://www.cambridgepublichealth.org> under the “I Want to...” menu, under APPLY FOR A PERMIT/Laboratory Biosafety. This page is also directly accessible using the link: <https://www.cambridgepublichealth.org/laboratory-biosafety/>

Applicants are responsible for obtaining copies and keeping printed and electronic copies of the NIH Guidelines and the BMBL. The most recent versions of these documents are available on the same Laboratory Biosafety page under “Additional Resources”, Biosafety training materials for laboratory staff, public health officials and resident stakeholders are also available at: <https://www.cambridgepublichealth.org/resources/cambridge-biosafety-forum/>

Section 2.00 Definitions

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

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

Any Applicant 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”) collectively referred to as a “Laboratory Biosafety Permit”) from the CBC prior to any such contemplated use. Any Applicant applying for a Permit, or any Applicant seeking to amend a Permit, shall appear before a regularly scheduled meeting of the CBC to present that Applicant’s application. Thereafter, the CBC may conduct a site visit of the Applicant’s facilities in conjunction with the CBC’s review of the Applicant’s application.

Section 4.00 Documents required to Apply (via OpenGov account)

Any Applicant applying for a Permit shall submit the following materials by uploading to an online permit account hosted by OpenGov. See CPHD Laboratory Biosafety website for a link to this permit portal or visit: <https://cambridgepublichealth.viewpointcloud.com/categories/1081>

Only Applicant company/institution staff can serve as Applicant (no biosafety consultants).

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Once this OpenGov account has been created the application must be submitted in order for our staff to track and schedule a required presentation. All documents required for a new application should be uploaded by the time of the presentation to the Committee or (at latest) the inspection.

- A. **An invoice** for the permit fee will be auto-generated once the initial (or renewal) application is submitted. After submission information entered into the Details section cannot be change by the Applicant, but can be edited by our staff. Access to the Attachments section will continue after an application has been submitted.
- B. **We require that the online permit account has an assigned Applicant who is a regular employee at the company or institution** that holds the permit (no consultants). A shared or general email (e.g.biosafety@biotech.com) can be used for this OpenGov profile, but anyone later become the account owner must create their own OpenGov user profile with contact information. Consultants can access the account to upload documents and monitor the status of the application, but cannot initiate a renewal, unless logged on as Applicant (account owner).
- C. **Companies may only have one account at one time and for all locations.** Each location (if there is more than one on the permit) is listed in the Details section of the online account. **If you have trouble accessing the account, do not start a new account.** Instead, please contact Cambridge Biosafety Committee staff for all renewal or account access issues.
- D. **Biosafety Manual**
This comprehensive biosafety procedures document should include at minimum:
 - 1) A summary or outline of required annual biosafety training (training slides may be submitted to meet this requirement in the Other Attachments section below)
 - 2) Biological spill control and infection control procedures (Standard Precautions)
 - 3) Summary of biosafety practices specific to all containment levels (BSLs) requested by the applicant, including summaries of the NIH Guidelines and BMBL
 - 4) Summary of special practices or enhanced PPE requirements for specialized work at permitted containment level (typically BSL-2 Enhanced practices for viral vector work)
 - 5) Post-spill or post-exposure notification procedures and requirements
- E. **Other Documents Required for Initial Application**
 - **Medical Surveillance Agreement**
Letter from the Occupational Health provider indicating coverage for all laboratory employees and the date upon which this agreement is in effect
 - **Summary of Decontamination and Management of Biomedical Waste**
Description or summary of protocol for disposal or decontamination of infectious waste in accordance with MA regulation 105 CMR 480 (Storage and Disposal of Infectious Biological or Medical Waste).

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- **Pressurization Summary (if requesting BSL-2 or BSL-3 permit)**

This is not a complete air balance report. Please submit a recent air flow diagram (“pressurization summary”) using a floor plan diagram indicating rate of negative air flow into any lab areas designated as BSL-2 or higher at all points of entry. The areas adjacent to the BSL-2 zone may be designated BSL-1, Restricted Lab Support area (no food/drink), or Non-lab (usually office).

- **Protocol Summaries, Registrations or Hazard Screening forms**

Experimental protocol summaries, registrations, BARs (biological assessments of risk), or hazard screening forms. If summaries are included, essential detail should include Risk Group info of agents used and mitigating or aggravating risk factors. Should support and explain BSL assignments granted for each protocol.

- **IBC Minutes (some flexibility on initial IBC mtg for new Applicants)**

Minutes for at least one IBC meeting (to be held EVERY CALENDAR YEAR) must be submitted before the permit will be renewed in January of every year. These minutes should include the meeting agenda and should record the discussion that took place. A detailed agenda by itself is NOT SUFFICIENT to meet this requirement.

- **IBC Membership Roster**

A roster of the full membership of the Institutional Biosafety Committee (IBC) with phone, e-mail and mailing addresses listed. Home address for Community Representatives ("non-institutional members") must be listed. All others may list work contact information

- **Resumes for two Community Representatives.**

One of the two representatives must live, work or study in Cambridge. Neither outside member can have any financial ties to the host company, per MA Public Meeting Law.

- **BSL-3 APPLICANTS ONLY - Documentation of a third-party laboratory commissioning firm**

A laboratory commissioning agent with the appropriate experience in the evaluation of facilities with BSL-3 or BSL-4 containment must be retained to complete a review of the laboratory facility upon completion. 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 challenge the selected commissioning agent at its discretion if the sufficient experience and expertise in commissioning BSL-3 laboratories cannot be demonstrated. BSL-3 proponents will contact permit staff before design work has been completed and will arrange one or two subsequent meetings to update the Committee on the adherence to the original design as build-out is executed.

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Section 5.00 Protected Documentation Submitted with Application

Applicants applying for a new or amended Permit may redact specific information required in Section 4.00 (above) which the Applicant believes should be confidential and unavailable for public records requests. 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

Any Applicant holding a Permit shall notify the CBC of their intention to use Biological Agents and/or rDNA which require BSL-3 containment at least thirty (30) days prior to such use. Such Applicant 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 Applicant. If a Applicant 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 Applicant may contact the CBC to request a waiver of the thirty (30) day prior notification period. A Applicant 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 Applicant has notified the CBC, as set forth herein, the Applicant may engage in such use but the Applicant 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 Applicant holding a Permit shall notify the CBC of the Applicant's intention to employ a Select Agent at least thirty (30) days prior to such use. Such Applicant 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 Applicant. If a Applicant 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 Applicant may contact the CBC to request a waiver of the thirty (30) day prior notification period. A Applicant 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 Applicant has notified the CBC, as set forth herein, the Applicant may engage in such use but the Applicant 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.

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Section 8.00 Other Applicable Permits and Approvals

Applicants applying for a Permit shall be responsible for obtaining all required federal, state, and local permits and regulatory approvals for the use of the Applicant'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 Applicants have applied for such other permits. The Applicant 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 required permit or approval may be grounds for the denial or revocation of a Permit.

Section 9.00 Presentation to the Cambridge Biosafety Committee

A 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. Presentation to Committee can be arranged by contacting Laboratory Biosafety staff 4-6 weeks before the intended presentation date. Meetings are generally held on the 3rd Thursday of each month at 3:00 pm. Please provide the following information in order to reserve a spot on the agenda:

- Company name and address
- Biosafety Level requested (BSL-1, BSL-2/BSL-1, BSL-2 ONLY, BSL-3)
- Name and email address of anyone who wishes to be a presenter for the applicant

Cambridge Biosafety Committee meetings are currently conducted remotely, as allowed by *An Act Relative to Extending Certain State of Emergency Accommodations* signed by Governor Baker on July 16th, 2022 extending to March 31st, 2023. Future meetings will conform to requirements for in-Applicant meetings if the remote public meeting rules are rescinded. Zoom links to participate will be sent to anyone identified as a Presenter for an applicant.

Presentation slides are requested two days before the presentation (Tuesday before the Thursday meeting) in order to allow Committee members time to review. These slides should utilize the template provided on our [Biosafety Committee Presentation webpage](https://www.cambridgepublichealth.org/laboratory-biosafety/laboratory-biosafety-presentation/) (<https://www.cambridgepublichealth.org/laboratory-biosafety/laboratory-biosafety-presentation/>) and must include a labeled floor plan of the facility indicating designated BSL areas, access routes, waste removal routes.

Section 10.00 Site Visits

Prior to the commencement of the use of rDNA or regulated Biological Agents, any Applicant applying for or seeking to amend a Permit shall submit to and arrange for a visit to the Applicant'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;

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- 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 Applicant 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 Applicant 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 Applicant 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.

Section 13.00 Designation of Community Representatives to the IBC

Two members of the surrounding community shall be designated for membership on every 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 Community Representative must **live, work or study** in 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.

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Section 14.00 Fees

Any Applicant who holds a Permit shall pay a fee which shall be paid at the time of application when any Applicant 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 Applicant 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 **\$500** 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 **\$1,000** 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 **\$1,500** annually. All payments should be made to the order of the **Cambridge Public Health Department**.

Section 15.00 IBC 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 summarize information presented, capture a narrative summary of discussions, questions asked and answers provided. In addition to review and approval or amendment of experimental protocols, IBC meetings should cover all laboratory safety topics, unless covered by another safety committee. Every effort should be made to engage community members, provide background material on science and technology related to work under review, and offer material in advance of meetings.

Section 16.00 Decommissioning Procedures

Should a Applicant using rDNA or a Biological Agent seek to cease said use, all laboratory areas employed in said use shall be decontaminated before a Applicant'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

CAMBRIDGE			
<u>Jurisdiction</u>	<u>Permit or Regulation</u>	<u>Contact</u>	<u>Phone / email</u>
Cambridge Public Health Department Cambridge Biosafety Committee	Laboratory Biosafety	Sam Lipson Sr. Dir of Envl Health https://www.cambridgepublichealth.org/laboratory-biosafety	617-665-3838 slipson@cambridgepublichealth.org
Cambridge Public Health Department	Care & Use of Research Animals (Lab Animal permit)	Erin Bryant Comm. of Lab Animals https://www.cambridgepublichealth.org/laboratory-animals	781-288-9235 bryanthall@cambridgepublichealth.org
Cambridge Water Department	Cross Connection Control & Backflow Prevention	Cross Connection Control Program https://www.cambridgema.gov/water/administration/crossconnectioncontrol	617-349-4770
Cambridge Fire Department	Flammables Storage Cryogenic Gasses	Fire Prevention Office https://cambridgema.portal.opengov.com/categories/1125	617-349-4918 https://www.cambridgema.gov/cfd/firedeptdivisions/firepreventionbureau/permits
Local Emergency Planning Committee, Cambridge Fire Dept	Risk Management Plan & Site Inspection	LEPC Office (Fire Dept) https://www.cambridgema.gov/cfd/firedeptdivisions/epac/lepc	617-349-4944 lepc@cambridgefire.org
Cambridge Inspectional Services Department	Electrical, Plumbing, HVAC; Occupancy, Food Code	ISD permits https://www.cambridgema.gov/inspection/buildingelectricplumbingpermits	617-349-6100
Cambridge Dept of Public Works	Stormwater Control Permit	https://cambridgema.portal.opengov.com/categories/1101/record-types/6712	617-349-4800

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Common Permits, Licenses and Regulations - MASS

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	https://www.mwra.com/media/file/090524-sewerusedischargepermitinstructions	617-305-5627
Massachusetts Water Resources Authority	Wastewater: pH neut. (Category I Operator, facility grading report)	https://www.mwra.com/your-sewer-system/toxic-reduction-and-control-trac	508-767-2781
Massachusetts Department of Public Health, Envl Health	Medical or Biological Waste (Compliance with 105 CMR 480)	Bharathi Patimalla-Dipali, MDPH www.mass.gov/community-sanitation	617-624-5757 bharathi.patimalla-dipali@state.ma.us
Massachusetts Department of Envl Protection (MADEP)	Hazardous Waste Generator (VSQG, SQG, LQG)	MA DEP https://www.mass.gov/guides/hazardous-waste-generation-generators	James Paterson ID #s and Manifests james.paterson@mass.gov Generator List: Michael Hurley michael.m.hurley@mass.gov
Massachusetts Department of Envl Protection (MADEP)	Release/Spills of Oil or hazardous materials	MA DEP https://www.mass.gov/how-to/report-a-spill-or-environmental-emergency	DEP Emergency Hotline 1-888-304-1133
Massachusetts Department of Public Health, Rad. Control	Radiation Control Permit (fee for use of any radionuclides)	RadiationControl@mass.gov	617-624-5757