Somerville Biosafety Committee
POLICIES AND PROCEDURES

Section 1.00 Introduction

Pursuant to Somerville Municipal Code Somerville Biotechnology Ordinance Article IV, Sec. 6-56 (the "Somerville Biotechnology Ordinance") the Somerville Biosafety Committee ("SBC") herein promulgates the following policies and procedures applicable to the application for and/or amendment to and administration of permits issued pursuant to the Biotechnology Ordinance.

All communications and submissions shall be sent to Somerville Biosafety Committee ("SBC") to the attention of the **Inspectional Services Department Representative to the Somerville Biosafety Committee, Colin Zeigler, 1 Franey Rd. Somerville MA, 02145**. More specific contact information and supporting materials are available at: https://www.somervillema.gov/biosafety

Applicants are responsible for obtaining copies of the applicable Guidelines. The most recent versions of these documents with amendments are available through the website under "Documents". Pertaining to training materials and other background materials are also available at that location or by contacting SBC 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 SBC's Permit Application and Review Process

Any Institution seeking to use recombinant DNA ("rDNA") or Biological Agents, (as defined by the Somerville Biotechnology Ordinance) shall first obtain a permit pursuant to Biotechnology Ordinance to research and/or use rDNA and/or Biological Agents (hereinafter collectively referred to as a "Permit") from the SBC prior to any such contemplated use. Any institution applying for a Permit, or any institution seeking to amend a Permit, shall appear before a regularly scheduled meeting of the SBC to present that institution's application. Thereafter, the SBC may conduct a site visit of the Institution's facilities in conjunction with the SBC's review of the institution's application. During the process of review the SBC retains the right to request additional documents and information from the applicant.

Section 4.00 Composition of the SBC

The Chair shall be designated by a majority vote of the SBC.

The SBC shall be composed of the director of sustainability and environment or their designee, the agent or director of the board of health pursuant to M.G.L. c. 111, s. 30 or their designee or if no such agent or director is appointed, the HHS director or their designee, the emergency management director or their designee, a representative from the fire department, the director of the office of strategic planning and community development or their designee, the director of inspectional services or their designee; and three members to be appointed by the mayor and approved by the city council, which shall include an expert in the biotechnology field from the academic community and two members representative of the community members of Somerville. The membership should be

broad-based and as representative as possible. The members appointed by the mayor shall serve for a three-year term. Any person appointed to fill a vacancy shall serve for the unexpired term of that vacancy.

Professional assistance authorized; costs: The SBC may retain competent professional assistance in carrying out their duties under this article, in accordance with the regular city procedures for obtaining such assistance.

Section 5.00 Registration for Low-Risk Facilities (BSL-1 only):

Low Risk Facilities as defined by sec. 6-59 must register under the requirements of sec. 6-61. Please submit registration documents online through the Citizen Serve portal and select the BSL-1 option:

(1) Name and curriculum vitae of a person in the organization familiar with the proposed rDNA research or use and the NIH Guidelines.
(2) A brief summary from the above-named person describing the proposed rDNA research or use and providing:

(A) A list of all of the institution's facilities within the City of Somerville, including the address and a description of the research or use of rDNA at each facility.
(B) Name and type of organisms (host/donor [foreign DNA]/vector) being used.
(C) Reference to the section of the NIH Guidelines where the rDNA research or use falls.
(D) If rDNA Molecules containing eukaryotic viruses are propagated in cells, give the approximate percentage of viral genome present.
(E) The scale (in liters) on which the organisms will be grown.
(F) An assurance that all rDNA research or use will be carried out following the NIH Guidelines, where applicable.
(G) 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.
(H) Description of annual safety training and refresher training provided to laboratory staff.

Section 6.00 Required Documentation for an Application (BSL2-3):

Please submit applications and all required documents online through the Citizen Serve portal:

(1) A statement by the institution that it shall comply with the provisions of this article, the guidelines, and all federal and state laws.
(2) A list of all of the institution's facilities within the City of Somerville, including the address and a description of the research or use of rDNA or biological agents at each facility.
(3) A written agreement that reasonable inspections of facilities and pertinent records by the SBC shall be allowed.
(4) A health and safety manual which shall contain all procedures relevant to the research or use of rDNA or biological agents at all levels of containment in use at the particular facility.
(5) A plan for waste disposal in compliance with all applicable federal, state and local laws.
(6) A training program of safeguards and procedures for personnel researching or using rDNA or biological agents.
(7) An emergency response contingency plan which addresses but is not limited to addressing containment during fire or other emergencies, the education and safeguarding of first responders,

responses to inclement weather and power loss or brown-outs, and protection of employees and visitors in the building, responders, and the surrounding community.
(8) An appropriate medical and environmental surveillance program in accordance with the guidelines.
(9) A risk assessment of the activities to take place in the lab and possible impacts to employees, other building occupants, and the public.
(10) Proof of Liability Insurance in an amount deemed sufficient by the SBC and naming the City of Somerville as an additional insured.
(11) Effective rodent and insect control programs which shall be in place on premises where permitted research and use takes place in accordance with Article 2 section 11- 38.
(12) A plot plan showing the proposed location of the facility and a floor plan showing the layout of the facility.
(13) A list of all containment levels and decontamination procedures to be employed.

Section 7.00 Protected Documentation Submitted with Application

A Institution applying for or seeking to amend a Permit may redact specific information required by Section 6.00 above which the Institution believes should be confidential and unavailable for inspection by members of the public. If the SBC is unable to evaluate the application for or amendment to a Permit without the redacted information, the SBC shall go into executive session to discuss the redacted information.

Section 8.00 Renewal period and process

The SBC will begin considering renewals to permits January 1st until March 30th. Renewals can be submitted through the online permitting portal. Some institutions may apply outside this timeframe due to the ordinance updates in 2022. By 2024 all permitted facilities must apply between the dates above.

Section 9.00 Prior Notification to the SBC of the Use of Biological Agents and rDNA Requiring BSL-3 Containment

A Institution holding a Permit shall notify the SBC of the Institution's intention to use Biological Agents and/or rDNA which require BSL-3 containment at least thirty (30) days prior to such use. Such Institution shall submit an executive summary of the proposed work with sufficient detail to demonstrate that the work shall be done in full compliance with Biosafety Ordinance and to allow the SBC to assess the nature of the biological hazard that requires BSL-3 containment. The SBC may request further clarification or assurance that such use may be conducted safely and in compliance with the Guidelines by the Institution. If a Institution 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 Institution may contact the SBC to request a waiver of the thirty (30) day prior notification period.
Institution 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 Institution has notified the SBC, as set forth herein, the Institution may engage in such use but the Institution shall comply with the remaining requirements of this Regulation within thirty (30) days of such notification to the SBC. Required presentation to the SBC.

Section 10.00 Prior Notification to the SBC of the Use of Select Agents

An Institution holding a Permit shall notify the SBC of the Institution's intention to employ a Select Agent (as defined by CDC, HHS, USDA guidelines 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73) at least thirty (30) days prior to such use. Such Institution 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 Biosafety Ordinance and to allow the SBC to assess the nature of the biological hazard posed by the contemplated use of a Select Agent. The SBC may request further clarification or assurance that this use may be conducted safely and in compliance with the Guidelines by the Institution.

If an Institution 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 Institution may contact the SBC to request a waiver of the thirty (30) day prior notification period. An Institution 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 Institution has notified the SBC, as set forth herein, the Institution may engage in such use, but the Institution shall comply with the remaining requirements of this Regulation within thirty (30) days of such notification to the SBC. All documentation regarding the use of Select Agents shall be kept confidential to the extent permitted by law. Required presentation to the SBC.

Section 11.00 Other Applicable Permits and Approvals

Institutions applying for a Permit shall be responsible for obtaining all required federal, state, and local permits and regulatory approvals for the use of the Institution'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 SBC may request documentation that these Institutions have applied for such other permits. The Institution applying for a Permit shall be under a continuing obligation to notify the SBC 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 12.00 Presentation to the Somerville Biosafety Committee

Upon submission of an application, the SBC 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 SBC 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 SBC shall contact the SBC staff to be placed on the agenda for a subsequent meeting of the SBC. A template for this presentation is available at https://www.somervillema.gov/biosafety An electronic copy of the presentation should be submitted two days before the meeting; 10-15 printed copies should be brought for meeting participants, if in-person.

Section 13.00 Site Visits

Prior to the commencement of the use of rDNA or Biological Agents, any Institution applying for or seeking to amend a Permit shall submit to and arrange for a visit to the Institution's facility by the

SBC. All maintenance and laboratory safety records shall be made available to the SBC members at the time of the site visit. Areas of particular interest to the SBC 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 14.00 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 SBC and the SBC determines that a subsequent site visit is unnecessary. Formal approval shall be contingent upon the Institution providing documentation to the SBC 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 SBC may conduct subsequent site visits to confirm that such deficiencies have been resolved to the satisfaction of the SBC. Formal approval may be granted at a subsequent SBC meeting, once any deficiencies are resolved.

Section 15.00 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 Somerville, 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 an Institution seeks to amend a Permit, it shall contact the SBC and request to be placed on the agenda for a subsequent SBC meeting. If that Institution has already appeared before the SBC within the past three (3) years and the SBC 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 16.00 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 Somerville and shall be identified as a member of the IBC before an application for use of rDNA or Biological Agents is submitted to the SBC.

Section 17.00 Fees

Any Institution who holds a Permit shall pay a fee which shall be paid at the time of application when any Institution 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 Institution in connection with a permitted use under the Somerville Biotechnology 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 **$350 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 **$700 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 Somerville Inspectional Services Department through the online permitting portal.

Section 18.00 Reporting Requirements

All Permit holders shall electronically submit to the SBC 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 19.00 Decommissioning Procedures

Should an Institution using rDNA, or a Biological Agent seek to cease said use, all laboratory areas employed in said use shall be decontaminated before a Institution'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 SBC upon completion.