

CITY OF SOMERVILLE
ORDINANCE NO. 2022-
IN THE CITY COUNCIL: _____, 2022

**AN ORDINANCE REPLACING THE PROVISIONS OF CHAPTER 6,
ARTICLE IV AND AMENDING SECTION 1-11(b) OF THE CODE OF
ORDINANCES OF THE CITY OF SOMERVILLE**

Be it ordained by the City Council, in session assembled, that the provisions of Chapter 6, Article IV, "Biotechnology Research" are hereby stricken and replaced with the following provisions:

- **Sec. 6-56. - Biotechnology ordinance.**

This article shall be known and may be cited as the "Somerville Biotechnology Ordinance."

- **Sec. 6-57. - Biotechnology ordinance purpose.**

It is the purpose of this article and the policy of the city to protect the public health, safety and general welfare of the residents of the city, and to promote the development of clean and pollution-free industry, through the regulation of the research and use of recombinant deoxyribonucleic acid ("rDNA") and biological agents. The research and use of rDNA and biological agents in the city shall be undertaken only in strict conformity with the guidelines as herein defined, this article and the SBC policies and procedures authorized herein.

- **Sec. 6-58. - Biotechnology ordinance applicable to rDNA and/or biological agent research**

This article shall apply to all institutions in the city which research or use rDNA technology or biological agents as herein defined. This article shall require that rDNA and biological agent research and use be done only in strict conformity with the guidelines as herein defined, this article, and the SBC policies and procedures authorized herein. However, should a conflict arise between this article and the guidelines, this article shall take precedence.

- **Sec. 6-59. - Definitions.**

The following words, terms and phrases, when used in this article, shall have the meanings ascribed to them in this section, except where the context clearly indicates otherwise:

Biological Agents: any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia or protozoa) or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance that requires BSL-2 through BSL-4 containment as defined below.

Biosafety Level (BSL): the level of protective measures needed in a laboratory setting to protect workers, the environment and the public. The BSL of individual biological agents shall be that which is recommended in the ~~most recent version of the Centers for Disease Control (CDC)/NIH Publication: "Biosafety in Microbiological and Biomedical Laboratories (BMBL)"~~ BMBL (defined below).

Brown-out: is an intentional or unintentional drop in voltage in an electrical power supply system. Intentional brownouts are used for load reduction in an emergency. A voltage reduction may be an effect of disruption of an electrical grid, or may occasionally be imposed in an effort to reduce load and prevent a power outage, known as a blackout.

Chair: the Chair of the Somerville Biosafety Committee, unless the context clearly indicates otherwise.

Guidelines shall mean:

(1) *NIH Guidelines*: National Institutes of Health (~~("NIH")~~) Guidelines for Research Involving Recombinant DNA Molecules as published in the Federal Register of May 7, 1986, as well as NIH's Design Requirements Manual as amended, March 5, 2020 for proposed BSL-3 laboratories, and

(2) *BMBL*: Biosafety in Microbiological and Biomedical Laboratories ~~(BMBL): unless otherwise specified, is defined~~ as published by the Centers for Disease Control and Prevention ("CDC") and National Institutes of Health, as amended, and

(3) Any amendments, revisions, new editions, or substitutions to the NIH Guidelines or the BMBL, which are adopted by the ~~DHHS, Centers for Disease Control~~ US Department of Health and Prevention ("Human Services, CDC"), and NIH ~~and (or a successor agency)~~ that are accepted by the SBC. ~~Amendments~~ Any such amendments, revisions, new editions, or substitutions not acted upon by the SBC within sixty (60) days of their effective date shall be considered accepted. In the event that NIH Guidelines or BMBL are discontinued or abolished, those ~~Guidelines~~ guidelines in effect at the time of such discontinuance shall remain in effect ~~in Somerville~~ for purposes of this article.

In the event that there is a conflict between the NIH Guidelines and the BMBL, the BMBL shall control.

Institution: a single individual, group of individuals, association, organization, corporation, educational institution, or medical facility conducting rDNA or biological agent research or use, which may include, but is not limited to, development, production, therapies, or diagnostics.

Institutional Biosafety Committee: (IBC): a local institutional committee established by an institution in accordance with the guidelines, section 6-67, and the SBC policies and procedures to review and oversee research and use of rDNA and biological ~~research agents~~ conducted by the institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment. (See section IV-B-2 of the NIH Guidelines.)

Low Risk Facility: any institution that creates, propagates, imports or uses rDNA in any form where: (1) the experiments are all exempt from the NIH Guidelines under Section III-F of the NIH Guidelines, or (2) users are not constructing rDNA organisms but are merely propagating

them; or any institution conducting rDNA research or use that only requires BSL-1 containment.

Recombinant deoxyribonucleic acid (rDNA) and molecules and organisms and viruses containing RDNA: as defined in the NIH Guidelines ~~promulgated in the Federal Register on May 7, 1986, and such amendments thereto unless otherwise not accepted by the Somerville Biosafety Committee.~~

Somerville Biosafety Committee or SBC: the committee established pursuant to section 6-60 to oversee the registration of low risk facilities and permitting of institutions conducting research or use of rDNA or biological agents.

SBC Policies and Procedures: the policies, procedures and criteria established by the SBC pursuant to section 6-60 to aid in the implementation of this article.

- **Sec. 6-60. - Biosafety committee.**

(a) Establishment: There is hereby established a Somerville Biosafety Committee (hereinafter "SBC") which shall oversee the registration of low risk facilities, and permitting of institutions conducting or proposing to conduct research involving the use of and developments of rDNA or other biological agents that require BSL-2, BSL-2 (Enhanced) or BSL-3. The SBC shall address safety concerns associated with areas of biotechnology research and make recommendations to the board of health and the City of Somerville.

(b) Composition; terms of members; vacancies: 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.

(c) Appointment of the Chair: The Chair shall be designated by a majority vote of the SBC.

(d) 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.

(e) Responsibilities: Specific responsibilities of the SBC shall include:

(1) Establishing policies, procedures, and criteria to aid in the implementation of this article.

(2) Determining the manner in which permit holders, registered institutions, and low risk facilities and institutions applying for registration or a permit pursuant to this article make reports or applications to the SBC and the type of information required in such reports or applications.

(3) Reviewing reports, registrations, applications, and recommendations by the ~~institutional biosafety committees (IBC)~~, Institutional Biosafety Committees, and all other relevant documents.

(4) Conducting site visits to proposed BSL-2, -BSL-2 (Enhanced) and BSL-3 facilities.

(5) Reviewing manuals and worker training programs, approving health-safety programs, waste removal processes and emergency response contingency plans, and monitoring the procedures required by this article.

(6) Establishing procedures for individuals reporting violations of this article, the guidelines or any health regulations to the SBC.

(7) Providing assistance to institutions during the permitting process.

(8) Accepting all amendments to the guidelines before implementation.

(f) In addition to the duties listed above, the SBC may:

(1) Recommend to the Mayor and City Council amendments to this article to keep it abreast of the best scientific and industrial practice.

(2) Recommend to the Mayor and City Council amendments to other City ordinances bearing on biological and chemical laboratories.

(3) Share relevant documents with City departments and the board of health as needed to aid in the implementation of this article.

• **Sec. 6-61. – Registration for low risk facilities**

(a) Low risk facilities, as defined above, may conduct research and use of rDNA without a permit, provided, however, that such facilities shall register with the SBC and the City Clerk prior to conducting such research and use.

(b) The written application for registration shall be submitted to the SBC in writing on a form provided for such purpose, accompanied by the required fee, if any, and shall include:

(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 ~~Recombinant DNA~~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.

(c) A registration application shall be approved by the SBC if all of the information in subsection (b) is provided and the registration application is deemed complete by the SBC. The SBC may require additional information to be submitted if the application is incomplete, and may require the applicant to submit a full permit application pursuant to section 6-62 (Biosafety permits) of this article if the SBC determines that such permit is required under this article.

(d) The SBC shall make a final determination on a registration application within thirty (30) days of the submission of the application. The SBC shall notify the City Clerk of such final determination, and, upon the acceptance of the City Clerk, the applicant shall be promptly notified, and registration shall be issued, if approved.

(e) A registration shall be valid for a period of one year and shall be renewed annually, unless sooner revoked in accordance with this article. Applications for registration renewal shall be submitted to the SBC. Registrations may be amended in accordance with the policies and procedures of the SBC.

(f) The SBC may set forth policies and procedures consistent with this article for the submission, review, and approval of registration applications and issuance, amendment, and renewal ~~and revocation~~ of registrations. The SBC may establish fees for the processing of registrations as defined by SBC policies and procedures.

- **Sec. 6-62. - Biosafety permits.**

(a) Any institution conducting or proposing to conduct research or use of rDNA or biological agents that require BSL-2, BSL-2 (Enhanced) or BSL-3 shall obtain a permit from the SBC. The institution shall submit an application for a permit to the SBC containing the following information:

(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 ~~and~~/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 ~~and~~/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.

(b) The applicant shall agree to release, indemnify, defend and hold the City of Somerville and its agents harmless as to any claims, assessments, damages or causes of action arising out of or related to the activities proposed or permitted.

(c) As part of the process of reviewing the permit application, the SBC may request additional information from the applicant.

(d) A permit shall be issued to the applicant if all of the above information is completed and complies with the guidelines, this article, and current industry standards. Permits shall be valid for one year from the date of issuance and shall be renewed on an annual basis, unless sooner revoked in accordance with this article. Applications for permit renewal shall be submitted to the SBC. In accordance with the policies and procedures of the SBC, permits may be amended and may be issued with reasonable conditions or restrictions relative to the SBC's interest in protecting public health.

(e) The SBC may set forth policies and procedures consistent with this article for the submission, review, and approval of permit applications and issuance, amendment, ~~and~~ renewal ~~and revocation~~ of permits. The SBC may establish fees for the processing of permits as defined by SBC policies and procedures.

- **Sec. 6-63. – BSL-4 containment not permitted**

Institutions requiring containment defined by the guidelines as BSL-4 shall not be permitted in the City of Somerville.

- **Sec. 6-64. –Exemptions**

Laboratories in educational institutions used exclusively for instruction and not research experiments, and medical or clinical facilities that collect patient samples for testing at offsite laboratories, shall be exempt from the registration and permitting requirements of this article; provided, however, that clinical laboratories that are developing new diagnostic testing using rDNA or biologic agents shall comply with said requirements. All such facilities shall operate in compliance with all other applicable laws and regulations of the ~~City~~city.

- **Sec. 6-65. - Permit procedure.**

(a) Applications for a permit under this article shall be made to the SBC on a form provided for that purpose, accompanied by the required fee, if any. When an application has been received in a completed form, as designated herein, a copy thereof shall be forwarded to the City Clerk, and the acceptance of the City Clerk shall designate the date of filing.

(b) The SBC shall meet to discuss the completed application within ~~forty-five~~ (45) days after the date of filing with the City Clerk, and the SBC shall make a final determination on a completed application within ~~sixty~~ (60) days after such date of filing. If no action is taken within the time permitted, the permit is deemed denied. The SBC shall notify the City Clerk of such final determination, and, upon the acceptance of the City Clerk, the applicant shall be promptly notified, and a permit shall be issued if so approved.

- **Sec. 6-66 Compliance with zoning ordinance**

All institutions registered, permitted or applying for a registration or permit shall comply with the zoning ordinance of the City of Somerville.

- **Sec. 6-67. - Institutional biosafety committee.**

An institution applying for a registration or permit pursuant to this article shall establish an IBC in accordance with the guidelines to review and oversee research and use of rDNA and biological research agents and use conducted by the institution, provided, however, that the IBC shall include two community representatives approved by the SBC, at least one of whom shall be a resident of the city. The IBC shall be the final arbiter within an institution regarding the implementation of this article and the guidelines.

- **Sec. 6-68. – IBC reports**

Each registered or permitted institution shall file regular reports with the SBC and IBC, in a manner to be determined by the SBC. The IBC shall forward all meeting minutes to the SBC, and shall submit to the SBC in a timely manner copies of all reports submitted to outside regulatory agencies.

The IBC shall notify the SBC, in a written report, of any significant changes to the research or use, equipment, facilities or any other significant changes to the information submitted as part of the registration or permit application.

- **Sec. 6-69. Emergency procedure: accident, illness and violation reports.**

(a) Any accidental release or exposure, or research or use related accident or illness, which represents a potential hazard to employees or the public, shall be reported by the permit holder or registered institution immediately to the fire department via 911, the agent or director of the board of health pursuant to M.G.L. c. 111, s. 30, the emergency management director, and the SBC no later than 24 hours after such release, exposure, accident, or illness.

(b) The permit holder or registered institution shall report to the SBC in writing any violations of the guidelines or this article no later than thirty (30) days after such violation is known or should be known; unless the violation creates an emergency situation under subsection (a).

(c) The permit holder or registered institution shall provide the SBC, within fourteen (14) days of any incidents pursuant to subsection (a), a written report describing how emergency measures complied with the emergency response contingency plan, and what actions shall be taken to correct the problem or violation and prevent the problem or violation from recurring.

(d) The mayor may, in their discretion, if satisfied that a dangerous condition exists relating to any rDNA and/or biological agent research or use, declare an emergency and take action as necessary to remedy the emergency.

- **Sec. 6-70 Confidentiality of documents.**

Proprietary documents as designated by the institution proposing to research or use rDNA or biological agents shall be separated from the documents available to the public, subject to applicable public records law, ~~The~~ SBC shall develop policies and procedures to protect the confidentiality of any information including but not limited to that which, if released, could jeopardize the health and safety of the public, such as but not limited to lab locations and security measures.

- **Sec. 6-71. - Enforcement.**

(a) Any institution which violates any provision of this article shall be subject to a fine -in accordance with the provisions of [section 1-11](#). Each day a violation continues shall constitute a separate and distinct offense.

(b) Once a registration or permit has been issued, it may be revoked, suspended, or modified by the SBC upon determination by the SBC, after due notice and hearing, that the registered or permitted institution has materially failed to comply with this article, the terms of the registration or permit, or the guidelines.

(c) Notwithstanding subsection (b), the SBC, upon a determination that any violation constitutes an immediate and severe threat to the public health and safety, may order the immediate revocation of the registration or permit and preliminary closure of any low-risk facility, institution or laboratory within a facility or institution engaging in or contributing to such threat, without prior notice and hearing, but with subsequent timely notice and hearing.

(d) Final decisions of the SBC may be appealed to the extent permitted by law, in a court of competent jurisdiction.

- **Sec. 6-72. – Severability**

If any section, subsection, sentence, clause, or portion of this article is for any reason held invalid by any court of competent jurisdiction, such portion shall be deemed a separate, distinct, and independent provision, and such holding shall not affect the validity of the remaining portions thereof.

- **Sec. 6-73. – Effective date**

This ordinance shall take effect thirty (30) days after approval of the ~~C~~city ~~C~~council and the ~~M~~mayor.

- **Sec. 6-74. – Existing institutions**

This article shall apply to all institutions applying for a permit or registration after the effective date. An institution that was permitted prior to the effective date shall not be required to submit a new permit application under section 6-62 until renewal of their permit, provided, however that said institutions shall otherwise comply with this article and the guidelines, and shall respond to

SBC requests for updated documents or additional information prior to the permit renewal as needed for the protection of public health and safety.

An institution that has submitted a permit application prior to the ~~effective date~~date of approval of the city council and the mayor that is still under review by the SBC shall make a reasonable effort to comply with the SBC requests for additional documentation and information to bring the institution into compliance with the permit application requirements herein provided, however, that an institution that submits a permit application subsequent to approval of the city council and the mayor but prior to the effective date shall be required to submit the information set forth in section 6-61 and section 6-62.

Be it further ordained by the ~~C~~city ~~C~~council, that Section 1-11(b) of the Code of Ordinances of the City of Somerville is hereby amended as follows:

Offense	Fine	Enforcing Personnel
Biotechnology Research (Chapter 6, Article IV).	\$300.00	Police, biosafety committee, inspectional services

APPROVED:

President
City Council