CITY OF REVERE: *REGULATIONS ON BIOSAFETY AND THE USE OF REGULATED BIOLOGICAL AGENTS*

Section 1.00 Purpose.

A. In order to safeguard the health and welfare of the Citizens of Revere (the "City"), the City of Revere Board of Health (the "Board of Health") hereby promulgates this regulation governing the use of all regulated biological agents (defined herein) in the City. The use of regulated biological agents requiring Biosafety Level 1 (BSL-1) and Biosafety Level 2 (BSL-2) shall be permitted in the City of Revere. Such uses requiring Biosafety Level 3 (BSL-3) and Biosafety Level 4 (BSL-4) shall not be permitted in the City of Revere.

B. Unless specifically exempted under this regulation, all research or manufacturing involving regulated biological agents, as defined below, in the City of Revere shall be undertaken only in strict conformity with the most recent edition or version of the National Institutes of Health Guidelines for Research ("NIH Guidelines"), the current edition of the Department of Health and Human Services' Centers for Disease Control (the "CDC") publication entitled "Biosafety in Microbiological and Biomedical Laboratories" ("BMBL"), and all other health regulations as the Board of Health may from time to time promulgate. For the purpose of this regulation, research or manufacturing will not include clinical or healthcare services or professional analytical services that directly support clinical or healthcare services.

Section 2.00 Definitions.

As used in this regulation, the following terms shall have the meanings indicated:

A. "City" shall mean City of Revere.

B. "Board of Health" ("BOH") shall mean the Board of Health of the City of Revere.

C. "Director of Public Health" shall mean the current Director of Public Health of the City of Revere.

D. "Laboratory" shall mean a building, room, or workplace designed and/or used for the development, conduct, or observation of scientific, including but not limited to the medical, chemical, physical, or biological disciplines, experimentation or research, including non-routine testing, analysis, experimentation, or other similar activities that involve the use or storage of hazardous materials. Specifically excluded from this definition are classroom laboratories, dark rooms, autoclave rooms, pharmacies, drug stores, physician's offices or the offices of other direct-care health care providers, hospital or health care dispensaries, or other facilities providing medication directly to patients.

E. "Laboratory facility" shall mean a building or a portion of a building containing one or more laboratories operated by a single owner-operator.

F. "Regulated Biological Agents" shall mean: any microorganisms including, but not limited to, mammals, plants, bacteria, viruses, fungi, rickettsia or protozoa, or any infectious substance, or

any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance that is:

1. Identified as any "Recombinant and Synthetic Nucleic Acid Molecule" in Section I-B (Definition of Recombinant DNA Molecules) of the most recently adopted version of the NIH Guidelines, defined below under "Guidelines," or,
2. Classified as a Risk Group 3 through 4 Agent by NIH Guidelines (as defined below), or;
3. Identified by the United States Department of Health and Human Services ("DHHS") or the United States Department of Agriculture ("USDA") as a "Select Agent" (as defined below).

G. "Biosafety Level" or "BSL" means physical containment as defined in Appendix G-II (Physical Containment Levels) of the latest amendment of the NIH Guidelines and the latest edition of BMBL.

H. "Biological Risk Group" means the Risk Group for any biological pathogen as defined in subsection II-A-1 (Risk Groups) of the latest amendment of the NIH Guidelines and as specified in the latest edition of the BMBL. This designation pertains to the natural risk to human health and the likelihood of transmission associated with the unaltered form of that biological agent.

I. "BMBL" means the current edition of the Department of Health and Human Services' Center for Disease Control (CDC) Publication No. 21-1112, entitled "Biosafety in Microbiological and Biomedical Laboratories."

J. "Institution" means an individual person or a group of persons, and/or a corporation, firm, partnership, association, executor, administrator, guardian, trustee, agent, organization and any other group acting as a unit responsible for compliance with the requirements set forth in this regulation.

K. "Institutional Biosafety Committee" ("IBC") means a committee established in accordance with Subsection IV-B-2 (institutional biosafety committee or IBC) of the NIH Guidelines and any applicable requirements of this regulation. The IBC shall meet the requirements for membership as specified in the Guidelines and be the final arbiter within an institution with regard to the implementation of this regulation, with oversight by the Board of Health as described herein.

L. "NIH Guidelines" ("Guidelines") means the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules ("rDNA") published in the Federal Register of June 1, 1983, and any subsequent federal amendments thereto adopted by the Recombinant DNA Advisory Committee within the National Institutes of Health (NIH).

M. "Select Agents" means any microbial and toxic agents listed at 42 Code of Federal Regulations (CFR) §73.3, 42 CFR §73.4, 42 CFR §73.5, 42 CFR §73.6, 7 CFR §331.3 and 9 CFR §121.4, and the rulings made by the CDC and the USDA relative thereto, as such regulations and rulings may be amended from time to time. However, Select Agent shall not include any de minimis amount of agents or toxins which are excluded from 42 CFR 73.00 et seq.

Section 3.00 Institutional Governance.

Institutions seeking a permit from the Board of Health shall establish an Institutional Biosafety Committee (IBC). The IBC shall be composed as described in the NIH Guidelines.

A. This regulation requires that the IBC shall include as members: representatives of the institution, the Director of Public Health of the City of Revere or their designee, plus one additional community representative who is a resident of the City of Revere, is chosen by the Institution, and is approved by the Board of Health within 30 days.
B. The IBC shall meet no less than once a year. All minutes of the IBC meetings shall be forwarded to the Board of Health within 30 days.
C. The community member of the IBC and the Director of Public Health, or their designee, shall have no substantial undisclosed financial interest in the applying or permitted institution, or any other institution in competition therewith. Such representatives shall be bound to the same provisions as to non-disclosure and non-use of proprietary information and trade secrets as all other members of the IBC, except to the extent necessary to alleviate any public health hazard. As used in these regulations proprietary information and trade secrets shall be defined as set forth under the law of the Commonwealth of Massachusetts.
D. In accordance with the NIH Guidelines, the IBC, acting on behalf of a permitted entity, shall review and approve all work involving rDNA for compliance with those Guidelines. This process shall include completion of a comprehensive risk assessment, as required by the Guidelines. The IBC will additionally be responsible for reviewing all work with other regulated biological agents to assure compliance with the standards set forth in the Guidelines as defined herein. A description of each project or protocol approved by the IBC, indicating the assigned biosafety containment level, and the rationale for designation of that BSL, and a statement certifying that the experiment conforms with the Guidelines shall be filed with the Board of Health.
E. A complete roster of all IBC members, including names, home addresses, phone numbers, e-mail addresses and resumes or curriculum vitae (CVs), including institutional and community members, shall be maintained and submitted upon initial application or within 30 days after a submission of a completed application. An updated roster of IBC members, with resumes or CVs of new members (community or institutional) appointed to the IBC since the previous roster submission shall be provided with IBC minutes and other required annual documentation.

Section 4.00 Permit Requirements.

A. Institutions seeking a permit from the Board of Health must submit a completed application form obtained from the Board of Health, accompanied by a non-refundable permit application fee, that will include the following:
    1. Company name and address.
    2. Name(s) of corporate officer(s) authorized to sign the application and full contact information for those individuals signing on behalf of the institution.
    3. State of incorporation.
    4. Name of the institution's designated official responsible for compliance with this regulation. This is most often the designated biosafety officer, as defined by NIH Guidelines.
    5. Designation of the appropriate biosafety levels (as defined in this regulation) for all laboratory areas, which are consistent with the NIH Guidelines or BMBL for all IBC-approved

protocols. This designation should be reflected in the IBC minutes before work commences in the permitted facility or, at latest, no more than 30 days after that work commences.

6. A detailed table in a format provided by the Board of Health, including at a minimum: a listing of all organisms, the source of the organism, whether the organism is used in an exempt or non-exempt rDNA experiment, BSL, and standard decontamination procedures to be employed during proper decommissioning of laboratory areas.
7. A protocol for strain verification of all potentially pathogenic organisms being used within the permitted facility or sufficient documentation to demonstrate that such a screening process has been completed by another laboratory, in order to insure that proper characterization of the virulence, replication competence, and extent of resistance to therapeutic antibiotics.
8. Copy of a completed biosafety manual. Copies of updated biosafety manual(s) are to be submitted upon annual permit renewal.
9. An emergency response plan for the purpose of orienting City representatives, including but not limited to, the Board of Health, Fire and Police Departments, to the physical plant and to procedures to be utilized in the event of an emergency. This documentation must include a floor plan showing the internal layout of the facility with specific biological containment and nonbiological laboratory areas, biological waste storage areas, and biological waste removal routes clearly indicated. Amendments to this plan must be submitted as they are incorporated.
10. Medical surveillance agreement: this service may be provided through the institution's internal clinical resources or through an independent third-party provider. A letter indicating the completion of a contractual agreement for provision of occupational medicine and medical surveillance services shall be submitted upon application and whenever the clinical provider of these services has changed thereafter. Such services shall include, but shall not necessarily be limited to:
    a. Oversight by an occupational health physician.
    b. Consideration of workers from susceptible populations (e.g. pregnant or immunocompromised).
    c. Reporting within 30 days to the IBC and Board of Health of a confirmed or suspect clinical result of any employee illness that is potentially related to Regulated Biological Agents.
    d. Retention of medical and health records for 10 years. Medical or employee health records shall be made available for inspection.
11. A plan for treatment or management of all biological waste that is consistent with the requirements of 105 Code of Massachusetts regulations (CMR) 480, Minimum Requirements for the Management of Medical or Biological Waste.
12. A treatment and/or monitoring plan and signed vendor agreement for systematic pest control management in laboratories, contiguous facilities and food service establishments in any and all segregated buildings.
13. Written authorization to allow inspection of facilities and pertinent records by the Board of Health, its agent(s) and employees, and any independent consultant(s) that may be retained by the Board of Health.

B. The Board of Health shall review the institution's application for a permit and supporting documents. The BOH shall take final action on the permit application within 60 days after the application is filed electronically with the BOH, provided a date for an IBC meeting--including the Director of Public Health representative--is scheduled within that timeframe. The period within which final action shall be taken may be extended for a definite period by mutual consent of the Board of Health and the applicant. Should an IBC meeting fail to be held as scheduled, a permit will not be issued or renewed by the Board of Health and a Cease-and-Desist order for use of regulated biological agents may be issued until such time as the IBC meeting is held.
C. The fee for a permit granted by the Board of Health, or annual renewal thereof, shall be $500.
D. Upon closing an institution that was permitted by the Board of Health under these regulations, the institution must submit a report to the Board of Health indicating that the facility was properly decommissioned including but not limited to: cleaning and sanitizing drain lines and tanks, removal of all hazardous materials and wastes, and removal of all biological material and waste. Upon receipt of this documentation, the BOH may conduct a final inspection of the facility.

Section 5.00 Inspection and Review.

A. The Board of Health shall retain the authority to designate an independent consultant, professionally competent and paid for by the institution, to perform inspections and reviews. Frequency of inspections will be reasonably determined by the Board of Health in accordance with the risk associated with the regulated activity. These results shall be reported to the Board of Health and the institution involved.
B. The Board of Health, its agent(s) and employees, and any independent consultant(s) that may be retained by the Board shall conduct no less than two inspections for the duration of one calendar year of the facilities, procedures, and practices of all institutions involved in the use of Regulated Biological Agents.
C. In order to confirm compliance with this regulation, the Board of Health, its agent(s) and employees, and any independent consultant(s) that may be retained by the Board of Health shall be allowed to conduct unannounced inspections of the facilities, procedures, and practices of all institutions involved in the use of regulated biological agents.
D. The Board of Health, its agent(s) and employees, and any independent consultant(s) shall maintain the confidentiality of all proprietary information released to them by reason of these regulations.
E. The institution shall report within 24 hours to the Director of Public Health, followed by a written report within 15 days to the Board of Health, any significant accident or risk of illness or major release to the environment related to the use of regulated biological agents if that release constitutes a violation of 105 CMR 480 and/or involves the release of a viable and potentially infectious agent. An additional inspection of facilities and procedures may be deemed necessary by the Board of Health based upon its judgement of the nature and extent of the problem.

Section 6.00 Restrictions.

A. Biological research, manufacturing, or processing that has been determined by the IBC to require BSL-3 and BSL-4 containment shall not be permitted in the City of Revere.
B. Experiments for which containment levels are not prescribed in the Guidelines, must be assigned an appropriate containment level after the completion of a comprehensive risk assessment by the members of the IBC, either independently or in consultation with an outside agency or consultant.

Section 7.00 Penalties and Violations.

A. Violation of these regulations shall subject the violator to a fine of $500 per day and, in addition, the facility in which the violation occurs may be closed by the Board of Health. Each day of violation shall constitute a separate and distinct offense.
B. If, in the opinion of the Board of Health, the use of regulated biological agents causes a nuisance or adversely affects the public health, safety and welfare in the City, the permit may be revoked. Once a permit has been issued it may be revoked by the Board of Health upon determination, after due notice and hearing, that the institution involved has materially failed to comply with these regulations, the permit agreements, or the guidelines.
C. In addition to the foregoing penalties, the Board of Health shall have the right to enforce these regulations through an equitable action in a court of competent jurisdiction.
D. Any institution, person, or entity aggrieved by the decision of the Board of Health in connection with the Board of Health's enforcement of this regulation may request a hearing by filing a written petition with the Board of Health within 10 days of action. The Board of Health shall set a time and place for such hearing no later than 60 days upon receipt of such petition. The Board of Health shall inform the petitioner and the institution of such hearing in writing. At the hearing, the petitioner shall be given an opportunity to be heard and to show cause why the Board of Health's decision was inconsistent with the requirements set forth in this regulation. The Board of Health, upon presentation of all evidence, shall issue a final decision in connection with relief sought.

Section 8.00 Variances.

A. The Board of Health may vary the application of any provision of this regulation with respect to any particular case when the Board of Health finds the enforcement thereof would do manifest injustice and the applicant has provided that the same degree of protection required by this regulation can be achieved without strict application of the particular provision.
B. Every request for a variance shall be submitted in writing to the Board of Health and shall set forth the specific variance sought and the reasons therefor.
C. The Board of Health may establish additional conditions in connection with the granting of a variance where the interest of public health so requires.
D. No determination with respect to a variance shall be binding unless issued in writing by the Board of Health. Copies of said variance shall be available to the public on the Board of Health's website.
E. The institution shall post any variance granted by the Board of Health at the permitted facilities in a prominent location for the duration that the variance is in effect.

SECTION 9: EFFECTIVE DATE

This regulation shall be effective as of December 22, 2022.

Dr. Drew Bunker

Dr. Craig Castanza

Nezha Louaddi