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BIOLOGICAL SAFETY REGULATIONS

SECTION 1: AUTHORITY

This regulation is adopted pursuant to the authority granted to local Boards of Health under Massachusetts General Laws, Chapter 111, Section 31.

SECTION 2: PURPOSE

To safeguard the health and welfare of the residents of the Town of Boxborough, the Boxborough Board of Health (BOH) hereby promulgates this regulation governing the use of all Regulated Biological Agents, as defined herein, within Boxborough. The use of biological agents requiring Biosafety Level 3 (BSL-3) containment is not permitted in the Town of Boxborough.

SECTION 3: APPLICABILITY

These regulations shall apply to any institution involved in or in any way undertaking any and all types of research or manufacturing involving Biological Agents in the Town of Boxborough. All research or manufacturing involving Regulated Biological Agents, as defined below, in the Town of Boxborough shall be undertaken only in strict conformity with the most recent edition or version of the "NIH Guidelines", CDC's "Biosafety in Microbiological and Biomedical Laboratories (BMBL)," and all other health regulations as the Board of Health may promulgate.

Any Institution currently engaged or initiating activity in these regulated activities at the time of passage of these Regulations, shall be required to apply for and receive a permit on or before 6 months from the passage hereof and then annually in accordance with the permit procedures set forth herein.

For the purposes of this regulation, clinical laboratories that exist in direct support of healthcare or veterinary services, unless these facilities are also engaged in research or production of biological agents, are not required to comply with these permitting requirements.

Educational institutions or groups utilizing only commercially available molecular biology teaching kits that have been designated by the manufacturer for use at Biosafety Level 1 are not required to comply with these permitting requirements.

SECTION 4: DEFINITIONS

The following terms are used in this Regulation as defined below.

Biological Agent: 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.

Biological Risk Group: Equivalent to the risk group for any biological pathogen as defined in *Risk Groups* (Subsection II-A-1) of the latest amendment of the NIH Guidelines (defined below), and as specified in the latest edition of the BMBL (defined below). Risk Group designation describes the natural risk to human health and the likelihood of transmission associated with the unaltered form of each biological agent.

Biosafety Level: Physical containment as defined in *Physical Containment Levels* (Appendix G-II) of the latest amendment of the NIH Guidelines (defined below) and the latest edition of BMBL (defined below).

BMBL: The current edition of the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) Publication No. 21-1112, entitled "Biosafety in Microbiological and Biomedical Laboratories."

Board of Health: The Boxborough Board of Health

Clinical Laboratory: Healthcare facilities providing a range of laboratory procedures which aid physicians in carrying out the diagnosis, treatment, and management of patients.

Healthcare Facility: Places that provide healthcare including hospitals, clinics, outpatient care centers and specialized care centers, such as birthing centers and psychiatric care centers.

Institution: Any public or private entity (individual person or group, corporation, firm, partnership, association, executor, administrator, guardian, trustee, agent, organization) acting as a unit responsible for compliance with the requirements set forth in this regulation.

Institutional Biosafety Committee (IBC): A committee established in accordance with Subsection IV-B-2 of the NIH Guidelines (defined below) and any applicable requirements of this regulation. The IBC shall be the party responsible within an institution with regard to the implementation of this regulation, with oversight by the Board of Health as described.

NIH Guidelines: The National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules published in the Federal Register of July 23, 1976, and any subsequent federal amendments thereto adopted by the Recombinant DNA Advisory Committee (RAC) within the National Institutes of Health (NIH).

Regulated 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:

1. Is identified as a "Recombinant or Synthetic Nucleic Acid Molecules " in Section I-B (Definition of Recombinant or Synthetic Nucleic Acid Molecules) of the most recent revision of the NIH Guidelines (as defined above), or

2. Is classified as a Risk Group 3 or 4 agent in the NIH Guidelines or the BMBL (as defined above), or

3. Is identified as a "select agent" by the United States Department of Health and Human Services (USDHHS) or the United States Department of Agriculture (USDA), which shall mean any microbial and toxic agents listed at 42 CFR 73.3, 73.4, 73.5, 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. “Select agent" as used herein shall not include *de minimis* amounts of agents or toxins which are excluded from 42 CFR 73.00 et seq.

Veterinary Facility: Places that provide clinical care and/or laboratory support for healthcare of animals including hospitals, clinics, outpatient care centers, and specialized care centers such as dental or surgical facilities.

SECTION 5: PROFESSIONAL ADVISORY ASSISTANCE

The Board of Health retains all final responsibility for enforcement of this regulation, however, whenever the facts and circumstances deem necessary, the Board of Health shall be authorized to retain assistance from a professional consultant with appropriate professional and academic experience and training to support review and assessment of applications, documentation, inspections, and proposals. Costs incurred by the Board of Health in utilizing a professional consultant may be assessed to a permit holder/applicant according to the time required to inspect facilities, review documentation, and communicate opinions. This cost assessment is in addition to any established permit fee(s).

SECTION 6: GENERAL REQUIREMENTS

A. All Institutions proposing to use Regulated Biological Agents, unless specifically exempt herein, must obtain a permit from the Board of Health before commencing or continuing research, manufacturing, or other use of regulated biological agents.

B. Institutions receiving such a permit shall conduct research, manufacturing or other use only as specifically set out in their permit applications and supporting documents as filed with said application. The use of regulated biological agents requiring BSL-3 (and therefore BSL-4) containment as described in the NIH Guidelines and the BMBL shall not be permitted in Boxborough.

C. Each institution applying for a permit under these regulations shall establish and operate an Institutional Biosafety Committee (IBC) in accordance with NIH Guidelines unless specifically exempted.

D. Each institution seeking permit approval shall certify and attest in its application that it will comply with the NIH Guidelines, the biosafety standards established in the BMBL, and all other conditions set forth in this regulation. Access for site inspection of facilities and pertinent records by the Board of Health or its designees upon reasonable notice, should it be deemed necessary by the Board of Health, is required by the Board of Health as a condition of permit approval.

E. Institutions permitted pursuant to these regulations shall file a report to the Board of Health annually, and for permit renewal. This report, at a minimum, shall include copies of all IBC minutes for the previous year consistent with instructions below, certification that the entity is in compliance with this regulation and the NIH Guidelines and BMBL, a report on any quality assurance and quality improvement efforts made during the previous year, and a complete roster of current IBC members.

F. Institutions permitted pursuant to these regulations shall provide a written summary of any incidents or adverse event involving biological agents, toxins, or other hazardous materials (consistent with Town of Boxborough Hazardous Materials / Hazardous Waste Proposed Bylaw Amendment March 9, 2021), that may have resulted in an exposure within the facility, or in the release from the facility involving groundwater, wastewater, direct airborne release, or any improper disposal of potentially contaminated solid waste. This report shall be sent to the Board of Health as soon as it is feasible, but not more than seven days from the date of the incident.

SECTION 7: INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) REQUIREMENTS

A. Each institution applying to the Board of Health for a permit under these Regulations must form an Institutional Biosafety Committee (IBC), as defined by the NIH Guidelines. The IBC shall include as members representatives of the institution, one member of the Board of Health or its designated agent, plus one additional community representative, appointed by the Board of Health, who is a resident of Boxborough.

B. Members of the IBC representing the Board of Health and community shall not have a substantial conflict of interest in the applicant/permitted institution or in any institution in relevant competition. Representatives shall be bound to the same provisions of non-disclosure and non-use of proprietary information and trade secrets as all other members of 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.

C. The IBC will provide to the Board of Health with the submission of a permit application a complete roster of all IBC members, including names, e-mail addresses and resumes or curriculum vitae (CVs). The Board of Health will be provided with an updated roster of IBC members, including resumes or CVs of new members, in a timely manner following any change in IBC membership.

D. The IBC will meet no less than once a year. All minutes of the IBC meetings must be forwarded to the Board of Health. The minutes of the IBC submitted at least annually to the Board of Health will include sufficient detail to allow the Board of Health and its staff or professional consultants to understand the risk assessment or risk assignment process by which the IBC determined biosafety level and corresponding safety practices. All protocols reviewed and approved by the IBC within the previous year, including, at a minimum, a listing of all biological agents utilized (e.g., host cell lines, biological vectors), any inserted gene sequences that would elevate risk (e.g., oncogenes), the BSLs assigned after IBC review and the rationale or guidance document upon which the selected BSL was based.

E. The IBC, acting on behalf of an institution, shall review and approve all work involving regulated biological agents, assessing risk and biosafety policy in compliance with NIH Guidelines and BMBL, in an ongoing manner. The IBC is responsible for assuring all work in the facility is in compliance with the standards set forth in these regulations at all times. The IBC will provide the Board of Health description of each project or protocol as approved by the IBC, indicating the assigned biosafety containment level, in a format that provides sufficient detail to understand the nature and extent of the biological risk associated with that project.

F. Information sent to the Board of Health may have essential proprietary information and trade secrets removed, however, the full text of meetings shall remain on file in the records of the institution, and must be available for inspection at all reasonable times by any member of the IBC, the Board of Health, or a professional consultant acting on behest of the Board of Health.

SECTION 8: PERMITTING REQUIREMENTS

All Institutions which are subject to these Regulations shall obtain a permit from the Board of Health. Permit applications will be provided by the Board of Health. Application for permitting must be accompanied by a nonrefundable permit application fee. The application must include the following information:

A. Institution name and address.

B. Name(s) of corporate officer(s) authorized to sign the application and emergency contact information for those individuals signing on behalf of the institution.

C. Name and emergency contact information of the institution's designated official responsible for compliance with this regulation. This is most often the designated biosafety officer, as defined in the NIH Guidelines.

D. An emergency response plan for the purpose of orienting Town 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 the location of the facility on a local map, a plot plan showing the location of the permitted facility with all points of entry clearly indicated, and a floor plan showing the internal layout of the facility with specific biological containment and non-biological laboratory areas, biological waste storage areas, and biological waste removal routes clearly indicated.

E. 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.

F. Floor plans showing laboratory areas. All biosafety containment, biosafety levels, and designated waste storage areas should be indicated. Updated floor plans to reflect any changes in assigned biosafety level or expansion of laboratory areas shall be submitted upon annual permit renewal.

G. Description of all organisms in use, and all protocols reviewed and approved by the IBC in the past year, in sufficient detail to allow the Board of Health and its Agents or professional consultants to understand the risk assessment and risk assignment process by which the IBC determined biosafety level and corresponding safety practices. Documentation must include, at a minimum, a listing of all biological agents utilized (e.g., host cell lines, biological vectors), any inserted gene sequences that would elevate risk (e.g., oncogenes), and the BSLs assigned after IBC review, with the rationale or guidance document upon which the selected BSL was based.

H. Copy of a completed biosafety manual. Copies of updated biosafety manual(s) are to be submitted upon annual permit renewal.

I. An evaluation of the public health and environmental risks associated with all biotechnology-byproduct effluents generated by the facility and a determination of the applicability of conditions, including appropriate effluent treatment requirements for waste disposal, consistent with 105 CMR 480.

J. A treatment and/or monitoring plan and signed vendor agreement for systematic pest control management in laboratories, contiguous facilities and food service establishments (separately permitted by the Board of Health) in any and all facility buildings.

K. The institution’s health monitoring and surveillance plan for an appropriate medical surveillance program including oversight by an occupational health physician, or documentation of a signed medical surveillance agreement with a qualified provider. Plan must include consideration of workers from susceptible populations such as pregnant or immunocompromised.

L. Upon submission of a permit application, the applicants will present an overview of the use of all regulated biological agents during a regularly scheduled meeting of the Board of Health. The presentation shall include a general introduction of the institution, its mission, its research or production plans, a timeline of the use of rDNA or other biological agents, an overview of the applicant’s biosecurity risk assessment and program, and a discussion of the facilities. Questions raised by the Board of Health

during or subsequent to this the presentation must be addressed by the institution to the satisfaction of the Board of Health to be granted a permit.

M. The application fee for a permit or annual renewal by the Board of Health shall be $500.00.

N. Acceptance of this permit is acknowledgement that it is the responsibility of the institution to properly decommission the facility at end of use. Upon moving or closing a facility permitted by the Board of Health under these regulations, the institution commits to and will 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 wastes. Upon receipt of this documentation, the Board of Health may conduct a final inspection of the facility.

O. Permit renewal applications must be submitted by January 31 each year. Permits are valid for one year from March 1 to February 28. New permits will be issued after March 1 and the permit shall be valid from the date of issue through February 28.

SECTION 9: PROHIBITIONS AND EXEMPTIONS

A. The use of biological agents determined by the IBC to require BSL-3 and BSL-4 containment shall not be permitted in Town of Boxborough.

B. Agents classified as a Risk Group 4 in the NIH Guidelines or the BMBL shall not be permitted in Town of Boxborough.

C. The IBC is responsible for completion of a comprehensive risk assessment to assign an appropriate containment level when one is not prescribed in the NIH Guidelines. The IBC risk assessment may be completed independently or in consultation with an outside agency or consultant.

D. Use of more than 1500 gallons of live culture of any Regulated Biological Agent(s) shall not be permitted on site unless a variance is first obtained from the Board of Health.

E. Precautions and testing as requested by the Board of Health shall be followed in order to prevent the release of any viable biological organisms into the environment, of particular concern are contamination of the local aquifer or aerosol releases, and to comply with all provisions of 105 CMR 480, *Minimum Requirements for the Management of Medical or Biological Waste.*

F. The institution shall report within 24 hours to an agent of the Board of 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 judgment of the nature and extent of the event.

SECTION 10: ENFORCEMENT

A. The Board of Health may require any institution permitted by these Regulations, at any time or on a schedule set by the Board of Health, to comply with water, effluent or soil testing, evaluation or other procedure to demonstrate conditions are in compliance with the health and safety needs of the community.

B. This regulation shall be enforced by the Board of Health or its Agent.

SECTION 11: PENALTIES

Whoever violates any provision of this regulation may be subject to penalties as follows:

A. If a designated agent of the Board determines that a party has violated this regulation, such agent may issue a written order ("Order") to the Institution (permit holder) and its designated agent to correct the offending deficiencies within a reasonable specified time.

B. Violation of any provision of this regulation may subject the violator to a fine of $500 per day. Each day of violation shall constitute a separate and distinct offense.

C. In addition to a fine, an institution which violates any provisions of this regulation, or persists in activities covered under this regulation, that pose an immediate threat to the public health or environment may be closed by the Board of Health.

D. An Institution to whom an order has been served pursuant to this Regulation may request a hearing before the Board of Health by filing a written petition requesting a hearing with the Board of Health within seven days after the day the order was served. Upon receipt of such petition, the Board of Health will set a time and place for such hearing not later than 30 days after the day on which the order was served. The Board of Health may postpone the date of a hearing for a reasonable time beyond such 30-day period, if in the judgment of the Board of Health the petitioner has submitted sufficient reason for such postponement.

E. The Board of Health may suspend or revoke a permit if it determines that the institution has failed to comply with this regulation, or other applicable permit conditions. Suspension or revocation shall follow written notice and a hearing.

F. In the event the Board of Health or its agent determines there is an imminent threat to public health and safety it may suspend a permit immediately without prior notice. Any Institution thereafter may invoke a hearing process to appeal said suspension. After a hearing, the Board may affirm, modify or rescind said Order, or take any other action it deems warranted and appropriate.

SECTION 12: SEVERABILITY

Each provision of this regulation shall be construed as separate to the end that if any part of it shall be held invalid for any reason, the remainder shall continue in full force and effect.

SECTION 13: VARIANCE

Variances from these Regulations may be authorized by the Board of Health when, in its opinion, the enforcement thereof would do manifest injustice, provided that the decision of the Board of Health shall not conflict with the spirit of this regulation or any minimum standards required by Federal or State law; and provided that the applicant demonstrates to the reasonable satisfaction of the Board that a sufficiently equivalent level of protection can be achieved. Any variance granted by the Board of Health shall be in writing and shall be subject to such conditions as the Board deems appropriate.

SECTION 14: EFFECTIVE DATE

This regulation shall become effective upon publication pursuant to M.G.L. c. 111 §31

BOXBOROUGH BOARD OF HEALTH

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3/31/21