OXFORD BOARD OF HEALTH
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 and visitors of the Town of Oxford (the "Town"), the Town of Oxford Board of Health (the "Board of Health") hereby promulgates this regulation governing the use of all Regulated Biological Agents (as defined herein) in the Town.

All research or manufacturing involving Regulated Biological Agents, as defined below, in the Town 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 from time to time promulgate.

SECTION 3: APPLICABILITY

These regulations shall apply to any 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 (hereinafter collectively "Institutions") involved in or in any way undertaking any and all research or manufacturing involving Regulated Biological Agents in the Town.

SECTION 4: DEFINITIONS

AAALAC: Association for Assessment and Accreditation of Laboratory Animal Care International

Animals: Warm-blooded animals as defined in the Animal Welfare Regulations as listed under 9 CFR 1.1 – Definition of Terms

Animal Research Components: Animals used in research that are not covered under the definition as set under 9 CFR 1.1. This includes, but is not limited to birds, rats of the genus Rattus or mice of the genus Mus that are bred for use in research, reptiles, amphibians, fish, and invertebrates.

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 Subsection II-A-1 (Risk Groups) of the latest amendment of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (https://osp.od.nih.gov/biotechnology/nih-guidelines/) and as specified in the latest edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). This designation pertains to the natural risk to human health and the likelihood of transmission associated with the unaltered form of that biological agent.

Risk Group 1: RG1 agents are not associated with disease in healthy adult humans.
Risk Group 2: RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.
Risk Group 3: RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available
Risk Group 4: RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

Biosafety Level: Physical containment as defined in Appendix G-II (Physical Containment Levels) of the latest amendment of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (published by the National Institutes of Health, Recombinant DNA Advisory Committee) (https://osp.od.nih.gov/biotechnology/nih-guidelines/) and the latest edition of Biosafety in Microbiological and Biomedical Laboratories (published by the Centers for Disease Control and Prevention) (https://www.cdc.gov/labs/BMBL.html).

Biosafety Manual: A document that provides information, guidelines, policies, and procedures that will enable and encourage those working in the Institution's environment to work safely and reduce or eliminate the potential for exposure to biological hazards.

Biosafety Officer (BSO): Individual assigned by the Institution responsible for developing, implementing, and maintaining a comprehensive biosafety, biocontainment, and biosecurity management program for an Institution. The BSO is responsible for managing the Institution's biological safety program and conducts periodic inspections to ensure compliance with developed programs and this Regulation.

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." (https://www.cdc.gov/labs/BMBL.html).

Board of Health: The Town of Oxford 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: 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.

Institutional Biosafety Committee (IBC): A committee established in accordance with Subsection IV-B-2 (institutional biosafety committee or IBC) of the NIH Guidelines (https://osp.od.nih.gov/biotechnology/nih-guidelines/) and any applicable requirements of this regulation. The IBC shall 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.

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) (https://osp.od.nih.gov/biotechnology/nih-guidelines/).

Principal Investigator: An individual designated by an institution to direct the biological research project or program conducted using Regulated Biological Agents (as defined herein).

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. Are 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 (https://osp.od.nih.gov/biotechnology/nih-guidelines/) (as defined herein);
2. Are classified as a Risk Group 3 Agent in the NIH Guidelines (https://osp.od.nih.gov/biotechnology/nih-guidelines/) or the BMBL (https://www.cdc.gov/labs/BMBL.html) (as both are defined herein); or
3. Are 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. However, "select agent" as herein defined shall not include any de minimis amount 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, The Board of Health shall retain the authority to designate an independent consultant, professionally

competent, paid for by the Institution, to review applications, perform inspections, conduct testing, and investigate incidents.

SECTION 6: GENERAL REQUIREMENTS

A. Unless specifically exempted under this regulation, all research or manufacturing involving Regulated Biological Agents in the Town shall be undertaken only in strict conformity with the NIH Guidelines, the current edition of the BMBL, and all other health regulations of the Board of Health

B. All Institutions proposing to use or continue the use of regulated biological agents at BSL-1, BSL-2 or BSL-3 containment levels must obtain a permit from the Board of Health before commencing or continuing said research, manufacturing, or other use of regulated biological agents and annually thereafter. Institutions receiving such a permit shall conduct research, manufacturing or other use only as specifically set out in their permit applications, and supporting documents filed with such application. The use of regulated biological agents requiring BSL-4 containment and/or classified as Risk Group 4 Agents in the NIH Guidelines or the BMBL shall not be permitted.

C. 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.

D. All Institutions permitted under these regulations shall designate a biosafety officer. The biosafety officer shall be responsible for facilitating compliance with this Regulation on behalf of the Institution. In the event the BSO is replaced, the Institution shall notify the Board of Health within seventy-two (72) hours of appointment.

E. Institutions governed hereby shall establish and operate an IBC in accordance with NIH Guidelines unless otherwise stated herein.
    1) The IBC shall consist of:
        a. At least one community representative.
        b. A Board of Health member or their designee.
        c. The principal investigator.
        d. The designated biosafety officer from the Institution.
        e. If research components, plants or recombinant DNA work is conducted, a committee member who is an expert in that field.
        f. And other applicable staff or representatives as determined necessary by the Board of Health in order to safeguard the public health.
    2) The IBC shall meet whenever changes to the plan occur but no less than once a year. All minutes of the IBC meetings must be forwarded to the Board of Health.
    3) The community member of the IBC and the Board of Health member 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 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.

4) Provide to the Board of Health a complete roster of all IBC members, including names, e-mail addresses and resumes or curriculum vitae (CVs) with the submission of a permit application. If there is a change in IBC membership, an updated roster of IBC members, with resumes or CVs of new members (community or institutional) appointed to the IBC shall be provided immediately following the new member's appointment.

F. Each institution seeking permit approval shall certify and attest in its application that it will comply with the following requirements and that it shall:
    1) Conform with the NIH Guidelines.
    2) Conform with the biosafety standards established in the BMBL.
    3) Conform with other conditions set forth in this regulation.
    4) Conform with any specific requirements prescribed by the Board of Health as a condition of permit approval.
    5) Allow 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.
    6) Laboratories permitted to operate at BSL-3 containment will additionally be required to submit a summary of protocols in line with best practices for BSL-3 containment and approved by the IBC that identifies the specific regulated biological agents and describes the nature of the associated research, manufacturing and/or use to be conducted. This summary may conform to the NIH project registration format or may follow any other format that provides sufficient detail to understand the nature and extent of the biological risk associated with that project. Any IBC approval of a protocol or experiment that is deemed to require BSL-3 containment must be reported to the Board of Health within 30 days of that decision.

G. Institutions permitted pursuant to these regulations shall file an annual report with the Board of Health upon permit renewal. Such report, at a minimum, shall include:
    1) Complete copies of all IBC minutes for the previous year.
        a. To the extent IBC minutes contain information regarding the agent, its location, or security measures, where the release of the information may jeopardize the health and safety of the public or proprietary information, such information may be deemed confidential under the Massachusetts Public Records Law, however, the Board of Health cannot guarantee same. The Board of Health may develop procedures for assuring confidentiality to the extent allowable under the Massachusetts Public Records Law.
    2) Certification from the IBC that the entity is in compliance with this regulation and the NIH Guidelines and CDC's BMBL.

3) A report on any quality assurance and quality improvement efforts made during the previous year.
4) A complete roster of current IBC members.

H. 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 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 (7) days from the date of the incident. Animal bites will be considered to represent potential human exposures unless the animal was known to be free of infection and this can be documented upon request. The Board of Health reserves the right to ask for a summary of the corrective action that was taken of any incidents that were reported. This requirement does not supersede or replace notification required by any other federal, state, or local regulation.

I. In the event of an incident or adverse event, as described in Section 6. H. of this Regulation, 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 480.000, Minimum Requirements for the Management of Medical or Biological Waste.

SECTION 7: PERMIT APPLICATION REQUIREMENTS

All Institutions that 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 a permit must be accompanied by a nonrefundable permit application fee as indicated on the current Board of Health schedule of fees. The application must include the following information:

A. Institution name and address, both physical and corporate.
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, including the designated biosafety officer, as defined in the NIH Guidelines.
D. 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.
E. Copy of a completed biosafety manual. Copies of updated biosafety manual(s) are to be submitted upon annual permit renewal.
F. 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:

a. The location of the institution on a local map.
b. A plot plan showing the location of the permitted facility with all points of entry clearly indicated.
c. A floor plan showing the internal layout of the facility with specific biological containment, laboratories, non-biological laboratory areas, biological waste storage areas, chemical storage areas, and biological waste removal routes clearly indicated. Amendments to this plan must be submitted as they are incorporated.
d. Ventilation system plan insuring air and substances are not entering common areas, residences, shopping areas or areas of high population density.

G. Description of all biological agents 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 or risk assignment process by which the IBC determined biosafety level and corresponding safety practices. Documentation must include, at a minimum:
    a. A listing of all biological agents utilized (e.g., host cell lines, biological vectors)
    b. The source of all biological agents utilized.
    c. Any inserted gene sequences that would elevate risk (e.g., oncogenes)
    d. The BSLs assigned after IBC review, with the rationale or guidance document upon which the selected BSL was based.
    e. Standard documentation procedures to be employed during proper decommissioning of laboratory areas.
H. 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 to include but not limited to pregnant or immunocompromised individuals.
I. Submit a protocol for strain verification of all known human pathogens that are considered to be attenuated or noninfectious approved by the IBC within the previous year for use within the permitted facility, if any, or sufficient documentation to demonstrate that such a screening process has been completed by another laboratory, in order to ensure the proper characterization of the virulence, replication competence, and extent of resistance to therapeutic antibiotics.
J. A plan for treatment or management of all biological waste and 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 the requirements of 105 Code of Massachusetts Regulations (CMR) 480, Minimum Requirements for the Management of Medical or Biological Waste.
K. A treatment and/or monitoring plan and signed vendor agreement for systematic pest control management in laboratories, contiguous facilities in any and all segregated buildings.
L. A laboratory training program including safeguards and safety procedures for laboratory personnel upon hire and annually thereafter.

M. Upon submission of a permit application, the applicants will present an overview of the use of rDNA or 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 regulated biological agents, an overview of the applicant's biosecurity risk assessment and program, and a discussion of the facilities. A presentation is not required for permit renewals unless otherwise determined by an Agent of the Board of Health.
N. Institutions shall notify the Board of Health of any proposed changes in assigned biosafety level, use of Biological Agent(s) or expansion of laboratory areas. Board of Health approval shall be granted prior to any implementation of changes in the Institution's operation. Failure to do so may result in suspension or revocation of permit.
O. Upon submission of a permit application to operate a BSL-2 or BSL-3 Institution and dependent on proximity to residential buildings or high density population areas for the proposed location of the Institution, the Board of Health may require additional action from the applicant. This action includes, but is not limited to enhanced Institution ventilation systems, prevention of cross ventilation conditions, physical barriers, or additional containment structures.
P. Permit renewal applications must be submitted by November 30 each year. Permits are valid for one year from January 1 to December 31. New permits will be issued after January 1 and the permit shall be valid from the date of issue through December 31.
Q. The Board of Health shall review the institution's application for a new permit and supporting documents. The Board of Health shall take final action on the permit application within 45 days after the application is filed electronically with the Board of Health, provided a date for an IBC meeting, including the Board of 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.
R. The application fee for a permit or annual renewal by the Board of Health shall be determined by the Board of Health.
S. 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 wastes. Upon receipt of this documentation, the Board of Health may conduct a final inspection of the facility.

SECTION 8: PROHIBITIONS

A. The use of biological agents requiring Biosafety Level 4 (BSL-4) containment (as defined herein), and/or classified as a Risk Group 4 Agent in the NIH Guidelines or the BMBL (as both are defined herein) shall not be permitted in the Town.
B. The use of warm-blooded "animals", as defined in the USDA Animal Welfare Regulations, 9 CFR 1.1, shall not be permitted in Institutions operating in the Town *unless* a variance has been obtained from the Board of Health.

C. The use of Animal Research Components shall only be allowed provided the Institution meets the requirements of Section 6., D (1) (e), and applies for AAALAC accreditation and receives this accreditation within a time determined sufficient by the Board of Health through the accreditation process established by AAALAC.
D. Use of more than 5,000 liters of live culture of any Regulated Biological Agent(s) shall not be permitted *unless* a variance has been obtained from the Board of Health.

SECTION 9: EXEMPTIONS

A. For the purposes of this regulation, clinical laboratories located within health care facilities, professional analytical services that directly support clinical or health care services, or healthcare services or professional analytical laboratories conducting routine air, water or food quality tests, or veterinary facilities shall not be required to obtain a permit or comply with any permit requirements as stated herein unless these facilities are also engaged in research or production of biological agents.
B. Educational institutions utilizing only commercially available molecular biology teaching kits that have been designated by the manufacturer for use at Biosafety Level 1 shall not be required to obtain a permit or comply with any permit requirements stated herein.

SECTION 10: CONFIDENTIALITY OF INFORMATION

A. Information submitted to the Board of Health is subject to public records laws. Upon receipt of any request for public records under these laws, the Oxford Records Access Officer may consult with the Board of Health and will make a determination as to whether the requested information is exempt from disclosure for safety and security or other enumerated purposes under **G. L. c. 4, § 7(26)** and withhold any documents, or portions thereof, that are covered by an exemption.

   Any institution seeking to qualify any particular document or submission as confidential shall:
   a. Submit said information as "Confidential Information"; and
   b. Provide the applicable statutory citation warranting the exclusion of such information from disclosure under the Commonwealth of Massachusetts' Public Records Law (MGL Chapter 66).

B. Notwithstanding this designation by the institution, any documents that are referred to during a public meeting may be subject to public review. The exchange of information pertaining to compliance with the permit may take place in an executive session, if the information shared in a public meeting would pose a security threat or compromise proprietary information.

SECTION 11: ENFORCEMENT

This regulation shall be enforced by the Board of Health or its approved agents.

A. All institutions involved in the use of Regulated Biological Agents shall allow inspection of their facilities, procedures and practices by the Board of Health, its agent(s) and employees, and any independent consultant(s) that may be retained by the Board of Health, in order to confirm compliance with this regulation.
B. The Board of Health shall retain the authority to designate an independent consultant, professionally competent, 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. The results shall be reported to the Board of Health, and the institution involved.
C. The Board of Health, its agent(s) and employees, and any independent consultant(s) retained to perform inspections shall maintain the confidentiality of all proprietary information released to them by reason of these regulations.

SECTION 12: PENALTIES

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

A. If a designated agent of the Board of Health 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 for which continued conduct or recombinant DNA technology or other activity covered under this regulation poses an immediate threat to the public health or environment may be closed by the Board of Health.
D. 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 in accordance with the time frame set forth in Section 13.
E. 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 the hearing process in Section 13 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 13: HEARING

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 (7) 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.

SECTION 14: VARIANCES
Upon written application and a hearing before the Board of Health, the Board of Health may in its sole discretion vary the application of any provision of this regulation with respect to any particular case when it determines that 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 of Health 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 of Health deems appropriate.

SECTION 15: 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 16: EFFECTIVE DATE
This regulation shall be effective as of *March 8, 2023*

By the Board of Health