Bedford, MA Board of Health
Regulations on Biosafety and the Use of Regulated Biological Agents

1. Purpose

In order to safeguard the health and welfare of the citizens of the Town of Bedford (the "Town"), the Town of Bedford Board of Health hereby promulgates this Regulation governing the use of all Regulated Biological Agents (as defined herein) in the Town. The use of Regulated Biological Agents as defined herein requiring Biosafety Level 3 ("BSL-3") and Biosafety Level 4 ("BSL-4") containment shall not be permitted in the Town of Bedford.

All research or manufacturing involving Regulated Biological Agents, as defined below, in the Town of Bedford 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. For the purposes of this regulation, research or manufacturing will not include clinical or healthcare services or professional analytical services that directly support clinical or healthcare services.

2. Definitions

For the purpose of these regulations, the following definitions are adopted:

a) Regulated Biological Agents mean: any microorganisms including, but not limited to, mammals, plants, bacteria, viruses, fungi, rickettsiae 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 revision of the *NIH Guidelines*, defined below under "Guidelines"; or,
   2) classified as a Risk Group 3 through 4 Agent by the 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).

b) 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.

c) 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.

d) Guidelines mean:
   1) NIH Guidelines for Research Involving Recombinant DNA Molecules published in the Federal Register of March 5, 2013, and any subsequent Federal amendments thereto; and,
   2) Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th or most recent edition; and,
   3) any amendments, revisions, new editions or substitutions to the NIH Guidelines or the BMBL, unless otherwise noted herein. In the event that the National Institutes of Health shall discontinue or abolish their Guidelines, those guidelines in effect at the time of such discontinuance shall remain in effect as to all activities within the Town of Bedford.

e) Institution means: Any public or private entity including Federal, State, and local governmental agencies.

f) Institutional Biosafety Committee (IBC) means: A committee that (i) meets the requirements for membership specified in the Guidelines and (ii) reviews, approves, and oversees projects in accordance with the responsibilities as defined in the Guidelines.

g) Principal Investigator means: An individual who has primary responsibility for the design, execution, and management of a research project and who will be involved in the project in a significant manner. The Principal Investigator is responsible for full compliance with the Guidelines and for ensuring that all reporting requirements are fulfilled.

h) Exempt Recombinant DNA Experiments means: As defined in the "NIH Guidelines", Section III-F (*Exempt Experiments*), those experiments (e.g. research with *e. coli K-12*) that are not subject to those guidelines, but are subject to the practices and standards provided by the CDC in *Biosafety in Microbiological and Biomedical Laboratories*. These experiments shall be reviewed by the Institutional Biosafety Committee and shall be reported to the Bedford Board of Health on a form titled "REGISTRATION OF EXEMPT RECOMBINANT DNA EXPERIMENTS" and included on the detailed table required in Section 4. b) 4.

i) 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 minimus* amount of agents or toxins which are excluded from 42 CFR 73.00 *et seq*.

j) Significant deviation means: Any deviation that might have an adverse effect on personal or public health.

3. Institutional Biosafety Committee

a) This regulation requires that each institution applying for a permit under these Regulations form an Institutional Biosafety Committee (IBC), as defined by the NIH Guidelines and shall include as members representatives of the institution, the Director of Public Health of the Town of Bedford or his/her designee, plus one additional community representative appointed by the Board of Health, who shall be a resident of Bedford.

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.

c) The community member of the IBC and the Director of Public Health, or his/her 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.

d) In accordance with the Guidelines (specifically 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) All information sent to the Board of Health may have any proprietary information and trade secrets removed therefrom. The full text shall remain on file in the records of the institution for inspection at all reasonable times by any member of the IBC.

4. Permits

a) All institutions planning to use Regulated Biological Agents must obtain a permit from the Board of Health before commencing said work. All permits are issued for one year and may be revoked for cause.

b) Institutions seeking such a permit from the Board of Health shall submit the following, to the Board of Health in an electronic format (.pdf):

1) A completed Application for Permit or Permit Renewal.

2) Project Summaries or Registration Forms for all work involving Regulated Biological Agents (both exempt and non-exempt under the NIH Guidelines).

3) A plan for orienting representatives of the Bedford 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 plot plan showing the location of the permitted facility with all points of entry clearly indicated, the location of the facility on a local map, 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.

4) A detailed table in a format provided by the Board of Health, including at a minimum: a listing of all organisms, the source or 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.

5) 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 the proper characterization of the virulence, replication competence, and extent of resistance to therapeutic antibiotics.

6) Designation of the appropriate BSL by the IBC that is consistent with the Guidelines, inclusive of a comprehensive appropriate risk assessment completed by the IBC.

7) An updated and complete roster of names, addresses, phone numbers, e-mail addresses, and a recent resume for each IBC member, including the Community Representative.

8) 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.

9) 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.

10) The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the IBC and consistent with the Guidelines for all persons

engaged in the use of Regulated Biological Agents. Such programs shall include, but shall not necessarily be limited to:

a. Oversight by an occupational health physician.
b. Consideration of work with Regulated Biological Agents and all substances and materials subject to Article 50 of the Town of Bedford by-laws (*Control and Management of Hazardous Materials).*
c. Consideration of workers from susceptible populations (e.g., pregnant or immunocompromised).
d. 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 and all substances and materials subject to Article 50 of the Town of Bedford by-laws (*Control and Management of Hazardous Materials).*
e. Retention of medical and health records for ten years. Medical or employee health records shall be made available for inspection and may be used for public health studies.

11) A laboratory training program including safeguards and safety procedures for laboratory personnel upon hire and annually thereafter.

12) The name(s), email address(es) and business and emergency phone numbers of the Principal Investigator(s) who shall be responsible for enforcing the guidelines.

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.

c) The Board of Health shall review the institution's application for a 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 Institutional Biosafety Committee 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.

d) The fee for a permit granted by the Board of Health, or annual renewal thereof, shall be $500.00.

e) 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.

5. Inspection and Review

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.

6. Restrictions

a) Biological research, manufacturing or processing that has been determined by the IBC to require BL3 and BL4 containment shall not be permitted in the Town of Bedford.

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.

c) 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 Bedford Board of Health.

d) Precautions shall be followed in order to prevent the release of viable biological organisms into the environment (i.e. sewers, storm drains, or aerosol releases) and to comply with all provisions of 105 CMR 480, *Minimum Requirements for the Management of Medical or Biological Waste*.

e) The institution shall report within 24 hours to the Director 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 problem.

7. Penalties

a) Violation of these regulations shall subject the violator to a fine of Five Hundred Dollars ($500.00) 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 Regulated Biological Agents causes a nuisance or adversely affects the public health, safety and welfare in Bedford, 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.

8. Assessments

Upon initial application, a fee of $2,000 shall be supplied to the Town of Bedford to be held in an account for the salaries and expenses paid by the Town for inspections, reviews, staff and consultants for work directly related to carrying out the requirements of these regulations. An accounting of these costs will be furnished annually to each institution if used. At no time shall the balance held in that account fall below $1,000 at the time of annual permit renewal. The remaining funds held in this account shall be returned upon submission to the Bedford Board of Health of an appropriate decommissioning report.

9. Severability

Each part of these regulations is construed as separate to the end that if any section, item, sentence, clause or phrase is held invalid for any reason, the remainder of these regulations shall continue in full force and effect.

10. Variance

Variances from these Regulations may be authorized by a two-thirds vote the Board of Health after notice and public hearing if the Board reasonably determines that the relief sought will not be detrimental or injurious to the public health.

Adopted by unanimous vote on July 22, 2013. Regulation effective: September 1, 2013.

BEDFORD BOARD OF HEALTH

Bea Brunkhorst, Co-Chair

Tom Kinzer, Co-Chair

Anita Raj

Sarah Thompson

Kevin Wormstead

This regulation replaces "Section 9: Regulations for Use of Recombinant DNA Molecule Technology," adopted November 5, 2003.