

**Town of Walpole
Regulations for the Use of Recombinant DNA Molecular Technology
and Biosafety Level 3 Materials**

The Board of Health, Town of Walpole, Massachusetts, acting under the authority of Section 31, Chapter 111 of the General Laws and amendments and additions thereto, and by any other power thereto enabling, hereby adopts the following rules and regulations in the interest of and for the preservation of public health.

Section 1: Applicability

These rules and regulations shall apply to all Institutions in the Town of Walpole which use or experiment with recombinant DNA (“rDNA”) technology in any Biosafety Level and/or BSL-3 Materials as defined herein. **Use of BSL-4 Materials as defined herein shall be prohibited in the Town of Walpole.**

Section 2: Definitions

1. “Affiliate” shall mean any corporation or other business entity that directly or indirectly is Controlled by, Controls, or is under common Control with an Institution that holds a permit under these regulations.
2. "Biosafety Professional" shall mean an individual holding documented university education or who has successfully completed a training program in biological safety disciplines.
3. “Biosafety Level 1” or “BSL-1” includes activities, practices, equipment, safety equipment, and facility design and construction that are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other laboratories in which work is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy humans. Biosafety Level 1 represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for hand washing.
4. “Biosafety Level 2” or “BSL-2” includes activities, practices, equipment, safety equipment, and facility design and construction that are appropriate for and applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk biological agents that are present in the community and associated with human disease of varying severity. To qualify for this designation, such biological agents shall be, with good microbiological techniques, capable of being used safely in activities conducted on the open bench, provided the potential for producing splashes or aerosolization is low. Hepatitis B virus, HIV, the salmonellae, and Toxoplasma spp. are representative of microorganisms assigned to this containment level. Biosafety Level 2 shall be deemed appropriate when work is done with any human-derived blood, body fluids, tissues, or primary human cell lines where the presence of an

infectious agent is unknown. Even though organisms routinely manipulated at Biosafety Level 2 are not known to be transmissible by the aerosol route, procedures with aerosol or high splash potential that may increase the risk of such personal exposure shall be conducted in primary containment equipment, or in devices such as a safety centrifuge cup. Other primary barriers shall be used as appropriate, such as splash shields, face protection, gowns, and gloves. Secondary barriers such as hand washing sinks and waste decontamination facilities shall be available to reduce potential environmental contamination.

5. "Biosafety Level 3" or "BSL-3 Materials" shall mean biological materials with a potential for respiratory transmission and which may cause serious and potential lethal infection upon exposure but for which there is available vaccines or treatments. Novel (new) influenza viruses and tuberculosis are representative of microorganisms assigned to this containment level. All procedures for Biosafety Level 2 also apply to this category.

6. "Biosafety Level 4" or "BSL-4 Materials" shall mean biological materials with dangerous and exotic agents of any type that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy. **BSL-4 is not permitted in the Town of Walpole.**

7. "Change of Control" shall mean the acquisition of Control of an Institution holding a permit under these regulations by an Institution that was not an Affiliate of such permit holder prior to such transfer.

8. "Control" shall mean the direct or indirect beneficial ownership of at least fifty (50%) percent of the voting stock of, or at least a fifty (50%) percent interest in the income of, an Institution, or the power to elect at least fifty (50%) percent of the directors or trustees of such Institution, or such other relationship which in fact constitutes actual control.

9. "Guidelines," unless otherwise specified, are defined as:

- a. "NIH Guidelines" - National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant DNA Molecules," as published in the Federal Register of September 22, 2009.
- b. "BMBL" – Biosafety in Microbiological and Biomedical Laboratories 5th Ed. 2007.

For purposes of these regulations, the NIH Guidelines, when applied to an Institution that is subject to the NIH Guidelines solely by reason of these regulations, shall include the modifications to the NIH Guidelines set forth in Section IV-D thereof applicable to persons complying with NIH Guidelines on a voluntary basis. In the event that there is a conflict between the NIH Guidelines and the BMBL, the more restrictive shall control.

10. "Initial Application" shall mean an application for a permit by an Institution that intends to use Recombinant DNA Molecular Technology and/or Biosafety Level 3 Materials in the Town of Walpole.

11. "Institution" shall mean any person, sole proprietor, corporation, limited liability company, partnership, trust, association, public or private organization, federal, state or local government agency, or any other individual or entity acting on its own or in any representative capacity.

12. "rDNA technology" shall mean constructing or handling for experimental purposes or otherwise (i) "Recombinant DNA molecules" ("rDNA") defined as molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or DNA molecules which can result from the replication of a molecule, and (ii) organisms and viruses containing such Recombinant DNA molecules, except for any such activity that is the subject of an exemption under the NIH Guidelines.

13. "Transfer Application" means an application for a new permit by an Institution that certifies its intention to acquire the operations of a current permit holder, to continue such operations in accordance with all terms of the existing permit, to establish an Institutional Biosafety Committee ("IBC") with the same membership as the IBC of the current permit holder, and not to change such membership without the approval of the Board of Health or change in any material aspect any of the facilities or procedures of the current permit holder without the approval of such IBC.

14. Any other terms, not specifically defined herein, shall have the meaning as defined in the Guidelines. If the Guidelines do not define the term, it shall have the meaning as is commonly used.

Section 3: Responsibilities of the Board of Health

1. The Board of Health and/or its agent shall be responsible for overseeing all activities to which this Regulation applies.
2. The Board of Health shall:
 - a. Review and act on all initial and transfer applications for permits under this Regulation.
 - b. Determine the manner in which permit holders make reports or applications to the Board of Health, and the type of information required.
 - c. Review reports, applications and recommendations from all IBC meetings and approve where appropriate.
 - d. Responsible for revocation of a permit when an Institution is not in compliance with these regulations.

Section 4: Permit Requirements

1. All Institutions proposing any use of rDNA technology and/or BSL-3 Materials shall obtain a permit from the Board of Health before commencing any such use. Any Institution already using rDNA technology and/or BSL-3 Materials as of the

- effective date of these regulations shall apply for and obtain a permit or cease such use within six (6) months from such effective date.
2. Permit requirements shall, at minimum, include written agreement and evidence to demonstrate the capacity to:
 - i. Follow the Guidelines as defined in these regulations.
 - ii. Adhere to any other conditions as set forth in these regulations or permit conditions.
 - iii. Allow inspections, during normal operating hours or at a scheduled appointment, of both the Institution's facilities and records, as related to these regulations.
 - iv. Adhere to a set of safety documents, prepared by the Institution, according to the Guidelines listed in Section 2.9 of these regulations, which contains all procedures relevant to the use of BSL-3 Materials and/or rDNA technology at all levels of containment in use at the Institution. The safety documents shall also include a plan for waste disposal in compliance with all applicable federal, state, and local regulations.
 - v. Establish and implement a training program of safeguards and procedures for personnel using rDNA technology and/or BSL-3 Materials which shall include standard operating procedures ("SOPS") for each manufacturing process.
 - vi. Establish an IBC in accordance with Section 5.1 of these regulations.
 - vii. Provide relevant training (either in house or through workshops) to all community and Board of Health IBC members in order for them to fulfill their roles on the IBC.
 3. Initial Application: The Board of Health shall hold a public hearing to review the Institution's Initial Application for a permit including supporting documentation. The Board of Health shall take final action on the Initial Application for permit within sixty (60) days.
 4. Transfer Application: The Board of Health shall hold a public hearing to review the Institution's Transfer Application for a permit including supporting documentation. The Board of Health shall take final action on the Transfer Application within 30 days.
 5. Final action shall mean a vote to grant or deny an Initial Application or a Transfer Application. In the event that the Board of Health fails to take final action within the prescribed period (as noted in section 3 and 4), no constructive grant shall result, only a right to compel, by an action in the nature of mandamus, the Board of Health to act. Any extension of time shall be mutually agreed upon by the Board of Health and the applicant.
 6. Annual Review of Permit: The Board of Health shall review the Institution's permit annually (at least 30 days prior to the annual maintenance fee). At a minimum, the Board of Health will review its permit conditions and any possible

violations. The Health Director or his/her designee shall inspect the laboratories which have been permitted to conduct work with rDNA technology and/or BSL-3 Materials to ensure compliance with this regulation.

7. A permit shall remain in force and effect unless and until it is revoked by the Board of Health pursuant to Section 12 of this Regulation. An application fee shall be paid by the applicant with each application for the issuance or re-instatement of a permit, and an annual maintenance fee shall be paid by each permit holder, on or before March 15 of each calendar year after the calendar year in which the permit was issued. The fees for permits issued by the Board of Health under this Regulation shall be:

- a. Application Fee for rDNA at BSL-1 and BSL-2 \$500
- b. Application Fee for BSL-3 \$1,000
- c. Annual Maintenance Fee \$500

8. A permit shall be obtained and maintained by the Institution conducting the activities for which such permit is required, regardless of the ownership of the facility in which the activities are conducted.

9. The permit shall not be assignable except in the case of an assignment to an Affiliate of the current permit holder where the proposed assignee certifies to the Board of Health that:

- a. the proposed assignee is an Affiliate of the current permit holder as defined in these regulations;
- b. The proposed assignee will acquire the operations of the current permit holder and continue such operations in accordance with all terms of the existing permit;
- c. The proposed assignee has established an IBC with the same membership as the IBC of the current permit holder, and will not change such membership except in accordance with these regulations;
- d. Except as approved by the proposed assignee’s IBC, the proposal assignee will not change in a any material aspect any of the facilities or procedures of the current permit holder approved by the current permit holder’s IBC.

10. In connection with any Change of Control of a permit holder, the permit may be revoked upon a finding by the Board of Health, after notice to the permit holder and an opportunity for the permit holder to be heard, that the Change in Control is likely to affect the safety of operations under the permit.

Section 5: Institutional Biosafety Committee

1. The Institution shall establish an IBC in accordance with the Guidelines with a minimum of five (5) members. The IBC shall have as members, in addition to the Institution’s representatives, two members designated by the Board of Health to

- represent the community, of which one shall be the Health Director or designee and the other a member of the Board of Health or a community representative approved by the Board of Health.
2. The IBC shall meet at least three times a year with the membership noted above. The IBC can meet more often to review new SOPS for new or current manufacturing procedures. The minutes of each IBC meeting shall be kept on file for so long as any activities approved therein are continuing and an additional period of three (3) years after all activities approved at such meeting have terminated.
 3. Non-institutional members of the IBC shall have no controlling or substantial financial interest in the Institution or any other Institution in competition therewith. All financial interests shall be disclosed prior to appointment. Such representatives shall be subject to confidentiality agreements and 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 this Regulation, proprietary information and trade secrets shall be defined as set forth under the laws of the Commonwealth of Massachusetts or Federal statutes.
 4. The IBC reviews all projects of the Institution involving use of rDNA technology and/or BSL-3 Materials for compliance with the Guidelines. Project protocols must be approved by the IBC and a statement certifying that each project protocol conforms to the Guidelines shall be kept on file during the continuation of the project and for an additional period of three (3) years after project completion. At a minimum, the IBC shall discuss proposed changes since its last meeting (e.g. standard operating procedures, quality control, effluent testing, water usage, new materials). In the event of dissenting votes with respect to approval of a protocol, each dissenting voter shall provide a statement of reasons why the proposed protocol does not comply with the Guidelines, and all such statements shall be submitted to the Board of Health within five (5) business days after the IBC meeting at which the vote occurred. Any protocol with respect to which a dissenting vote is given shall not be implemented until after the next meeting of the Board of Health following the submission of the dissenter's statements. If the Board of Health finds by a majority vote that the proposed protocol does not comply with the Guidelines, such protocol shall not be implemented, provided that the decision of the Board of Health shall be subject to appeal to a court of competent jurisdiction.
 5. Information sent by the IBC to the Board of Health shall not contain proprietary information and/or trade secrets. Full documentation of IBC reviews and determinations shall remain on file in the records of the Institution for inspection by authorized individuals.

Section 6: Medical Surveillance Programs

All institutions using rDNA technology and/or BSL-3 Materials within the Town of Walpole shall provide appropriate medical surveillance programs as determined by their IBC and shall be consistent with the Guidelines.

Section 7: Restrictions

1. **Uses of BSL-4 Materials shall be prohibited in the Town of Walpole.**

Section 8: Consultant Review

1. **Applicability:** The Board of Health may determine that the review of the permit or the activities of the Institution or the IBC warrants the use of outside consultants. Such consultants shall assist the Board of Health or the IBC in overseeing all activities to which this regulation applies (e.g. review reports, applications and recommendations from the IBC where appropriate).
2. **Selection:** The Board of Health shall provide a list of three (3) proposed consultants together with a scope of work and cost estimate to the Institution. The Institution shall have at least seven (7) days to accept one (1) of the proposed consultants or object on grounds that the proposed consultants have a conflict of interest or do not possess the minimum qualifications of an appropriate educational degree and three (3) or more years of practice in, or closely related to, the field at issue. In such an event, the Institution and the Board of Health shall endeavor to mutually agree upon a consultant within seven (7) days and should an impasse remain, to arbitrate the same through established State conflict resolution processes..
3. **Special Account:** The Institution shall deposit with the Town of Walpole Treasurer-Collector the amount of money agreed upon as necessary for the consultant to complete its assignment. Such funds shall be deposited into a special account to be established by the Town of Walpole Treasurer-Collector. Expenditures from this special account may be made at the direction of the Board of Health without further appropriation, but only in connection with the review of a specific project for which a consultant review fee has been collected. An additional fee shall be deposited as mutually agreed upon if the amount deposited is insufficient to complete the assignment. Any unexpended balance, including all accrued interest from the date of deposit, shall be repaid to the applicant or its successor-in-interest at the completion of the consultant's services.

Section 9: Violations

It shall be a violation when the Institution does not follow these Guidelines or the conditions of operation under the permit.

Section 10: Notification

Institutions shall report to the Board of Health, no later than thirty (30) days but as soon as the Institution is aware of the violation, any violations of the Guidelines or conditions of operation under their permit. Any release that results in a potential hazard to employees or public health shall be reported immediately to the Board of Health (by calling the Health Department during normal Town Hall hours or by calling the Police Department outside of normal Town Hall hours and then the Police Department will contact an agent of the Board of Health). The Health Director or designee will then determine who shall be notified of the release to start any procedures necessary as outlined in the Town's Comprehensive Emergency Management Plan.

Section 11: Penalties

Any Institution that violates any provision of this regulation shall be punished by a fine of \$300 for each separate violation under the non-criminal disposition procedure and/or court action. Each day that a violation continues shall be considered a separate offense and shall be subject to a separate fine.

Section 12: Enforcement

Enforcement of this regulation shall be the responsibility of the Board of Health and/or its agent. The Board of Health may also deem any violation of this regulation, as it may be amended by the Board of Health, to be a nuisance pursuant to Massachusetts General Laws Ch. 111 and may take such action as it deems proper. In addition to any other penalties set forth herein, the Board of Health, after notice to the permit holder and an opportunity for the permit holder to be heard, may revoke; in whole or in part, any permit granted hereunder if it finds the permit holder has violated any provisions of this regulation.

Section 13: Severability

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

Section 14: Effective Date

This Regulation becomes effective (effective date to be added on date of final approval of these regulations by the BOH)]