

**Town of Wilmington**

Board of Health

121 Glen Road

Wilmington, Massachusetts 01887

RDNA/BSL

\_\_\_\_ NEW APPLICATION **$500.00** \_\_\_\_\_RENEWAL **$100.00**

The Wilmington Board of Health Regulations entitled “Regulations for Use of Recombinant Molecule Technology Section 22” effective as of September 18, 2018 requires institutions that conduct recombinant DNA work or biological agents covered under these regulations to obtain a permit.

In addition to the information below, 1st time applicants please supply all information required in the Permit Checklist. (this can be done electronically)

Name & Address of Institution \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Applicant (on-site institution contact information) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Name of IBC Chair, Administrator or Biosafety Officer, phone & email

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Name of Biosafety emergency contacts, phone & email

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(Applicant) (Biosafety Officer)

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PERMIT CHECKLIST

Institutions seeking a first time permit from the Board of Health shall submit a summary (where indicated) and/or attach documentation of the following:

\_\_\_\_\_\_\_Please provide a brief summary of the rDNA or biological agent work being performed at your institution.

\_\_\_\_\_\_\_Please provide a plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the part of the facility where work is performed.

\_\_\_\_\_\_\_Please provide a listing of all organisms, containment levels, and decontamination procedures to be employed.

\*Summary items will be descriptions of each of the documents housed at your institution.

\_\_\_\_\_\_\_ A summary of a documented review process to insure the safe handling and containment of research and development activities using rDNA or biological agents. This review must include a review and approval by an IBC or Institution’s designated Biosafety representative.

\_\_\_\_\_\_\_ A summary of your plan for systematic monitoring of waste to assure that surviving rDNA organisms will not be released into the environment.

\_\_\_\_\_\_\_A summary of your plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in any and all segregated buildings. Please include Pest Management Company information

\_\_\_\_\_\_\_ A summary of your plan for systematic security of the premises. Please include any outside security company contacts if applicable.

\_\_\_\_\_\_\_A summary of your institution’s occupational health program, biosafety manual and Standard Operating Procedures pertinent to the work being performed as determined by the IBC or biosafety representative for the institution.

a) For first time applicants the Board of Health shall review the institution’s application for a permit and supporting documents within 30 days.

b) The fee for a 1st time permit granted by the Board of Health, shall be $500.00

c) Annual permit renewal will be on or before January 1st of each calendar year and will cost $100.00 and will involve an abbreviated permit renewal if the type of work and material used has not changed since the previous permit issuance.

d) Supporting documentation can be sent electronically via email listed below and will be kept on file

REGULATIONS FOR USE OF RECOMBINANT DNA MOLECULE TECHNOLOGY SECTION 22

The Board of Health, Town of Wilmington, 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, adopt the following rules and regulations in the interest of and for the preservation of the public health.

1. APPLICABILITY

All research and development activities associated with constructing and handling the following materials within the Town of Wilmington shall be performed in strict accordance with regulations set forth in this Section including requirements in the Center for Disease Control (CDC) Biosafety in Microbiological and Biomedical Laboratories (BMBL) and National Institutes of Health (NIH) Guidelines. These regulations shall govern in addition to the CDC and NIH:

1. Recombinant DNA (rDNA) molecules
2. Organisms and viruses containing rDNA molecules
3. Biological agents which:
4. are classified as a Risk Group 3 through 4 Agent by the National Institutes of Health (“NIH”) Guidelines
5. require Biosafety Level-3 through Biosafety Level-4 containment as determined by an Institutional Biosafety Committee or Institution’s Biosafety representative
6. are identified by the United States Department of Health and Human Services (“DHHS”) or the United States Department of Agriculture (“USDA”) as a “Select Agent” and require registration for use under the Federal Select Agent Program.

These regulations do not apply to work requiring Biosafety Level-1, Biosafety Level-2 and finished products which contain rDNA molecules and have been approved by other government regulatory agencies for medical or other purposes.

1. DEFINITIONS

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

* 1. NIH Guidelines: “Guidelines for Research involving Recombinant DNA Molecules" promulgated by the National Institute of Health (NIH) of the United States Department of Health and Human Services. The most current available version of the guidelines will be used.

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 Wilmington.

* 1. Institution means: Any public or private entity including Federal, State, and local governmental agencies.
  2. Institutional Biosafety Committee (IBC) means: A committee that (I) meets the requirements for membership specified in the NIH Guidelines (Section IV- B-2) and (ii) reviews, approves, and oversees projects in accordance with the responsibilities defined in the Guidelines (Section IV-B-2 and IV-B-3).
  3. Institutional Biosafety representative means: A company employee or outside consultant who is responsible for establishing and monitoring workplace safety procedures designed to minimize or prevent injury or loss due to hazards involving materials outlined in these regulations.
  4. Large-scale means: The use of more than ten liters but less than 5000 liters of rDNA culture.
  5. Recombinant DNA Molecules mean (as defined by NIH Guidelines):
     1. molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids
     2. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids
     3. molecules that result from the replication of those described in (1) or (2) above
  6. Biological Agents: means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa) or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance
  7. Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guidelines. *MGL Ch.44 Sec.53G*. US Department of Health and Human Services, CDC and NIH. The most current edition and any subsequent amendments by NIH or the CDC.
  8. Four biosafety levels have been defined by CDC in the BMBL which specifies administrative procedures, safety equipment, and facilities for work with biological agent or toxins. Research with biological agents and toxins is assigned to a biosafety level based on the pathogenicity and transmission route of the particular agent or toxin used.

1. Biosafety Level 1 (BSL-1) is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment.
2. Biosafety Level 2 (BSL-2) builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment.
3. Biosafety Level 3 (BSL-3) is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure.
4. Biosafety Level 4 (BSL-4) is required for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, aerosol transmission, or related agent with unknown risk of transmission.
   1. Significant deviation means: Any deviation that might have an adverse effect on personal or public health.
   2. NIH Risk Group Agents are classified into four Risk Groups (RGs) according to their relative pathogenicity for healthy adult humans by the following criteria:
      1. Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans.
      2. Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.
      3. Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.
      4. Risk Group 4 (RG4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.
   3. Select Agents and Toxins means: biological agents classified under 7 CFR 331, 9 CFR 1221 or 42 CFR 73.
5. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)
   1. The Institutional Biosafety Committee (IBC), established per the NIH Guidelines, if required, shall include as members the Director of Public Health of the Town of Wilmington or his/her designee, plus one additional community representative.
   2. The IBC shall meet no less than once a year. All minutes of the IBC meetings shall be forwarded to the Board of Health.
   3. The community member of the IBC and the Director of Public Health, or his/her designee, shall have no financial interest in any institution involved in the use of rDNA, or any other institution in competition therewith, and 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. In accordance with the NIH Guidelines, the IBC, acting on behalf of an institution, reviews all rDNA use, falling under the purview of the NIH, for compliance with the NIH Guidelines and approves those projects that conform with the NIH Guidelines
   5. All information sent to the Board of Health shall 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.
6. PERMITS
   1. All institutions planning to use rDNA or biological agents referenced in applicability (1) must obtain a permit from the Board of Health before commencing said technology. All permits are issued for one year on January 1st and may be revoked for cause.
   2. Institutions seeking a first time permit from the Board of Health shall submit or make available the following that applies:
      1. A plot plan showing the proposed location of the facility and a floor plan shown in the internal layout of the facility.
      2. A listing of all organisms, containment levels, and decontamination procedures to be employed.
      3. A documented review process to ensure the safe handling and containment of research and development activities using rDNA materials or biological hazards. This review must include a review and approval by an IBC or Institution’s designated Biosafety representative.
      4. A plan for systematic monitoring of waste to assure that surviving RDNA organisms or biological hazards will not be released into the environment.
      5. A plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in any and all segregated buildings.
      6. A plan for systematic security of the premises.
      7. The institution’s occupational health program, biosafety manual and Standard Operating Procedures pertinent to the work being performed as determined by the IBC or biosafety representative for the institution
      8. The name(s) and credentials of the institution’s biosafety representative who shall be responsible for enforcing the guidelines and obtaining proper permits.
      9. A plan for orienting representatives of the Wilmington Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.
   3. For first time applicants the Board of Health shall review the institution’s application for a permit and supporting documents within 30 days.
   4. The fee for a 1st time permit granted by the Board of Health, shall be $500.00
   5. Annual permit renewal will be on or before January 1st and will involve an abbreviated permit renewal if the type of work and material used has not changed since the previous permit issuance. The fee for the annual renewal will be $100.00
7. INSPECTION AND REVIEW
   1. All institutions shall allow inspection of their facilities, procedures and practices in order to confirm compliance with these regulations upon notification of inspection.
   2. The Board of Health, its employees, and any individual or institution employed to perform inspections shall maintain the confidentiality of all proprietary information release to them by reason of these regulations.
8. RESTRICTIONS
   1. Work with rDNA and biological agents or toxins requiring BSL-3 and BSL-4 are not permitted in the Town of Wilmington.
   2. Large scale rDNA use shall not be permitted.
   3. Work with Select Agents requiring registration with the CDC Select Agent Program is not permitted in the Town of Wilmington.
   4. Precautions shall be adhered to, to preclude release into the environment that is to sewers, drains or the air, of any live organisms containing rDNA or active antibiotics.
   5. 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 accidents or illnesses or releases related to the use of rDNA. 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.
9. PENALTIES
   1. 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.
   2. If in the opinion of the Board of Health, work being performed under the guidelines of these regulations causes a nuisance or adversely affects the public health, safety and welfare in Wilmington, 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.
10. VARIANCE

Variances from these specific requirements of these Regulations may be authorized by the Board of Health after notice and public hearing if the Board reasonably determines that the variance requested will not be detrimental or injurious to the public health.

*Effective Date September 18, 2018*