

Biotechnology and the use of Recombinant DNA Molecule Technology

1. APPLICABILITY AND STATEMENT OF PURPOSE

Within the Town of Watertown, all activities associated with constructing and/or propagating: a) Recombinant DNA (rDNA) Molecules b) Organisms and Viruses containing rDNA Molecules and/or c) Biologic Agents, as defined in Section 2, below shall be performed in strict accordance with these regulations and with the National Institutes of Health (NIH) Guidelines as defined in Section 2-E below. These regulations shall govern where they differ from the Guidelines. These regulations do not apply to finished products which contain rDNA Molecules and which have been approved by other government regulatory agencies for medical or other purposes. Biological Agents requiring BSL-4 containment, and Attenuated strains thereof, are prohibited in the Town of Watertown.

The Watertown Board of Health is aware that the use of biohazards, including rDNA, other infectious agents and biologically active agents such as toxins, venoms, and allergens can pose health threats to Watertown residents. Therefore, acting under authority conferred by M.G.L. c. 111, section 31, the Watertown Board of Health enacts the following regulation, governing the use of Biologic Agents and rDNA in the Town of Watertown.

2. DEFINITIONS

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

- A. Attenuated: A bacterium, virus, or other biological organism that has a wild-type counterpart. The attenuated strain is a weakened strain that can be safely worked on at a lower level of biosafety.
- B. Biologic Agent: 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 that requires BSL-2 through BSL-4 containment as defined below.
- C. Biosafety Level (BSL): The level of protective measures needed in a laboratory setting to protect workers, the environment, and the public. The BSL of individual Biologic Agents shall be that which is recommended in the most recent version of the Centers for Disease Control (CDC)/NIH Publication: "Biosafety in Microbiological and Biomedical Laboratories (BMBL)".
- D. Facility: any building or buildings, or portions thereof, used in connection to Work or Projects as defined in Section 2-J below.
- E. Guidelines:
 - 1. The most recent version and any subsequent amendments thereto of the "National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules" published in the Federal Register.
 - 2. 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 unless and until successor guidelines are issued.
- F. Low Risk Facility: any Person that creates, propagates, imports or uses rDNA in any form where:
 - 1. The experiments are all exempt from the NIH Guidelines under Section III-F of the Guidelines; or

2. Users are not constructing rDNA organisms but are merely propagating them.
- G. Organisms and Viruses containing rDNA: those defined in the Guidelines referred to in Section 2-E above.
- H. Person: any person, corporation, business organization, institution, or any other group of individuals who create, propagate, import or use rDNA and/or Biologic Agents in any form in the Town of Watertown.
- I. Recombinant DNA Molecules (rDNA): those defined in the Guidelines referred to in Section 2-E above.
- J. Work or Project: the creation, propagation, import, and/or use of rDNA and/or Biologic Agents.

3. WATERTOWN BIOSAFETY COMMITTEE (WBSC)

- A. Watertown Biosafety Committee (WBSC) shall be established for the purpose of overseeing all Work with rDNA and/or Biologic Agents, and will advise the Board of Health with respect to issues concerning the use and handling of rDNA and/or Biologic Agents in the Town of Watertown.
- B. Specific responsibilities of the WBSC are as follows:
 1. Establishing policies, procedures and criteria to aid in the implementation of this Regulation.
 2. Proposing and reviewing proposed amendments to the Regulations before submitting their recommendations to the Board of Health for approval.
 3. Reviewing all permit applications for Work with rDNA and/or Biologic Agents in the Town of Watertown for compliance with the Guidelines, these Regulations and with other applicable laws. Making recommendations to the Board of Health with respect to such applications.
 4. Reviewing institutions' manuals, annual worker training programs, health-safety programs and monitoring procedures.
 5. Making recommendations to the Board of Health with respect to the manner in which institutions and Institutional Biosafety Committees make reports, applications or recommendations and the type of information required. Reviewing such reports, applications and recommendations. Carrying out site visits to institutional facilities as needed. Approving the community members of the Institutional Biosafety Committees (IBCs) who are appointed by the IBC chairperson at each respective institution.
 6. Developing a procedure for members of institutions to report to the WBSC violations of these regulations, the Guidelines, or any other health regulations the Board of Health may promulgate.
- C. The WBSC shall be composed of five members:
 1. The Chair of the Board of Health and the Director of Public Health, or their designees, shall serve as ex officio members.
 2. An individual with knowledge and experience in the handling of hazardous materials shall be appointed by the Board of Health in consultation with the Fire Chief, or his designee. This appointment is subject to the approval of the Town Manager.
 3. Two members of the public will be appointed by the Board of Health. The Board shall endeavor to appoint individuals with knowledge and experience in biotechnology.

- D. The Public Members of the WBSC shall serve three-year terms. Initially one member will be appointed for a 2-year term and the other for a 3-year term, thereafter the members will be appointed for 3-year terms.
- E. The WBSC shall be considered a public body subject to the Massachusetts Open Meeting Law, Public Records Law, Conflict of Interest Law and all other statutes, rules and regulations concerning the conduct of public bodies and officials in the Town of Watertown.

4. REGULATION OF THE USE OF rDNA

No Person as defined in section 2 H corporation, business organization, institution, or any other group of individuals shall create, propagate, import or use rDNA and/or Biologic Agents in any form in the Town of Watertown except in accordance with the Guidelines, these Regulations and all other applicable Federal, State and local laws concerning the creation, propagation, storage and use of rDNA and/or Biologic Agents.

5. REGISTRATION FOR LOW RISK FACILITIES

- A. Low Risk Facilities, as defined in Section 2 of these Regulations, may conduct rDNA Work without a permit, provided that they register with the WBSC through the Director of Public Health.
- B. Written registration is required prior to commencement of Work and includes:
 - 1. Name and curriculum vitae of a person in the organization familiar with the proposed rDNA Work and the NIH Guidelines.
 - 2. A brief summary from the above-named person describing the proposed Work and giving:
 - a. Name and type of organisms (host/donor [foreign DNA]/vector) being used.
 - b. Reference to the section of the NIH Guidelines where the Work falls.
 - c. If Recombinant DNA Molecules containing eukaryotic viruses are propagated in cells, give the approximate percentage of viral genome present.
 - d. The scale (in liters) on which the organisms will be grown.
 - e. An assurance that all Work will be carried out following the NIH Guidelines, where applicable.
 - f. Name of biological waste handler (if any) and written assurance that all waste will be disposed of according to all applicable federal, state, and local codes.
 - g. Description of annual safety training and refresher training provided to laboratory staff.
 - 3. An annual report summarizing the Work performed over the past year and addressing any ongoing Work according to the format given in 2 above.
 - 4. A registration fee of \$100.00, due upon initial application and upon annual renewals.
- C. Upon receiving and reviewing the submitted information, the WBSC may require additional information to be submitted, and it may recommend to the Board of Health other procedures or safeguards as it deems appropriate up to and including full permit application under the existing Board of Health Regulation.
- D. Release of agents that require reporting to Federal , State or Local agencies shall be reported to the Board of Health
- E. A registration shall be valid for a period of one year, unless sooner revoked in accordance with these Regulations.
- F. Applications for renewal shall be submitted to the Board of Health by November 1. Applications submitted late may be rejected or subject to a late fee.

6. PERMITS

- A. Any Person planning to conduct rDNA Work in any way other than as described in the Registration (Section 4), or non-rDNA Work with Biologic Agents (or Attenuated strains thereof) must obtain a permit from the Board of Health. All permits are issued for one year and may be suspended or revoked for cause.
- B. Any Person seeking such a permit from the Board of Health must first submit the following to the WBSC prior to the commencement of the Work and the application must be complete with all supporting documentation:
 - 1. A plot plan showing the proposed location of the Facility and a floor plan showing the layout of the Facility.
 - 2. A listing of all organisms, containment levels, and decontamination procedures to be employed.
 - 3. A plan for a screening process to ensure the purity of strains of host organisms used in experiments and a plan to test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics. Host organisms obtained from independent laboratories shall undergo the same screening process.
 - 4. A plan for systematic monitoring of waste to assure that surviving organisms will not be released into the environment.
 - a. All waste disposal will be done in accordance with 105 CMR 480.000, Chapter VIII, State Sanitary Code, Storage and Disposal of Infectious or Physically Dangerous or Biological Waste.
 - 5. A plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in the same building.
 - 6. A plan for systematic security of the premises.
 - 7. The applicant shall provide proof of Liability Insurance in an amount deemed sufficient by the Board of Health and naming the Town of Watertown as an additional insured, and shall agree to release, indemnify, defend and hold the Town of Watertown and its agents harmless as to any claims, assessments, damages or causes of action arising out of or related to the Work.
 - 8. Documentation of an active Institutional Biosafety Committee (IBC) that adheres to the below standards:
 - a. The Institutional Biosafety Committee (IBC), established by the Guidelines, shall have as members, in addition to the corporate representatives, one community representative of the Town of Watertown, who shall report back to the Director of Public Health, or his/her designee. The community representative shall be appointed by the Facility holding the permit and notification of the community appointment should be sent to the Director of Public Health, who shall report to the WBSC (see section c below).
 - b. The IBC shall meet at least once per year. All minutes of the IBC meetings must be forwarded to the Board of Health and the WBSC.
 - c. The community member of the IBC shall have no financial interests in the institution or any other institution in competition therewith, and such representative 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 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. The Community member shall not have a familial relationship

- (including common-law relationships) with an employee or Board member of the institution within the second degree.
- d. In accordance with the Guidelines the IBC, acting on behalf of the institution, reviews all rDNA use for compliance with the Guidelines and approves those Projects that conform with the Guidelines. A description of each protocol approved by the IBC, including all organisms and the containment to be used, and a statement certifying the experiment conforms with the Guidelines, shall be filed with the WBSC and the Board of Health.
 - e. All information sent to the Board of Health and the WBSC shall have any proprietary information 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.
 - f. The IBC must develop a policy for the verification of Attenuated pathogens. These pathogens are biological agents that in the wild-type strain, are virulent pathogens, typically requiring Biosafety Level Three containment. The policy should contain steps to ensure the IBC approves the method and verifies the data prior to the laboratory reducing the biocontainment and/or handling requirements of an Attenuated agent. Typical methods for distinguishing wild type from Attenuated strains include restriction analysis or related methods.
9. 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 for all persons engaged in the use of rDNA and/or Biologic Agents. Such programs shall include, but shall not necessarily be limited to:
 - a. Immediate reporting to the IBC Chairman of any employee exposure or illness, Facility spill, release or explosion that could be potentially related to the use of rDNA, Biologic Agents, or chemicals used on site from an approved IBC protocol. The IBC Chairman should consult with the administrative officials at the permitted Facility and provide a verbal report to the Town of Watertown, Director of Public Health, within 24 hours of the potential exposure or release. A formal accident report containing details of the accident, laboratory decontamination and follow-up of the potentially exposed personnel should be submitted to the Town of Watertown Director of Public Health the next business day following the verbal report.
 - b. Retention of medical and health records for at least ten years. Medical or employee health records related to incidents shall be made available for inspection.
 - c. An annual training program of safeguards and safety procedures for personnel.
 10. The name(s) of the Principal Investigator(s) responsible for enforcing the Policies of the IBC.
 11. A plan for orienting representatives of the Watertown Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.
 12. Written agreement to allow inspection of facilities and pertinent records by the Watertown Board of Health, Agents, Health Department employees and the WBSC, or their designated consultants.
 13. For Biosafety Level Three (BSL3) laboratories, evidence that the Facility has been designed according to the latest standards for BSL-3 containment, including the CDC/NIH Guidelines: "Biosafety in Microbiological and Biomedical Laboratories." In addition,

documentation of a maintenance schedule and annual commissioning by a 3rd party agent is required to be produced during the annual inspection by Town of Watertown.

- C. The WBSC shall review the institution's application for a permit and supporting documents and may require additional information. The WBSC shall make its recommendation on the permit to the Board of Health. Copies of the application, supporting documents and the WBSC recommendation shall be filed with the Board of Health.
- D. F. Following the WBSC recommendation, the Board of Health will make a determination on the permit.
- E. The fee for a permit granted by the Board of Health, or annual renewal thereof, shall be \$500.00.
- F. An annual report summarizing the Work performed over the past year and addressing any ongoing Work according to the format given in Section 4 (Registration) # 2. and in addition, the following:
 - 1. Current list of IBC members
 - 2. Copies of the previous year's IBC minutes
 - 3. Summary of the research and any changes in the past year
- G. Annual report deadline will vary by company. Deadline is based on the permit renewal date.
- H. Applications for renewal shall be submitted to the Board of Health by November 1. Applications submitted late may be rejected or subject to a late fee.

7. INSPECTION AND REVIEW

- A. By accepting a permit concerning the use of rDNA and/or Biological Agents, the permit holder agrees to inspection of their facilities, procedures and practices in order to confirm compliance with the Guidelines, these Regulations and all applicable federal, state and local laws by the Board or Health or its Agents at reasonable times. Inspections may be conducted annually or with greater frequency if deemed necessary by the Board of Health. Any Person who refuses a request for inspection shall be deemed in violation of these Regulations.
- B. The Board of Health may retain a professionally competent person, agency or institution to perform inspections and reviews at the permit holder's expense as set forth in Section 8 of these Regulations. The results shall be reported to the Board of Health, the WBSC and the institution involved.
- C. The Board of Health, its employees, all members of the WBSC, and any individual or institution employed to perform inspections shall maintain the confidentiality of all proprietary information released to them by reason of this regulation.
- D. Medical Facilities using rDNA materials for diagnostic testing are exempt from these regulations.
- E. The Board reserves the right to reclassify any individual Facility as being required to be registered or permitted under these regulations.

8. FEES FOR USE OF OUTSIDE CONSULTANTS

- A. Pursuant to Mass. Gen. Laws Ch. 44, § 53G, the Board of Health may, upon receipt of an application, impose reasonable fees upon applicants for the purpose of securing outside consultants, including engineers, scientists, biologists or other experts, in order to aid in the Board's review of applications and in conducting inspections. Such funds shall be deposited with the Watertown Treasurer, who shall create an account specifically for this purpose.

Additional consultant fees may be imposed where the requisite review is more expensive than originally calculated or where new information requires additional consultant services.

- B. The consultant fees collected for the Board's review of a specific Project may be used only for consulting Work done in connection with that Project, and expenditures may be made at the sole discretion of the Board of Health.
- C. Any consultant hired under this provision shall be selected by, and report exclusively to, the Board of Health. The Board shall provide applicants with written notice of the selection of a consultant, identifying the consultant, the amount of the fee to be charged to the applicant, and a request for payment of that fee. Notice shall be deemed to have been given on the date it is mailed or hand-delivered. The applicant may withdraw the application within 5 days of the date notice is given without incurring any costs or expenses.
- D. The entire fee must be received before the initiation of consulting services. Failure by the applicant to pay the requested consultant fee within 10 business days of the request for payment shall be cause for the Board to declare the application or request for determination administratively incomplete and to deny the permit, except in the case of an appeal. The Board shall inform the applicant of such a decision in writing.
- E. The applicant may appeal the selection of an outside consultant to the Town Council, who may disqualify the consultant only on the grounds that the consultant has a conflict of interest or is not properly qualified. The minimum qualifications shall consist of either an educational degree or 3 or more years of practice in the field at issue or a closely-related field. The applicant shall make his or her appeal in writing, which must be received within 10 days of the date that request for consultant fees was made by the Board. The appeal shall extend the applicable time limits for action upon the application or request for determination.

9. RESTRICTIONS

- A. Work classified by the NIH Guidelines as requiring any BSL-4 physical containment measures as prescribed in Appendix G of the NIH Guidelines under Standard Microbiological Practices, Special Practice Containment Practices, Containment Equipment or Laboratory Facilities is prohibited in the Town of Watertown.
- B. Biological agents and Attenuated strains thereof that are classified as requiring BSL-4 containment are prohibited in the Town of Watertown.
- C. The Board of Health retains the right to refuse permits or research if it believes that the research poses a risk to the community.

10. ENFORCEMENT

- A. The Board of Health may suspend or revoke any permit or registration issued pursuant to these regulations for any violation of the Guidelines, these regulations, or any other applicable federal, state or local law. Such revocation or suspension may take place after a hearing held by the Board of Health of which the permit holder is given seven (7) days written notice. Such notice shall be deemed given upon mailing same, certified mail, return receipt requested, to the address listed on the permit application.
- B. This regulation may be enforced by any agents of the Town's Board of Health. Whoever violates any provision of this regulation may be penalized by a noncriminal disposition process as provided in G.L. c.40, §21D and the Town's non-criminal disposition ordinance. If noncriminal disposition is elected, then the non-criminal fine for each such violation, if not otherwise specified, shall be:

First Offense:	\$100
Second Offense:	\$200
Third and Subsequent Offenses:	\$300

Each day or portion thereof shall constitute a separate offense. If more than one, each condition violated shall constitute a separate offense.

- C. Whoever violates any provision of this by-law may be penalized by indictment or on complaint brought in the district court. Except as may be otherwise provided by law and as the district court may see fit to impose, the maximum penalty for each violation or offense shall be one thousand dollars (\$1,000). Each day or portion thereof shall constitute a separate offense. If more than one, each condition violated shall constitute a separate offense. The Board of Health may enforce these Regulations or enjoin violations thereof through any lawful process, and the election of one remedy by the Board of Health shall not preclude enforcement through any other lawful means.

11. VARIANCES

- A. The Board of Health may vary the application of any provision of any of these regulations, through the issuance of a variance, with respect to any particular case when the Board finds the enforcement thereof would do manifest injustice and upon a showing that the applicant demonstrates to the satisfaction of the Board that an equal degree of protection for public health and safety can be achieved without strict application of the provision from which the variance is sought.
- B. Every request for a variance must be made in writing to the Board of Health and must state the specific variance sought and the reasons thereof.
- C. Any variance granted must be in writing with a copy available to the public, during normal business hours, in the office of the Board of Health. Any variance granted must be posted on the premises in a prominent location for the duration that the variance is in effect.

12. EXISTING FACILITIES

All existing facilities will be required to come into compliance with these regulations within one year after the effective date.

13. SEVERABILITY

If any provision of this Regulation is declared invalid or unenforceable, the other provisions shall not be affected thereby but shall continue in full force and effect.

14. INTERACTION WITH OTHER LAWS

This Regulation is intended to further the objectives of and to act in concert with any existing federal, state or local laws concerning the use of rDNA, and nothing herein shall be deemed to limit or restrict Town officials or any other public officials whatsoever from acting in accordance with such laws.

Effective Date

This Regulation shall take effect on April 1, 2020.....

Regulation effective date postponed to July 1, 2020