



BOARD OF HEALTH

TOWN OF WESTBOROUGH MASSACHUSETTS

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RULES AND REGULATIONS RELATIVE TO THE USE OF RECOMBINANT DNA TECHNOLOGY IN THE TOWN OF WESTBOROUGH, MASSACHUSETTS

In accordance with the authority granted by the General Laws of the Commonwealth of Massachusetts, Chapter 111, Section 31, the Westborough Board of Health hereby establishes the following rules and regulations restricting the use of Recombinant DNA Technology in the Town of Westborough.

SECTION I Requirements for the use of Recombinant DNA Technology in the Town of Westborough.

- A. The experimentation with, or use of, recombinant DNA technology in the Town of Westborough shall be undertaken only in strict conformity with the "Guidelines", so called, of the National Institute of Health (NIH), as set forth in the Federal Register "NIH Guidelines for Research Involving Recombinant DNA Molecules" dated January 2011 or any amendment thereof, or as may be established from time to time by the NIH, by other Federal Agency, or by Act of Congress; and in conformity also with such other health regulations as the Westborough Board of Health may from time to time promulgate.

Individuals, associations, organizations, corporations, educational institutions, medical facilities (all hereinafter referred to as institutions) proposing to experiment with or use recombinant DNA technology, as defined and regulated by NIH Guidelines, shall obtain a permit.

- B. To obtain and maintain a permit the institution must 1) prepare a manual which contains all procedures included in the NIH Guidelines to regulate said use at all levels of containment in use at the institution. Said manual shall be submitted for review to the Westborough Board of Health. Manual must be approved, in writing, by the Westborough Board of health before any recombinant DNA experimentation may take place. 2) Allow inspections of laboratory space and documentation as determined by the Board of Health 3) have mandatory training for all laboratory personnel in appropriate safe-guards and procedures for minimizing potential accidents 4) an emergency plan which describes procedures to be followed if an accident contaminates personnel, laboratory, or the environment, procedures for emergency notification of appropriate governmental agencies, shall

be included in this plan 5) have an annual review by the Board of Health.

- C. The institution must have an effective rodent and insect control program on premises where Recombinant DNA use under this chapter takes place.
- D. The Institutional Bio-safety Committee mandated by the NIH Guidelines should be broad-based in its composition. It should include members from a variety of disciplines, representation from the bio-technicians staff and it shall include at least two community representatives who shall be appointed by the Westborough Board of Health, one of whom shall be the Public Health Director, and both of whom shall have no financial interest in the institution or any other institution in competition therewith and such two 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 the Institutional Bio-safety Committee, except to the extent necessary to alleviate any public health hazard. As used in this ordinance proprietary information and trade secrets shall be defined as set forth under the law of the Commonwealth of Massachusetts.

The minutes required by the "Guidelines" (IV-D-2h) of all meetings of the Institutional Bio-safety Committee shall be delivered to the Westborough Board of Health within ten (10) days of the meeting after first removing any proprietary information and trade secrets 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 Committee.

SECTION II Medical Surveillance

- A. All institutions are to provide an appropriate medical surveillance program as determined by the Institutional Bio-safety Committee for all persons engaged in experimentation with, or use of, recombinant DNA technology as defined by and regulated by the NIH Guidelines.
- B. As part of the institution's health monitoring responsibilities, it shall in good faith, make every attempt, subject to the limitation of the available technology, to apply monitoring of the organism involved appropriate to the degree of hazard as determined by the Institutional Bio-safety Committee, in the laboratory worker and inside and outside the containment laboratory.

This shall include whatever means are available to monitor the intestinal flora of the laboratory worker, if warranted.

- C. The Institution's health monitoring responsibility shall include the implementation of the following measures:

- (a) All breaches in containment, which represent a significant potential hazard to employees or the public are to be recorded and reported immediately and in no case 24 hours after the release to the Institutional Bio-safety Committee for appropriate action which may include monitoring for the development of any illness.
- (b) All cases of illness occurring in persons involved in research with, or use of, recombinant DNA technology as defined and regulated by the NIH Guidelines shall be reported by that person, or his designee, in cases where that person is incapacitated, to the laboratory supervisor, if the cause was likely to be related to recombinant DNA technology. The supervisor shall file a report with the Institutional Bio-safety Committee and with an institutional medical official. Such report shall include the name and address of the person and the date, nature and length of the illness involved.

Said records shall be permanently maintained and periodically reviewed by the Institutional Bio-safety Committee under the supervision of the Institutional medical officer; and, it shall be the duty of the IBC to investigate all cases of unusual potentially work related illness associated with the use of recombinant DNA technology being carried out in the Town of Westborough and also to determine whether fuller investigation of any particular illness is warranted. The results of such investigations shall be forwarded to the Director of Public Health.

Said record shall otherwise be confidential and shall not be a public record.

- (c) All persons involved in research with, or use of, recombinant DNA technology, who are absent from work or laboratory due to illness for more than five (5) consecutive days, must report to a physician before being allowed to return to work or to the laboratory.

SECTION III Restrictions

- 1. Experimentation with, or use of, recombinant DNA technology classified by NIH Guidelines as requiring BL3 and BL4 level of containment shall not be permitted in the Town of Westborough, except that BL3 containment may be allowed if approved after a public hearing.
- 2. The use of humans as experimental subjects in recombinant DNA research, as defined and regulated by the NIH Guidelines, shall not be permitted in the Town of Westborough.

SECTION IV Registration

- A. All Institutions using recombinant DNA technology must be registered with the Westborough Board of Health.
- B. Application for registration must include the following information:

1. Company name and address
 2. Names of corporate officers and addresses
 3. Summary of the type of recombinant DNA technology and/or research to be conducted in the Town of Westborough
 4. Containment level required
 5. Copy of Training Manual
 6. Copy of Emergency Plan
 7. Names and addresses of Institutional Bio-safety Committee
 8. Copy of Medical Surveillance Program
- C. No recombinant DNA technology and/or research may be initiated in the Town of Westborough until registration has been approved, in writing, by the Westborough Board of Health.

SECTION V Penalties

A violation of any of the provisions of this ordinance shall subject the violator to a fine of Two Hundred Dollars (\$200.00) per day and in addition, the specific laboratory in which the violation occurs may be closed by the Westborough Board of Health. Each day of violation shall constitute a separate and distinct offense.

SECTION VI Variances

The Board of Health may vary any provision of these regulations with respect to any particular case, when in its opinion, (1) the enforcement thereof would do manifest injustice, and (2) the applicant has proved that the same degree of protection can be achieved without strict application of the particular provision. All variances shall be considered at a hearing by the Board of Health.

SECTION VII Severability of Sections

If any section, sub-section, sentence, clause, phrase or portion of this ordinance is for any reason held invalid or unconstitutional by any Court of competent jurisdiction, such portion shall be deemed a separate, distinct and independent provision, and such holding shall not affect the validity of the remaining portions thereof.

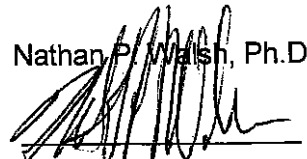
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