



**Town of Framingham  
Board of Health**

**RULES AND REGULATIONS  
REACTIVE TO THE USE OF RECOMBINANT  
DNA TECHNOLOGY  
WITHIN THE TOWN OF FRAMINGHAM**

**These regulations are adopted in accordance with  
the authority granted by the General Laws of the  
Commonwealth of Massachusetts, Chapter 111,  
Section 31**

# FRAMINGHAM BOARD OF HEALTH

## RECOMBINANT DNA

### SECTION 1. USE OF TECHNOLOGY

- A. The experimentation with, or use of, recombinant DNA technology in the Town of Framingham shall be undertaken only in strict conformity with the "Guidelines", so called, of the National Institutes of Health (NIH), as set forth in the Federal Register dated July 1, 1981, 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 Framingham 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 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. Training in appropriate safeguards and procedures for minimizing potential accidents shall be mandatory for all laboratory personnel. Said manual shall be submitted for review to the Board of Health.

- B. Manual must be approved, in writing, by the Framingham Board of Health before any recombinant DNA experimentation may take place.
- C. In addition to the training manual, an emergency plan which describes procedure 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.
- 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 Framingham Board of Health, one of whom shall be the Public Health Administrator, 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 Framingham 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.

- E. Institutions undertaking research with, or use of, recombinant DNA technology as defined by and regulated by the NIH Guidelines shall perform adequate screening to insure the purity of the strain of host organisms used in the experiments and shall test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics.

## **SECTION 2. 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 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.

- C. The Institution's health monitoring responsibility shall include the implementation of the following measures:
1. All breaches in containment are to be recorded and reported immediately to the Institutional Bio-Safety Committee for appropriate action which may include monitoring for the development of any illness.
  2. 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. The Supervisor shall file a report with the Institutional Bio-Safety Committee and with an institutional medical officer. 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 Framingham; 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.

3. 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 3. RESTRICTIONS**

- A. Experimentation with, or use of, recombinant DNA technology classified by the NIH Guidelines as requiring P3 and/or P4 level of containment shall not be permitted in the Town of Framingham.

- B. 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 Framingham.

#### **SECTION 4. REGISTRATION**

- A. All Institutions using recombinant DNA technology must be registered with the Framingham 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 Framingham.
  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 Framingham until registration has been approved, in writing, by the Framingham Board of Health.

#### **SECTION 5. PENALTIES**

- A. 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 Framingham Board of Health. Each day of violation shall constitute a separate and distinct offense provided, however, that no monetary fine shall be imposed for any violation which occurred at any time before the day of written notice of the violation by the Town of Framingham.

#### **SECTION 6. SEVERABILITY OF SECTIONS**

- A. 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.