ARTICLE III.
RECOMBINANT DNA RESEARCH

Sec. 12-21**. Regulation of recombinant DNA technology.**

(a) All recombinant deoxyriboneucleic acid (DNA) research or technology in the City of Newton shall be undertaken only in strict conformity with the "Guidelines", so called, of the National Institutes of Health (NIH), by other Federal Agencies, or by Act of Congress, and in conformity also with such other health regulations as the commissioner of health and human services may from time to time promulgate or as the Newton biosafety committee (NBC) may adopt.

(b) In the context of this article the following definitions are adopted:

(1) *Recombinant DNA molecules (rDNA)*, and organisms and viruses containing rDNA, are those defined in the NIH Guidelines promulgated in the Federal Register on July 1, 1981.

(2) An *institution* is any person, group of persons, business entity, association or any other organization, whether public or private, for profit or non-profit.

(3) *Guidelines* are defined as:

a) National Institutes of Health Guidelines for Research involving Recombinant DNA Molecules, published in the Federal Register on August 27, 1982, and any subsequent federal amendment thereto recommended by the commissioner of health and human services and approved by the NBC.

b) National Institutes of Health Physical Containment Recommendations for Large Scale Use of Organisms Containing Recombinant DNA Molecules, as published in the Federal Register of April 11, 1980, and any subsequent federal amendment thereto recommended by the commissioner of health and adopted by the NBC.

c) Administrative Practices Supplement to the NIH Guidelines for Research Involving Recombinant DNA Molecules, as issued by the Office of Recombinant DNA Activities, November, 1980, and any subsequent federal amendment thereto recommended by the commissioner of health and human services and adopted by the NBC.

(4) *Large-scale* means the use, for the purpose of containing recombinant DNA culture media, of any stainless steel vessel which has a volume greater than sixteen liters, or such use of any non-stainless steel vessel which has a volume greater than ten liters. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 5-26-2005)

Sec. 12-22. Newton biosafety committee.

(a) There shall be a Newton biosafety committee (NBC) which shall be comprised of nine (9) members which include the following:

The commissioner of health and human services;

Two (2) members of the Newton health advisory council, appointed by the commissioner of health;

Three (3) members appointed by the mayor, at least one of whom is a scientist knowledgeable in the

field of rDNA research and technology. The other two shall represent the fields of public health, occupational health, infectious disease or environmental health.

Three (3) members appointed by the board of aldermen, at least one of whom represents the fields of public health, occupational health, infectious disease or environmental health.

Members appointed by the mayor and the board of aldermen shall serve three (3) year terms; provided however, that of the first three members appointed to the committee by the mayor and the board of aldermen one shall serve for a term of one (1) year, one shall serve for a term of two (2) years, and one shall serve for a term of three (3) years. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-06)

Sec. 12-23. Institutional biotechnology committee.

(a) An institutional biotechnology committee (IBC) must be established for each institution conducting rDNA research or technology. The IBC shall include the commissioner of health and human services and two community representatives with expertise in rDNA research and technology and/or safety issues. One of these representatives shall be appointed by the mayor and one shall be appointed by the board of aldermen for a term of three years. The IBC shall meet at least once a year. Each institution shall name at least three (3) members of its staff to the IBC, including the safety officer.

(b) The IBC shall inspect each facility conducting rDNA research or technology annually and meet at least once annually to enforce these regulations. Each institution shall name a safety officer who shall be responsible for enforcing the policies of the IBC. In addition, the IBC shall immediately notify the commissioner of health and human services and the NBC upon discovery of non-compliance by the institution with any section of this ordinance or the NIH guidelines. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-05)

Sec. 12-24. Permit requirement.

(a) All institutions planning to conduct rDNA research or to use rDNA technology must obtain a permit from the commissioner of health and human services with the prior approval of the NBC, before commencing said research or technology. Institutions receiving such permits shall conduct research or technology only as specifically set out in its permit application and supporting documents filed with such application.

(b) All institutions requesting a permit from the commissioner of health and human services to commence rDNA research or technology in the Limited Manufacturing Zoning District (Sec. 30-12), the Manufacturing Zoning District (Sec. 30-12), and the Mixed Use 1 and 2 Zoning Districts (Sec. 30-13), must also receive a special permit from the board of aldermen pursuant to section 30-24 prior to the original issuance, but not the renewal, of said permit. Institutions seeking such permit from the commissioner of health and human services must first submit the following to the NBC:

(1) A completed application form obtained from the Newton health and human services department.

(2) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.

(3) A listing of all organisms, including containment levels, to be employed in rDNA research or technology, and including the screening process to be performed by institutions conducting rDNA research or technology in order to insure the purity of the strain of host organisms used in the experiments and 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 rDNA organisms will not be released into the environment.

(5) Establish a training program of safeguards and procedures for personnel using rDNA;

(6) 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. Such programs shall include, but shall not necessarily be limited to:

a) A pre-employment medical examination for employees. Facilities using rDNA research or technology requiring BL2 or BL3 as defined in the National Institutes of Health (NIH) guidelines published in the Federal Register, as amended, physical containment, or large scale use, shall take employee serum samples at the time of employment and maintain said samples to permit future testing for at least ten years.

b) Prompt reporting of significant or potentially related employee illnesses to the IBC.

c) Retention of medical and health records for at least ten years. Medical or employee health records shall be made available for inspection and may be used for public health studies.

d). Effective rodent and insect control programs must be in place.

(7) The name of the safety officer who shall be responsible for enforcing the policies of the IBC.

(8) A plan for orienting representatives of the Newton health and human services, fire and police departments to the physical plant and to procedures to be utilized in the event of an emergency.

(c) The NDC shall review the institution's application for a permit and supporting documents and make its recommendation of the same to the commissioner of health and human services.

(d) Not later than sixty (60) days after an institution has commenced rDNA research or technology as determined by the commissioner of health and human services, the institution shall file with the commissioner:

(1) The names and qualifications of members of IBC.

(2) Copies of Newton building department and Newton fire department certification.

(3) Evidence of certification, as necessary, from the Massachusetts Department of Environmental Quality Engineering and the Massachusetts Department of Public Health.

(e) Permits granted by the commissioner of health and human services shall be renewed annually.

(f) The fee for a permit granted by the commissioner of health and human services, or annual renewal thereof, shall be $250. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No.X-175, 05-26-05)

Sec. 12-25. Inspection and review.

(a) The institution shall allow inspections and review of the procedures and practices of rDNA use for compliance with this ordinance.

(b) The Newton health and human services department shall retain a competent professional person, agency or institution to perform inspections and review. The results shall be reported to the commissioner of health and human services, the NBC and the institution involved.

(c) Inspections will be conducted at least annually.

(d) The institution shall reimburse the city for the direct expense of inspections and review. (Ord. No. R-237, 3-15-82; Ord. No. X-175, 05-26-05

Sec. 12-26. Procedure for requesting and holding a hearing.

Institutions denied a permit, or the renewal thereof, or any person aggrieved by the granting of a permit, may request a hearing by filing a written petition with the commissioner of health and human services within ten (10) days from the denial or grant of a permit. Upon receipt of such petition the commissioner of health and human services shall set a time and place for such hearing and shall so inform the petitioner, and the institution if other than the petitioner, in writing. At the hearing the petitioner shall be given an opportunity to be heard and to show why the permit should be granted or denied. (Ord. No. R-237, 3-15-82; Ord. No. X-175, 05-26-05)

Sec. 12-27. Appeal.

Any institution or person aggrieved by the final decision of the commissioner of health and human services with respect to the denial or grant of a permit may seek relief therefrom in any court of competent jurisdiction, as provided by the laws of this commonwealth. (Ord. No. R-237, 3-15-82)

Sec. 12-28. Restrictions.

Recombinant DNA use requiring physical containment greater than the BL3 level shall not be permitted in the City of Newton. (Ord. No. R-237, 3-15-82)

Sec. 12-29. Violations.

An institution which violates any provision of this article shall be subject to a fine of three hundred dollars ($300.00) per offense, each day of violation constituting a separate and distinct offense. The commissioner of health and human services shall be empowered to enforce this ordinance in any court of competent jurisdiction. In addition to a fine, an institution which violates any provision of this ordinance or whose continued conduct of recombinant DNA technology poses an immediate threat to the public health or environment may be closed by the commissioner of health and human services. Any institution aggrieved by such action of the commissioner of health and human services shall appeal the same under the provisions of Sections 12-25 and 12-26. (Ord. No. R-237, 3-15-82; Ord. no. X-175, 05-26-05)

Sec. 12-30. Severability.

If any provision(s) or portion(s) of this article or the application of any provision(s) or portion(s) thereof to any person or circumstance is/are held to be invalid, such invalidity shall not affect the validity of the remainder of said provision or other provisions of this article. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-06)

Secs. 12-31—12-39. Reserved.