City of Gloucester
Board of Health
Regulations

Regarding the Use of Recombinant DNA Technology

Adopted
September 3, 2009

Public Health
Prevent. Promote. Protect.
Gloucester Health Department

Regulations Regarding the Use of Recombinant DNA Technology

Section 1: Purpose
The purpose of these regulations is to ensure the safety of workers and the general public by specifying the practices to be used for constructing and handling of recombinant deoxyribonucleic acid (rDNA) molecules as well as organisms and viruses containing rDNA molecules within the City of Gloucester. These regulations accomplish this by adopting the NIH Guidelines (see Section 3) as the primary standard of regulation and (i) not permitting rDNA work requiring a high level (BL3 or BL4 as defined by NIH Guidelines) of containment; (ii) establishing local mechanisms to inform the Gloucester Board of Health of the initiation and status of rDNA work; and (iii) issuing local registrations or permits for the initiation or continuance of rDNA experiments.

Section 2: Applicability
All activities associated with constructing and/or propagating rDNA molecules and organisms or viruses containing rDNA molecules within the City of Gloucester shall be performed in accordance with these regulations and the NIH Guidelines as defined in Section 3 below. These regulations shall govern where differences exist with those Guidelines. These regulations shall not apply to finished products (such as pharmaceuticals) which contain rDNA molecules and which have been approved by State or Federal regulatory agencies for medical or other purposes.

Section 3: Definitions
NIH Guidelines (or *Guidelines*)- the most recent version of and any approved additions to the *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules* as published in the Federal Register. See: http://oba.od.nih.gov/rdna/nih_guidelines_oba.html. Should the NIH discontinue or abolish their guidelines, those guidelines in effect and approved at the time of discontinuance shall remain in effect.

Large Scale- the use of more than 10 liters but less than 5,000 liters of rDNA culture.

Institution- shall mean any single individual, group of individuals or organization whether public or private. Individuals or unaffiliated organizations are encouraged to associate with an existing Institutional Biosafety Committee (see Section 5.2).

Section 4: Gloucester Biosafety Committee

4.1 A Gloucester Biosafety Committee (GBC) shall be established for the purpose of overseeing all uses of rDNA in Gloucester and advising the Board of Health

4.2 The GBC shall be composed of five members: the Chair of the Board of Health (or designee); the Health Director (or designee) and three other members to be appointed by the Mayor and approved by the Board of Health. These appointed members shall serve three year, staggered, terms. Of the first three members appointed to the GBC, one shall serve for one year, one shall serve for two years and one shall serve for three years.

4.3 Responsibilities of the GBC shall include:

a. establishment of policies, procedures and criteria to facilitate the implementation of these regulations;
b. review of all applications for registrations and permits for the use of rDNA in Gloucester for compliance with these regulations;
c. review of applicant manuals, worker training programs, health safety programs and monitoring procedures;
d. developing the format and manner in which applicants apply and permit holders make reports to the GBC, and establishing the type of information required in such applications and reports. This includes reports of Institutional Biosafety Committees (IBCs) and approving them where appropriate;
e. approve the community members of IBCs;
f. perform site-visits to permitted facilities;
g. develop a procedure for individuals or permitted facilities to report violations of these guidelines or any other health regulation the Board of Health may promulgate.

Section 5: Registrations and Permits

a) In addition to adherence to the NIH Guidelines, all work involving the construction or handling of rDNA or organisms or viruses containing rDNA must be approved by the Gloucester Board of Health. This will be done by either simple Registration for 'exempt' work (see: b), below) or by obtaining a Permit for all other rDNA work (see: c), below).

b) Some work (as defined by NIH Guidelines, Sections III-E and F) may be exempt from or minimally regulated by the NIH Guidelines. However, such work still requires Registration with the Gloucester Board of Health unless the applicant has obtained an rDNA permit from the GBC (see Section 5.2) for non-exempt work. The conditions for registration are defined below (Section 5.1). Application for registration must be accompanied by payment of a $100 fee.

c) All other recombinant DNA work must meet the requirements of the NIH Guidelines and requires the applicant to obtain a Permit from the Gloucester Board of Health. The requirements for application are defined below (Section 5.2). Permit applications must be accompanied by payment of a $500 fee.

5.1 Registration

a. rDNA users in the following categories are required to register their proposed work with the GBC (or with the Institutional Biosafety Committee, IBC, if already permitted (see Section 5.2):
    (1) Users whose work is exempt from the NIH Guidelines under Section III-F or falls under Section III-E.
    (2) Users not constructing rDNA organisms but whose work involves only their propagation (but not including viruses)

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b. Written registration is required and includes:
    (1) The name and c.v. of a person in the organization familiar with the proposed rDNA work and the NIH Guidelines
    (2) A brief summary from the above-named describing the proposed work, including:
        (i) Name and type of organisms being used (e.g. host and donor (foreign DNA/vector) being used)
        (ii) Reference to the section(s) of the NIH Guidelines pertinent to the work
        (iii) If recombinant eukaryotic viruses are to be propagated, provide the approximate percentage of the viral genome present.
        (iv) The scale (in Liters) to which the organisms will be grown
        (v) Written assurance that all work will be done following NIH Guidelines at the appropriate level of biosafety containment and that all exempt work will be done at the biosafety level designated as BL1.
        (vi) Name of the licensed biological waste handler and written assurance (e.g. a contract) that all waste will be disposed of in accordance with all applicable federal, state and local codes.
    (3) Commitment to provide an annual report summarizing the work performed over the past year and describing any continuing work using the format of the preceding section (Section 5.1 b.(2)).
    (4) A registration fee of $100, due upon initial application and subsequent annual renewals for continuing work.
c. Upon review of an application, the GBC may require additional information to be submitted and it may recommend to the Board of Health other procedures or safeguards deemed appropriate- up to and including the submission of a full permit application (Section 5.2).

5.2 Permits

a. All users planning to use rDNA in any way other than the procedures described in Section 5.1, Registration, must obtain a permit from the Gloucester Board of Health with the prior approval of the GBC before starting any of the proposed work. All permits are issued for one year and may be revoked for cause. Among other requirements, permits require the establishment of an Institutional Biosafety Committee (IBC, see Section 5.2 b. (7), below). An existing IBC can approve experiments falling under Sections III-D and III-E of the *Guidelines* as further restricted by these Regulations.
b. Users seeking such a permit from the Gloucester Board of Health must submit to the GBC:
    (1) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility;

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(2) A list of all organisms, containment levels and decontamination procedures to be employed;
(3) A plan for a screening process to ensure the purity of the strains of host organisms to be used and to test the organisms resulting from the proposed work for their resistance to commonly used therapeutic antibiotics. Host organisms obtained from independent laboratories shall undergo the same screening process;
(4) A plan for the systematic monitoring of waste to assure that surviving rDNA organisms will not be released into the environment. All waste disposal is to 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 areas and food service facilities in the same building;
(6) A plan for the security of the premises;
(7) Establishment of an Institutional Biosafety Committee (IBC):
    (i) The Institutional Biosafety Committee (IBC), established by the NIH Guidelines, shall have as members (in addition to the corporate or institutional representatives), one community representative and the Health Director (or designee). The community representative shall be appointed by the Mayor and approved by the GBC.
    (ii) The IBC shall meet on a regular basis and all minutes of meetings forwarded to the Board of Health and the GBC.
    (iii) The community member of the IBC as well as the Health Director (or designee) shall have no financial interest in the applicant institution or any other institution in competition with the applicant. Further, such representatives shall be bound to the same provisions of the non-disclosure of proprietary and trade secret information as all other members of the IBC, except to the extent necessary to address a public health hazard.
    (iv) The IBC shall act in accordance with the NIH Guidelines and therefore acts on behalf of the institution to review all rDNA use for compliance with the Guidelines and approves those projects that conform to the Guidelines. The IBC also acts on behalf of the GBC to assure compliance with these local regulations. A description of each protocol approved by the IBC, including all organisms and containment to be used, and a statement certifying that the work conforms to the Guidelines shall be filed with the GBC and the Gloucester Board of Health.

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(v) All information sent to the GBC and the Gloucester Board of Health shall have any proprietary information and trade secrets redacted. The full text shall remain on file within the applicant institution for inspection at all reasonable times by any member of the IBC.

(8) The applicant shall provide to the IBC the institution's health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program for all persons engaged in the use of rDNA. Such programs shall include at least:

(i) A pre-placement medical examination for employees;

(ii) Prompt reporting to the IBC of employee illnesses potentially related to rDNA use as well as any cluster of illness among employees;

(iii) Retention of medical and health records for at least 10 years;

(iv) A personnel training program for safe practices and procedures.

(9) The name(s) of the principal investigator(s) responsible for enforcing the policies of the IBC.

(10) A plan for orienting representatives of the Gloucester Health, Fire and Police Departments to the physical plant and to procedures to be used in emergencies.

(11) Written agreement allowing the inspection of facilities by the GBC.

c. The GBC shall review the application for a permit as well as any supporting documents and make its recommendation to the Gloucester Board of Health. Copies of the application, supporting documents and the GBC recommendation shall be filed with the Board of Health within 45 days after the complete application is filed with the GBC. The Gloucester Board of Health shall take final action on the permit application within 75 days after the complete application is filed with the GBC. The period within which final action must be taken may be extended for a definite period by mutual consent of the Gloucester Board of Health and the applicant.

d. The fee for permit application or annual renewal thereof shall be $500.

5.3 Inspections and Review

a. All institutions involved in the use of rDNA shall allow inspection of their facilities, procedures and practices in order to confirm compliance with these regulations.

b. The Gloucester Board of Health shall retain a professionally competent person, agency or institution to perform inspections. The results shall be reported to the Board of Health, the GBC and the institution involved.

c. The Gloucester Board of Health, its employees, all members of the GBC and any individual or institution employed to perform inspections shall maintain the confidentiality of all proprietary information released to them by reason of these regulations.

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5.4 Restrictions

a. rDNA use classified by the Guidelines as requiring any BL3 or BL4 containment (as described in Appendix G of the Guidelines) shall not be permitted.
b. Experiments for which containment levels are not prescribed in the Guidelines shall be approved by the GBC before work is initiated.
c. Use of more than 5,000 liters of rDNA culture shall not be permitted.
d. There shall be no deliberate release of any organisms containing rDNA into the environment- explicitly including to sewers, drains or the atmosphere.
e. The institution shall report within 24 hours to the Health Director, followed by a written report within 15 days to the GBC, any significant deviations from the Guidelines, including any significant accidents, illnesses or environmental releases related to the use of rDNA.

5.5 Violations and Penalties

a. Violation of the conditions of these regulations shall subject the violator to a fine of $500 per day. In addition, the facility in which the violation occurs may be closed by the Board of Health.
b. Once a permit has been issued or a registration filed, it may be revoked by the Board of Health upon determination, after due notice and hearing, that the institution has materially failed to comply with these regulations, the permit agreements or the Guidelines, or, if in the opinion of the Board of Health, the rDNA use adversely affects the public health or safety in Gloucester.

5.6 Assessment of Expenses

The salaries and expenses paid by the City of Gloucester for inspections, reviews, staff and consultants for work directly related to meeting the requirements of these regulations shall be assessed to the holders of the permits made under these regulations. An accounting of these costs will be provided annually to each permit holder.

Section 6: Severability

Each part of these regulations is considered separate to the end that if any section, item, sentence, clause or phrase is held invalid for any reason, the remainder of these regulations shall continue in full force and effect.

Section 7: Variances

The Board of Health may vary the application of any provision of these regulations with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice, provided that the decision of the Board of Health is not in conflict with the spirit of the purposes of these regulations. Any variance granted by the Board of Health must be in writing with a copy available to the public at all reasonable hours in the offices of the Gloucester Health Department.