

Walpole Policies and Procedures
To Administer Permits for the Use of
Recombinant DNA Molecular Technology and Biosafety Level 3 Materials

Section 1:00 Introduction

Pursuant to the Town of Walpole Regulations for the Use of Recombinant DNA Molecular Technology and Biosafety Level 3 Materials herein promulgates the following policies and procedures applicable to the administration of permits.

All communications and submissions shall be sent to the Walpole Health Department at 135 School Street, Walpole, MA 02081.

Applicants are responsible for obtaining copies of the NIH Guidelines and the BMBL.

Section 2:00 Definitions

All terms used herein shall have the same meaning as set forth in the Town of Walpole Regulations for the Use of Recombinant DNA Molecular Technology and Biosafety Level 3 Materials.

Section 3:00 Overview of the Permit Application and Review Process

Any Institution seeking to use Recombinant DNA Molecular Technology and/or Biosafety Level 3 Materials shall first obtain a permit pursuant to the Regulations from the Walpole Board of Health. Any Institution applying for a Permit shall appear before a regularly scheduled meeting of the Walpole Board of Health to present that Institution's application. Thereafter, the agent of the Board of Health may conduct a site visit of the Institution's facility in conjunction with the Board of Health's review of the Institution's application.

Section 4:00 Required Documentation for an Application

Any Institution applying for a Permit shall submit the following:

- A. Application form and fee.
- B. Executive summary of proposed work with a statement explaining the basis for the selection of the proposed biosafety level or use of Recombinant DNA Molecular Technology.
- C. Labeled Floor plan of the facility including BSL areas and access routes and an estimate of the laboratory and waste storage floor area (sq. ft.)
- D. Health and Safety manual with procedures relevant to the operations at the facility and a protocol for accidental employee or community exposure and/or illness
- E. Employee biosafety training program summary
- F. Documentation of pest control program to be employed at the facility
- G. Description of protocol for disposal or decontamination of infectious waste
- H. Documentation of medical surveillance

- I. Documentation pertaining to IBC memberships (names and contact information)
- J. Documentation establishing the retention of a third-party laboratory commissioning agent with the appropriate experience in the evaluation of facilities employing BSL-3 containment.

Section 5:00 Protected Documentation Submitted with Application

An Institution applying for a Permit may redact specific information required by Section 4:00 above which the Institution believes should be confidential and unavailable for inspection by members of the Public. If the Board of Health is unable to evaluate the application for a Permit without the redacted information, the Board of Health shall go into executive session to discuss the redacted information.

Section 6:00 Other Applicable Permits and Approvals

Institutions applying for a Permit shall be responsible for obtaining all required Federal, State and Local permits and regulatory approvals for the use of the Institution's facility.

Section 7:00 Presentation to the Walpole Board of Health

Upon submission of an application, the Health Department will schedule applicants to present an overview of its request by the Institution at a regularly scheduled Board of Health meeting. The presentation shall include a general introduction of the Institution, its mission, its research or production plans, a timeline of the use of rDNA or a Biological Agent and a discussion of the facilities.

Section 8:00 Site Visits

Prior to approval of the permit, and Institution applying for a permit shall submit to and arrange a visit to the Facility by the Board of Health and/or an agent. Areas of particular interest for the site visit include:

- A. General housekeeping and biological hygiene
- B. Physical separation and access control for BSL-3 laboratories
- C. Proper signage indicating biosafety level and emergency contact information
- D. Proper equipment such as appropriate biosafety cabinets for meeting the biosafety level containment standards with performance ratings clearly indicated
- E. Proper general ventilation and hygiene facilities (eg. Sinks) for the biosafety level
- F. Proper personal protective equipment in use by personnel (eg. Lab coats, gloves, eye protection)
- G. Possession of all required federal, state, and local permits and approvals
- H. Establishment of an appropriate medical surveillance program for all employees coming into contact with regulated materials
- I. All maintenance and laboratory safety records

