

**Rhode Island Hospital
Standard Practice
Instruction Manual**

Subject:
Biosafety Review of Proposed
Protocols

File Under:
Administration

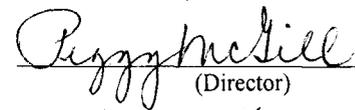
Issuing Department:
Research Administration
Biohazards & laboratory Safety
Committee

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Approved By:


(Director)

(Executive)

I. Introduction

The purpose of this policy is to provide a mechanism for the safety review of proposed research activities of clinical and research laboratories in order to accomplish the following:

- A. Assess and minimize risks of laboratory activities to the population within the Hospital (employees, patients and visitors).
- B. Protect the research animal population from cross-contamination
- C. Ensure compliance with pertinent codes and standards
- D. To have in place a review mechanism as required by federal and state regulatory groups

Laboratories are required to adhere to the hospital's Chemical Hygiene Plan and applicable OSHA regulations.

In addition, any protocol which utilizes potentially hazardous biological or chemical agents must be reviewed and approved for safety by the Biohazards and Laboratory Safety Committee (BLSC) or the Recombinant DNA Committee (RDC) as appropriate before being implemented.

For the purposes of Biohazards and Laboratory Safety Committee review; Hazardous Agents are defined as:

1. Chemical and biological agents that have been assigned a safety rating of 3 or greater in any category on the MSDS sheet

2. Any compound listed as a carcinogen, mutagen or teratogen in the Chemical Hygiene Plan
3. Any toxin including such proteins as ricin, cholera toxin and bacterial toxins
4. Any organism included in the list of Risk Group 2 (RG2) and Risk Group 3 (RG3) organisms in appendix B of the NIH Guidelines [http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_B.htm] or organisms that require Biosafety Level Containment Level 2 or greater (BSL2, BSL3, BSL4) as defined by the Centers for Disease Control (CDC) manual Biosafety in Microbiological and Biomedical Laboratories (BMBL) [<http://www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm>]
5. Any organism that will be administered to live animals. [Separate IACUC approval is required for any activity that uses live animals]

II. Procedure for Proposed New Research Projects

- A. The process for applying for a research project includes completing a "Request for Research Committee Review" form and project application forms as applicable. (These forms are available on the Research Administration web site. <http://www.lifespan.org/research/>) The application must include information about the agents used, their hazards, and precautions planned.
- B. When chemical or biological agents are indicated, the Office of Research Administration will forward copies to the Biohazards and Laboratory Safety Committee.
- C. When recombinant DNA agents are indicated, the Office of Research Administration will forward copies to the Recombinant DNA Committee.

III. Committee Duties

Included in the committee duties are the following:

- A. Review of new biological or chemical agents proposed to be used as parts of clinical or research protocols.
- B. Annual safety training for research laboratory personnel
- C. Address inquiries or complaints and problems referred to it regarding the use of hazardous biological or chemical agents, laboratory activities, and the like.

IV. Review Mechanism

- A. A committee of individuals with a variety of expertise will be established to review the information submitted for safety considerations. The Committee Chairperson and all members shall be appointed by the Institutional Official.

Representatives may be selected from the following areas from Rhode Island Hospital and The Miriam Hospital. This list is not meant to be inclusive.

Safety
Research Administration
Microbiology/Virology
Attending Veterinarian
Plant Engineering
Risk Management
Central Research Facilities
Physicist/Radiation Safety
Epidemiology & Infection Control
Molecular/Cell Biology
Emergency Medicine
Researchers

- B. The committee will issue an approval or indicate recommendations that must be met for approval. In some circumstances, the committee may feel the proposal should not be implemented and will so indicate.
- C. The Committee will develop policies and procedures to address safety precautions to be taken for the use of specific agents (i.e. ether) or activities (i.e. lab construction, relocation, or renovation) as needed.

V. Committee Authority

This committee will be a sub committee of the Rhode Island Hospital Environment of Care and The Miriam Hospital Environment of Care Committees (EOC) and have the authority of the EOC committees. The Committee Chairperson, or their representative, will report to the EOC committees quarterly on the BLSC activities.

The Recombinant DNA Committee (RDC) will be a sub committee of the Biohazards and Laboratory Safety Committee (BLSC). The RDC will be responsible for the review of proposals for the use of recombinant DNA agents and will report annually to the BLSC Chairman.

The Hood Committee will be a sub committee of the BLSC and will be responsible for evaluating requests for the purchase and location of new hoods and the relocation of existing hoods.