

**Lifespan System-wide Policy**

**Subject:**

**File under:** ORA RRC 004

Lifespan Biohazards and  
Laboratory Safety Committee  
(BLSC)

**Issuing Department:**

Lifespan Office of Research  
Administration

**Latest revision date:**

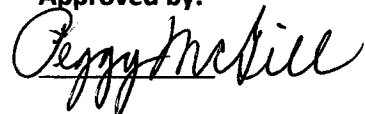
September 2015

**Original Policy Date:**

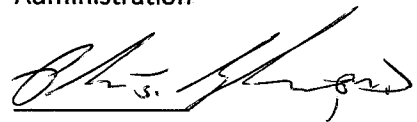
November, 2006

**Page 1 of 9**

**Approved by:**

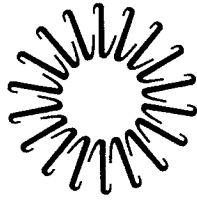


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- I. **Purpose:** The purpose of this policy and Procedure Manual is to define and describe the policies and procedures regulating the Biohazard and Laboratory Safety Committee (BLSC)
- II. **Eligibility:** The entire research community of the Rhode Island Hospital, The Miriam Hospital, Emma Pendleton Bradley Hospital, Newport Hospital, collectively known as Lifespan for the purposes of this manual.
- III. **Content:** The Manual is attached.



# **Lifespan**

## **Biohazards and Laboratory Safety Committee (BLSC)**

### **Manual of Operations**

**Rev. 9/2015**

# **Biohazards and Laboratory Safety Committee**

## **BLSC**

### **Purpose**

The Biohazards and Laboratory Safety Committee is a committee made up of staff from the hospital community with specific expertise in a variety of fields regarding the use of potentially hazardous agents in the laboratory setting.

Protocols with an animal component will submit a new (BLSC) application every 3 years.

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

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

### **SCOPE:**

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 4 or greater in any category on the (SDS) Safety Data 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) or higher or organisms in appendix B of the NIH Guidelines or organisms that require Biosafety Level Containment Level 2 (BSL2) or higher as defined by the Centers for Disease Control (CDC) manual Biosafety in Microbiological and Biomedical Laboratories

(BMBL). Please note that at this time RIH does not have the facilities to handle Biosafety Level Containment Level 3 or 4.

5. Any hazardous organism or chemical that will be administered to live animals as per IACUC protocol.

\*\*\* A list of commonly used hazardous agents has been created by the BLS committee that are considered exceptions and do not require review by the committee.

### **Committee Responsibilities**

1. Review of research protocols using hazardous agents with regard to containment levels, laboratory facilities, and practices and procedures.
2. Notify the principal investigator of the results of the committee's review
3. Ensure the research staff has adequate training and expertise to perform proposed research
4. Ensure that periodic inspections are conducted of laboratory facilities
5. Serve as a resource for those investigators conducting research involving hazardous agents.
6. Address inquiries or complaints and problems referred to it regarding the use of hazardous biological or chemical agents, laboratory activities, and the like.

### **Responsibilities of Principal Investigators**

The principal investigator is responsible for:

1. Registering all work involving hazardous agents or procedures with the BLSC
2. Ensuring that all review and approval requirements are fulfilled prior to initiating any new or modified research procedures
3. Ensuring that employees are adequately trained in safe work practices and techniques and in the procedures for dealing with accidental spills and personal exposure and adhere to these procedures and practices.
4. Adhering to the hospital's Chemical Hygiene Plan and applicable OSHA regulations
5. Providing copies of the protocols and safety information sheets to laboratory staff
6. Ensuring that necessary safety precautions and containment are maintained within the laboratory
7. Ensuring proper handling and disposal of biohazardous waste
8. Maintaining current Safety Certification for the laboratory
9. Notifying the BLSC of any significant changes in experimental protocol or location of the research
10. Providing information to the BLSC as necessary
11. Maintaining a current Chemical Inventory and having it available upon request

## **Policies and Procedures**

### **1. The Committee**

A committee of individuals with a variety of expertise has been established to review the information submitted for safety considerations. The Committee Chairperson and all members are appointed by the Institutional Official. Representatives may be selected from appropriate departments/areas from Rhode Island Hospital and The Miriam Hospital and other external members as appropriate.

The Executive Committee (BLS Exec) is comprised of the BLS Chairperson, BLS Associate Chairperson, Safety Officer for RIH, Safety Officer for TMH, the Director of the Central Research Facilities and the Attending or associate Veterinarian. The Executive Committee conducts preliminary review of research proposals and forwards recommendations to the convened committee. The committee is staffed by a coordinator reporting through the Office Of Research Administration.

### **2. Review Procedure**

Application forms for review by the committee are available on the Research Administration Website. The application must include information with regard to the agents used, their hazards, and precautions planned.

All research protocols involving hazardous agents, will be received by the Committee Coordinator in the Office of Research Administration and processed for review. The Coordinator will forward all applications to the Executive Committee. The Executive committee will determine whether the proposal requires consideration by the convened committee, or may be approved by an expedited review process.

#### **Expedited Review**

A list of commonly used hazardous agents has been created by the BLS committee to be reviewed on an expedited basis.

For proposals that are eligible for expedited review, the signed expedited application form is sent to the BLS chairman or designee for review. The BLS Chairperson or designee will then return any comments, corrections, or concerns by email. The BLS Chairperson or designee has the authority to approve, approve with minor modification, or defer to the full board any expedited application.

#### **Full Board Review**

For proposals that require full board review by the convened committee, all BLSC members will receive a copy of the application. The investigator may be asked to appear before the Committee at the next monthly meeting to present the research for review.

Minutes of Committee meetings will be prepared and retained by the ORA Committees Coordinator.

### **3. Resource, Education and Training**

The BLSC will, on an as-needed basis, provide interested members of the research community with educational and training information necessary for the investigator to maintain a safe laboratory environment. A member of the BLSC Executive Committee will be present and assist with training CRF animal care staff on hazardous agents that will be used in live animals

### **4. Training Requirements:**

PIs are to provide specific training for employees regarding:

- Hazardous agents used in their departments
- OSHA's Hazard Communication Standard
- Interpreting Safety Data Sheets
- How to interpret cautionary information on container labels
- How to protect themselves and others when using hazardous materials
- How to deal with a hazardous materials spill, accident, or other emergency
- Applicable Lifespan and departmental policies and procedures concerning hazardous materials including proper disposal of hazardous waste

Employee's educational background and past experience are taken into consideration when developing training plans. Retraining takes place at least annually and supplemental training takes place if new hazardous substances are used in the work area. Employees are to be familiar with important concepts, understand them, and demonstrate that they know how to safely handle and use workplace chemicals.

**PIs must keep attendance records on all employees who receive training or retraining involving hazardous substances. These records must be available upon request and at the time of annual lab inspections.**

### **5. Use of hazardous agents in animals:**

Each Principal Investigator is responsible for the care of animals in areas where hazardous agents are used and is responsible for ensuring that laboratory staff are supervised and trained. PIs or their designee must provide at least one week's notice to CRF Management before using the hazardous agent in live animals to allow for training of CRF animal care staff. The PI or an appropriate designee must also be present and assist with training CRF animal care staff in the proper handling and containment of the hazards before any use in animals. BLSC approval documents will not be released until appropriate training for lab personnel and CRF animal care staff has been documented and submitted to the Committee Coordinator.

## **6. Non-Compliance with BLS Protocol, Policies, Procedures, or Decisions**

Protocol non-compliance occurs when procedures or policies approved by the BLSC are not being followed. Examples include performing unauthorized procedures, unauthorized persons participating in a research project, or the use of hazardous agents that the BLSC has not approved. When faced with protocol non-compliance, the BLSC's first step will be to investigate the incident. When non-compliance is confirmed then it will be determined if there was intentional, unintentional or continuing non-compliance.

Based on this determination the following steps will be taken with the goal of bringing the protocol into compliance as quickly as possible:

### **Unintentional non-compliance**

If a clearly minor and unintentional misinterpretation of an BLSC policy that has created no problem for human health or welfare is noted, an explanation describing the problem and the corrective steps taken will be requested.

### **Intentional or continuing non-compliance**

When it has been determined by the BLSC that an offense was intentional or continuing non-compliance, the response will be based upon the severity of the event and may include:

- Written warning to the PI
- Mandatory retraining for the PI and their research staff
- Required attendance at a convened meeting of the BLSC to explain corrective actions taken to prevent a recurrence of the incident
- Implementing measures to prevent recurrence;
- Suspension of privileges regarding the use of hazardous agents
- Notifying the PI's department head
- Notifying the Institutional Official and Chief Research Officer

# **Expedited Review List**

## **Chemical hazards**

- 1. Bromodeoxyuridine (BrdU) when used in animals**
- 2. 5-ethynyl-2'-deoxyuridine (EdU) when used in animals**
- 3. Cisplatin**
- 4. Doxorubicin**
- 5. Streptozotocin (STZ)**
- 6. Tamoxifen**

## **Biological hazard**

- 1. Human Primary cells, cell lines and tissues when used in animals**
- 2. Lipopolysaccharide (LPS) when used in animals**

# **Commonly used hazardous agents not needing review**

**Formalin**

**Paraformaldehyde**