

EH&E #21570

Exposure Control Plan

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The Ragon Institute 400 Technology Square Cambridge, MA 02139-3583

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## 1.0 INTRODUCTION

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### 1.1 STATEMENT OF PURPOSE

This Ragon Institute Exposure Control Plan (ECP) is designed to minimize or eliminate employee exposure to bloodborne pathogens. All human blood and other potentially infectious materials (OPIM) are considered to be infectious for Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), and other bloodborne pathogens, and will be treated as infectious, i.e., with universal precautions. Definitions relevant to this document are found in Appendix A.

### 1.2 OBJECTIVE

This ECP is mandatory for all Ragon Institute research and clinical laboratory employees who have occupational exposure to human blood and OPIM, and perform research on bloodborne pathogens such as HIV and HBV. This plan has been customized so that it provides specific provisions to identify and protect all personnel who may be at risk of exposure. This plan must be updated at least annually, and whenever there are changes in procedures that may change a worker's exposure. A hard copy of this plan is available from the Ragon Institute Biosafety Officer and is accessible to personnel via a hard copy that is located on the Environmental Health & Safety (EH&S) shelf in Room 963.

### 1.3 POLICY

The Ragon Institute is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following ECP is provided in accordance with U.S. Occupational Safety and Health Administration (OSHA) standard Title 29 Code of Federal Regulations Section 1910.1030 (29 CFR 1910.1030), ['Occupational Exposure to Bloodborne Pathogens'](#)

The ECP is a key document to assist our laboratory in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- Employee exposure determination
- Compliance methods of control to prevent worker exposure
- Provisions for hepatitis B vaccination
- Post-exposure evaluation and follow-up
- Mandatory employee training requirements and hazard communication
- Recordkeeping

Implementation of these elements of the ECP is discussed in the subsequent pages of this document.

## 2.0 ROLES AND RESPONSIBILITIES

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- The Ragon Institute Biosafety Officer is responsible for the implementation of this ECP with the assistance of all Ragon Institute Principal Investigators.
- The Ragon Institute Biosafety Officer will maintain, review, and update this ECP at least annually, and whenever necessary to include new or modified tasks and procedures.
- Those employees, collaborators, and students who have occupational exposure to blood or OPIM must comply with the procedures and work practices outlined in this ECP.
- The Ragon Institute will maintain and provide all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags and waste boxes as required by the Standard. This will include ensuring that adequate supplies of the aforementioned equipment are available in the appropriate sizes. The Biosafety Officer will provide assistance to laboratory staff with selection, purchasing, use, storage, and disposal.
- The Biosafety Officer and the supervisor of the employee will be responsible for ensuring that all medical actions in response to an exposure incident are performed and that appropriate reporting to Occupational Health Services and the Massachusetts General Hospital (MGH) on-line safety reporting system will occur.
- The Biosafety Officer and the supervisor of the employee, will be responsible for making sure all employees have taken initial training upon employment at the Ragon Institute and annual training thereafter, documentation of training dates, and making the written ECP available to employees, OSHA, and other regulatory representatives. Online training for research personnel is assigned by the Partners Institutional Biosafety Office (PIBC) when they are added to a registration that includes work with human materials such as, but not limited to, blood and human cell lines. Clinical personnel are provided with a link for online training. All online training is found in the HealthStream training platform administered by MGH.

### 3.0 EXPOSURE DETERMINATION

The following is a list of tasks or procedures where exposure to blood or OPIM may occur, and the job titles of those individuals who have real or potential exposure as a result of performing those tasks:

<b>Table 3.1 List of Tasks or Procedures Where Exposure to Blood or OPIM May Occur</b>	
<b>Task or Procedure</b>	<b>Job Titles</b>
<ul style="list-style-type: none"> <li>● Phlebotomy with human subjects.</li> <li>● Handling human blood samples and human cell lines.</li> <li>● Laboratory research projects with Human Immunodeficiency Virus (HIV), Hepatitis B and C viruses, and other bloodborne pathogens.</li> <li>● Sorting of human cells on FACS Aria and similar equipment.</li> <li>● Autoclaving biohazardous waste.</li> </ul>	Nurse Practitioner Principal Investigator Laboratory Manager Research Fellow Research Technician Research Technologist Research Specialist Research Collaborator Student
OPIM      other potentially infectious materials	

## 4.0 METHODS OF IMPLEMENTATION AND CONTROL

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### 4.1 UNIVERSAL PRECAUTIONS

All employees will utilize universal precautions when handling blood and OPIM. For tasks in which differentiation between body fluid types is difficult or impossible, all body fluids will be considered potentially infectious materials.

### 4.2 EXPOSURE CONTROL PLAN

Employees covered by the bloodborne pathogens standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees have an opportunity to review this plan at any time during their work shifts. A copy of the plan is located on the EH&S shelf in Room 963

### 4.3 ENGINEERING CONTROLS, WORK PRACTICES, AND PERSONAL PROTECTIVE EQUIPMENT (PPE)

- **Engineering Controls.** Employees will use engineering controls whenever possible to prevent or minimize exposure. All aerosol-producing tasks (i.e., sonicating or vortex mixing), or tasks that may result in splashing or spraying, will be conducted in a certified biological safety cabinet. Other engineering controls such as sharps disposal containers, safety sharps devices (needles, scalpels, lancets etc.), and non-glass capillary tubes will be used as needed depending on the task being performed. Engineering controls should be examined, maintained, or replaced on a regular basis by the Principal Investigator or Laboratory Manager to ensure their effectiveness.
- **Work Practice Controls.** Work practice controls include policies and procedures to minimize exposure, and should be used in conjunction with engineering controls. Work practice controls include hand washing, safe needle practices (no recapping), no eating or drinking in the laboratory, and no mouth pipetting.
- **Personal Protective Equipment (PPE).** PPE will be used to prevent or minimize exposure to bloodborne pathogens, but should only be used when exposure remains after all reasonable engineering controls and work practice controls are in place. PPE includes such items as gloves, safety glasses, and laboratory coats and gowns. For procedures where splashing may occur (spill cleanup), eye protection and face protection (masks) must be used to prevent exposure. Face shields may be used as an alternative to the safety glasses / mask combination.

The following are the specific engineering controls and PPE that will be used by employees to minimize exposure to blood and OPIM for each task outlined in Section 4.1:

Table 4.1 Engineering Control Measures								
Task # (See 3.1)	Bench Top Splash Shield	Biohazard Waste Bags	Biosafety Cabinet	HEPA Vacuum Filters	Plastic Transport Containers	Self- Sheathing or Retractable Needles	Plastic instead of Glass	Other (Please Specify)
Phlebotomy with human subjects.		X			X	X (when feasible)		
Handling human blood samples and human cell lines.	X	X	X	X	X		X	Centrifuge safety cups
Laboratory research projects with Human Immunodeficiency Virus (HIV), Hepatitis B and C viruses, and other bloodborne pathogens.		X	X	X	X		X	Centrifuge safety cups
Sorting of human cells on FACS Aria and similar equipment.		X	X	X	X		X	
Autoclaving biohazardous waste.		X			X			

Table 4.2 Required Personal Protective Equipment										
Task # (See 3.1)	Lab Coat	Gloves	Safety Glasses with Side Shields	Surgical Mask	Solid Front Gown	Sleeve Covers	Booties	Respiratory Protection (Contact EHS)	Face Shield	Other (Please Specify)
Phlebotomy with human subjects.	X	X	X							
Handling human blood samples and human cell lines.	X	X	X		X				X	
Laboratory research projects with Human Immunodeficiency Virus (HIV), Hepatitis B and C viruses, and other bloodborne pathogens.		X	X	X (vivarium)	X	X	X (BSL-3 lab and vivarium)	X (BSL-3 lab)	X	
Sorting of human cells on FACS Aria and similar equipment.		X	X		X					
Autoclaving biohazardous waste.		X	X		X					Heat-resistant gloves

#### 4.4 SPECIFIC CONTROL MEASURES

- Sharps disposal containers are inspected and maintained or replaced by Laboratory Managers whenever necessary to prevent overfilling. Proper sharps containers must be puncture resistant, labeled with the biohazard symbol, or color-coded red and leakproof.
- This laboratory identifies the need for changes in engineering control and work practices through discussions with the Biosafety Officer.
- If needles or other sharps are used, there is an evaluation of new procedures or new products to improve safety. Various vendors are contacted and requested to provide samples of new products.
- Puncture-resistant glove liners are used when appropriate under disposable gloves, to provide protection from sharps injuries. For example, when injecting mice with HIV in the vivarium.
- Both front line workers and management officials are involved in this process: Employees are involved through department meetings where there is an open forum to bring up any issues or potential issues. In addition, the Biosafety Officer is available to discuss the selection and implementation of specific control measures.

PPE is readily accessible and located throughout all of the laboratory areas on the seventh, eighth, and ninth floors, and room 040B in the vivarium.

All employees using PPE must observe the following precautions:

- Wash hands immediately or as soon as feasible after removal of gloves or other PPE, and before leaving the work area.
- Remove PPE after it becomes contaminated, and before leaving the work area.
- Used PPE may be disposed of in biowaste containers.
- Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised. Double-glove if appropriate and if it will not impede dexterity.
- Never wash or decontaminate disposable gloves for reuse.



- Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth. Appropriate face and eye protection consists of mask and goggles or a face shield.
- Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

#### 4.5 HOUSEKEEPING

- Regulated waste is placed in containers that are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded, puncture proof (see Labels), and closed prior to removal to prevent spillage or protrusion of contents during handling. Do not overfill these containers. Close containers when they are 2/3 full.
- Sharps containers will be disposed of by closing their sharps containers when 2/3 full and place these in the large Biohazard boxes in the laboratory.
- All waste from the Biosafety Level Two Plus (BL2-Plus) and the Biosafety Level Three (BL3) laboratories must be autoclaved prior to removal from the laboratory.
- Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof, and color-coded red with the Universal Biohazard Symbol.
- Broken glassware that may be contaminated is picked up using a mechanical device such as tongs, forceps, or a brush and dustpan and placed in an appropriate sharps container.
- All laboratory surfaces and equipment must be decontaminated with an appropriate disinfectant after work is completed. Vesphene is the primary disinfectant in the BSL-3 laboratory. In all other laboratories, a variety of quaternary ammonium products, bleach, and 70% ethanol are available.

#### 4.6 LAUNDRY

The following articles, if contaminated, will require laundering. All other PPE is disposable.

- Cotton laboratory coats, in the Biosafety Level One (BL1) laboratories

A commercial laundry service will be used to clean contaminated clothing and other articles that require laundering.

The following laundering requirements must be met:

- Handle contaminated laundry as little as possible, with minimal agitation.
- Place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport to the laundry service.

#### 4.7 LABELS

The universal biohazard symbol will be used to mark regulated waste containers, refrigerators or freezers containing blood or OPIM, contaminated equipment, specimen containers, and specimen transport containers. The universal biohazard symbol must be located at the entrance to all laboratory rooms where blood or OPIM is used. Red bags can be used as a substitute for bags marked with the universal biohazard symbol for regulated waste only.

Laboratory Managers will ensure warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Biohazard labels may be obtained from the Biosafety Officer and are located on the EH&S shelf in Room 963.

#### 4.8 HIV AND HBV RESEARCH LABORATORIES

The Ragon Institute conducts work with HIV, HBV, and other bloodborne disease agents. This work is conducted in the “Tissue Culture” rooms that are BL2 facilities where selected BL3 practices and procedures are utilized. These laboratories are thus considered BL2-Plus laboratories.

- All work at BL2-Plus is registered with the Partners Institutional Biosafety Committee.
- Access to the BL2-Plus laboratories is controlled. Individuals authorized by the Laboratory Manager are provided with keycard access.
- The BL2-Plus laboratories include a self-closing door from the hallway into the anteroom, and from the anteroom into the main laboratory.
- The BL2-Plus laboratories contain a sink for handwashing, pass-through autoclaves, eyewash and safety showers, and have inward airflow.
- All work in the BL2-Plus laboratories takes place in biosafety cabinets that are certified on an annual basis. No work takes place on the open bench. Biosafety cabinets have protected vacuum lines. Centrifuges have safety cups with gasket seals.

- The use of sharps in the BL2-Plus laboratories requires prior approval from the Laboratory Manager.
- The Ragon Institute Biosafety Manual is available from the Biosafety Officer and can be found on the shelf in room 963.

In addition, work with HIV is permitted in the BL3 facility. The above items apply as do additional BL3-specific procedures.

## 5.0 HEPATITIS B VACCINATION

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Information on hepatitis B vaccinations, including safety, benefits, efficacy, methods of administration, and availability, will be provided to employees by MGH Occupational Health Services (OHS).

The hepatitis B vaccination series is available at no cost after training and within 10 days of initial assignment to employees identified in the exposure determination section of this plan (section 3.1). Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series, 2) antibody testing reveals that the employee is immune, or 3) medical evaluation shows that vaccination is contraindicated.

However, if an employee chooses to decline vaccination, the employee must sign a declination or waiver form available at OHS. Employees who decline may request and obtain the vaccination at a later date at no cost.

Vaccination will be coordinated, documented, and paid for through MGH OHS (617-726-2217).

## 6.0 POST-EXPOSURE EVALUATION AND FOLLOW-UP

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Should an exposure incident occur, do the following:

- Immediately wash affected areas with soap and water. If eye exposure occurred, immediately flush eyes with water for 10 – 15 minutes.
- Notify supervisor or Principal Investigator of the exposure.
- Call MGH OHS at 617-726-2217 to report the exposure.
- If directed to by MGH OHS, go directly to MGH OHS at 165 Cambridge Street, Suite 404, Charles River Plaza for medical evaluation and follow-up. Source blood testing will be determined by the physician.

### **MGH Occupational Health Service**

165 Cambridge Street, Suite 404

Boston, MA 02114

Phone: (617) 726-2217

Hours: Mon.-Fri. 7:00 AM – 5:00 PM

### **After Hours Injury Care**

**Call the extension above and follow the directions on the message. An OHS nurse practitioner will be paged to assist you after hours.**

**In the case of a serious injury, report immediately to the MGH Emergency Room in Boston. Call x911 if an ambulance is required.**

## 7.0 INCIDENT REPORTING

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An employee with a work-related injury or illness must complete the MGH on-line safety reporting form. This form can be accessed by clicking on the START button on your computer, go to Partners Applications and click on Safety Reporting MGH.

Identify and document the source individual/sample (unless it is established that the source is unknown).

After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status.

If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

## 8.0 TRAINING

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All Ragon Institute employees who have occupational exposure to bloodborne pathogens receive both initial and annual training through MGH HealthStream online training. Additional project or laboratory specific training is also offered by the Biosafety Officer, such as BL3 Laboratory Biosafety training.

Online training for research personnel is assigned by the PIBC when they are added to a registration that includes work with human materials such as, but not limited to, blood and human cell lines. Clinical personnel are provided with a link for online training. All online training is found in the HealthStream training platform administered by MGH.

All employees who have occupational exposure to bloodborne pathogens receive training on the epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements: a copy and explanation of the standard, an explanation of our ECP and how to obtain a copy, an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident, an explanation of the use and limitations of engineering controls, work practices, and PPE, an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE, an explanation of the basis for PPE selection, information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge, information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM, an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available, information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident, an explanation of the signs and labels and/or color coding required by the standard and used at this facility, an opportunity for interactive questions and answers with the Biosafety Officer at any time.

## **9.0 RECORDKEEPING**

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### **9.1 TRAINING RECORDS**

Training records are completed for each employee upon completion of training. These documents will be maintained in the MGH HealthStream system.

The training records include: Dates of the training sessions, content of the training sessions, the name of the person(s) conducting the training, and names of all persons attending the training sessions.

Training sessions are conducted online with an opportunity to liaise with the Biosafety Officer should questions arise.

### **9.2 MEDICAL RECORDS**

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records." Medical records, under most circumstances, will be maintained at the MGH OHS.

### **9.3 OSHA RECORDKEEPING**

The MGH OHS will evaluate all incident reports to determine if cases meet OSHA's Recordkeeping Requirements (29 CFR 1904) and are placed on the MGH OSHA 300 Log. All percutaneous injuries from contaminated sharps are also recorded in the MGH Sharps Injury Log.



## **APPENDIX A**

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### **GLOSSARY OF TERMS**

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**Blood** means human or non-human primate blood, blood components, and blood-based products.

**Bloodborne Pathogens** means pathogenic microorganisms that are present in human or non-human primate blood and can cause disease in humans. Examples include, but are not limited to, hepatitis B virus (HBV), and human immunodeficiency virus (HIV).

**Clinical Laboratory** means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

**Contaminated** means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

**Contaminated Laundry** means laundry that has been soiled with blood or other potentially infectious materials or may contain sharps.

**Contaminated Sharps** means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, and broken capillary tubes.

**Decontamination** means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

**Engineering Controls** means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

**Exposure Incident** means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of job duties.

**Handwashing Facilities** means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

**Licensed Healthcare Professional** is a person whose legally permitted scope of practice allows him or her to independently perform the activities required for Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

**HBV** means hepatitis B virus.

**HIV** means human immunodeficiency virus.

***Needleless systems*** means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

***Occupational Exposure*** means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of job duties.

***Other Potentially Infectious Materials*** means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV; (4) All primary human and non-human primate cell explants from tissues and subsequent in vitro passages of human or primate tissue explant cultures, unless characterized by documented, reasonable laboratory testing to be free of HIV, HBV, HCV, and other bloodborne pathogens.

***Parenteral*** means piercing mucous membranes or the skin barrier through such events as needlesticks, human/non-human primate bites, cuts, and abrasions.

***Personal Protective Equipment*** is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

***Production Facility*** means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

***Regulated Waste*** means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

***Research Laboratory*** means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

***Sharps with engineered sharps injury protections*** means a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

***Source Individual*** means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, research participants; hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

***Sterilize*** means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

***Universal Precautions*** refers to a method of infection control in which all human blood and other potentially infectious materials are treated as if known to be infectious for HIV and HBV. It does not apply to feces, nasal secretions, sputum, sweat, tears, urine or vomitus unless they contain visible blood.

***Work Practice Controls*** means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).