

Biological Safety Manual & Exposure Control Plan



siamab
therapeutics

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Biological Safety Manual & Exposure Control Plan

The following Biological Safety Manual & Exposure Control Plan dated July 2015, as written, has been approved by:

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1. PURPOSE

Siamab is committed to the prevention of employee exposures to biohazardous materials, including human source material such as blood, serum, tissue, human cell lines and any other potentially infectious material to which an employee may be exposed as a result of his or her job requirements. In order to reduce or eliminate the hazards of occupational exposure, Siamab has implemented this Biological Safety Manual & Exposure Control Plan (ECP) to provide details on safety guidelines and employee protection measures. This manual explains the use of various engineering and work practice controls, including the use of personal protective equipment, housekeeping requirements, medical surveillance, and hepatitis B vaccination programs as they apply to the work done on-site. Also addressed, are the means by which the existence of hazards to employees is communicated, including labels and signs, recordkeeping and training.

This plan was developed in accordance with the OSHA "Occupational Exposure to Bloodborne Pathogens: Final Rule" in 29 CFR 1910.1030, to minimize or eliminate employee exposure to bloodborne pathogens and other biological hazards. A copy of this OSHA Standard is located in the central safety files and online at www.osha.gov.

This manual applies to laboratory research, service and support activities that may involve exposure to biohazardous agents or materials and that come under the purview of the Biological Safety Officer. The manual is intended to give an overview of biological safety and to provide compliance with the OSHA Bloodborne Pathogens Standard. It is not meant to be an extensive guide for experiment-specific processes or provide specific safety protocols for all biological materials. In these cases, the Biological Safety Officer must perform a specific Job Safety Analysis that results in written procedures and training. This information can then be added to this manual as appendices, or kept separately in the safety files.

2. RESPONSIBILITIES

Biological Safety Officer (BSO)

As the official representative of the company, the Biological Safety Officer has biological safety overview of all ongoing scientific projects in the company. The BSO will provide guidance to all Principal Investigators, Supervisors and Employees of laboratories performing biological work.

The Biological Safety Officer at Siamab is Jillian Prendergast.

The BSO will ensure compliance with the Centers for Disease Control (CDC) and National Institutes of Health (NIH) publications, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) and the *Guidelines for Research Involving Recombinant DNA Molecules*, as appropriate. The BSO will ensure adherence and compliance with any local regulations regarding biological safety.

The BSO will be an active participant on the Safety Committee and Institutional Biosafety Committee (IBC).

The BSO will conduct an annual review and update of this manual. This will include information that reflects any changes in technology that eliminates or reduces occupational exposure by:

1. Implementing a safer sharps program that evaluates lab innovations and technological developments that reduce the risk of exposure, particularly medical devices designed to reduce needlesticks
2. Documenting the consideration and use of appropriate, commercially-available, and effective safer devices by describing the devices identified as candidates for use, the method used to evaluate those devices, and the justification for the eventual selection. The documentation can be done by listing the employees involved and describing the process by which input was requested; or through other documentation, including references to the minutes of meetings, copies of documents used to request employee participation, or records of responses received from employees.

Principal Investigator (PI)

A PI will ensure compliance with the Newton Board of Health, NIH guidelines and OSHA regulations, when work with regulated biological agents such as recombinant DNA, human source materials, or other potentially infectious material (OPIM) is conducted. The PI will register all work involving recombinant DNA with the Institutional Biosafety Committee (IBC) Chairperson.

The PI that oversees a project will ensure that all employees have project specific training for each particular experiment. The PI must ensure biological and physical containment conditions are maintained, such as strain or phenotype purity, proper practices, techniques and equipment.

Supervisors

Supervisors will assess all potentially hazardous agents involved in work activities within their laboratories and institute appropriate safeguards. Supervisors will have experiment specific protocols for biohazardous work which include measures for minimizing exposure incidents, informing personnel of potential hazards and the basis for assessing hazards, assuring proficiency of staff and maintaining and updating these protocols on a continuing basis.

Supervisors will ensure that their employees receive the proper training, follow all safety policies, report incidents and correct non-compliance issues as indicated by the BSO or Safety Committee. Supervisors must also ensure that all employees with the potential for occupational exposure to bloodborne pathogens follow the provisions of this plan and manual. This includes providing a copy of this Biological Safety Manual & Exposure Control Plan to those employees, requiring that they attend an annual training session, enforcing compliance with this plan, ensuring that new employees who will have occupational exposure are properly trained, and performing follow-up procedures for all exposure incidents.

It is recommended that all supervisors inform the BSO about the acquisition/ordering of any potentially biohazardous material. All biomaterial on-site at Siamab must be tracked by the biohazardous material spreadsheet located in the shared files. It is the supervisors' responsibility to instruct their people on the use of this database.

Employees

Employees are to perform tasks and procedures in a manner that minimizes or eliminates their own and others' exposure and to perform duties as established in this Biological Safety Manual & Exposure Control Plan and as trained. It is the employee's responsibility to report any incidents, accidents, exposure or needlesticks to their supervisor and the BSO immediately. All incidents must be documented by the employee on an incident report within 24 hours.

3. RISK AND CONTAINMENT LEVELS

Risk Groups

The American Biological Safety Association (ABSA, www.absa.org), NIH and the Canadian Laboratory Biosafety Guidelines have categorized risk group for biological organisms.

Risk Group 1- low individual and community risk

A biological agent:

1. That is well-characterized and not known to consistently cause disease in healthy adult humans
2. That poses little risk to the environment

Risk Group 2 - moderate individual risk, limited community risk

A biological agent:

1. That can cause human disease and might be a hazard to workers
2. That is unlikely to spread to the community
3. For which there is usually effective prophylaxis or treatment available

Risk Group 3 (RG3) - high individual risk, low community risk

A biological agent:

1. That can cause severe or lethal human disease and present a serious hazard to workers
2. That may present a risk of spreading to the community
3. For which there may be effective prophylaxis or treatment available

Risk Group 4 - high individual risk, high community risk

A biological agent:

1. That causes severe or lethal human disease and is a serious hazard to workers
2. That may present a high risk of spreading to the community
3. For which there is usually no effective prophylaxis or treatment available

Risk Assessment

In order to assess a biohazard and provide adequate containment, it is necessary to identify the risk group of an organism and then perform a risk assessment of the experimental situation. To assess occupational risk while working with biohazardous materials and to understand what types of containment are necessary, five factors must be considered before a decision is made:

1. What is the infectious dose of the organism?
2. What are the likely routes of entry?
3. What is the viability of the organism in specific environments?
4. Are suitable disinfectants available for the organism?
5. Is effective prophylaxis available?

After a risk assessment is performed, a physical containment level is assigned to the work being performed with that organism. It is important to note that although, risk group and biosafety level often coincide (ie risk group 1 organisms are handled at biosafety level 1) this is not always the case. Only a full risk assessment can determine the containment level for each biological agent in use in the laboratory.

When cell cultures are known to contain an etiologic agent, an oncogenic virus or amphotropic packaging system, the cell line must be classified at the same level as that recommended for the agent. This is the same for all cell cultures purposely inoculated with an infectious agent. An example is immortalized cells (also known as continuous or permanent cell lines). These are obtained by isolating cells from tumors, by mutating primary cells with mutagens, or using viruses or rDNA to generate indefinitely growing cells. Hybridoma cell lines are immortalized cell lines created by fusion of primary cells with a continuous cell line. In general, primary cell cultures are less characterized than permanent cell lines and are not typically tested for contaminating pathogens. Tumorigenic potential is a risk to consider with permanent cell lines.

Containment

Four levels of biosafety controls have been defined by the Centers for Disease Control (CDC) and the National Institutes of Health (NIH). They are combinations of lab practices, techniques, safety equipment and the physical design of the lab facility. Experience has shown that strict adherence to these guidelines contributes to a healthier and safer environment, both in the work place and in the surrounding community.

Biosafety physical containment levels and related safety practices may be applied to work with all types of biohazardous materials, such as genetically manipulated cell lines, potentially infectious human or animal body fluids and tissues, bacterial or viral cultures and live animals.

An in-depth description of biosafety containment levels 1 and 2 is given below because these are the two levels most commonly used. A table which summarizes the basics of all four biosafety levels is provided in Appendix 1. These descriptions are taken directly from the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>. Additional information on BL3 and BL4 can be found in the BMBL as well.

Biosafety Level One (BL1)

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BL1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science.

The following standard practices, safety equipment, and facility requirements apply to BL1:

A. Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
 - a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
 - b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - c. Non disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.
6. Perform all procedures to minimize the creation of splashes and/or aerosols.
7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:
 - a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
 - b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. The sign may include the name of the agent(s) in use, and the name and phone number of the laboratory supervisor or other responsible personnel. Agent information should be posted in accordance with the institutional policy.
10. An effective integrated pest management program is required.

11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices

None required.

C. Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Special containment devices or equipment, such as BSCs, are not generally required.
2. Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.
3. Wear protective eyewear when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses in laboratories should also wear eye protection.
4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Wash hands prior to leaving the laboratory. In addition, BL1 workers should:
 - a. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary.
 - b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
 - c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

D. Laboratory Facilities (Secondary Barriers)

1. Laboratories should have doors for access control.
2. Laboratories must have a sink for hand washing.
3. The laboratory should be designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.
4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
 - a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

5. Laboratories windows that open to the exterior should be fitted with screens.

Biosafety Level 2 (BL2)

Biosafety Level 2 builds upon BL1. BL2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BL1 in that 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

The following standard and special practices, safety equipment, and facility requirements apply to BL2:

A. Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
 - a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
 - b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - c. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.
6. Perform all procedures to minimize the creation of splashes and/or aerosols.
7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:

- a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
 - b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include: the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory. Agent information should be posted in accordance with the institutional policy.
10. An effective integrated pest management program is required.
11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices

1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
2. Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.
3. Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.
4. A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.
5. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
6. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
7. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
 - a. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
 - b. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
8. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety safety manual. All such incidents must be reported to the laboratory supervisor. Medical

evaluation, surveillance, and treatment should be provided and appropriate records maintained.

9. Animals and plants not associated with the work being performed must not be permitted in the laboratory.
10. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.

C. Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Properly maintained BSCs (preferably Class II), other appropriate personal protective equipment, or other physical containment devices must be used whenever:
 - a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
 - b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
2. Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.
3. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories should also wear eye protection.
4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers should:
 - a. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Wear two pairs of gloves when appropriate.
 - b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
 - c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
5. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

D. Laboratory Facilities (Secondary Barriers)

1. Laboratory doors should be self-closing and have locks in accordance with the institutional policies.
2. Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.
3. The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
 - a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
5. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.
6. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.
7. Vacuum lines should be protected with High Efficiency Particulate Air (HEPA) filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.
8. An eyewash station must be readily available.
9. There are no specific requirements on ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.
10. HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.
11. A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

A brief explanation of the remaining biosafety levels is given below. Appendix 1 gives a summary overview of all 4 levels.

BL2 Enhanced (BL2+)

This level is not described in the BMBL, but is often used as a hybrid safety level between BL2 and

BL3. With this level, there is work done with materials that may be infectious primarily via an aerosol and introduction through the skin or mucous membranes. Biological agents handled at BL2 enhanced generally pose a non-serious, non-fatal disease risk. Risk is elevated above basic BL2 due to the insert location, vector or cell line. At this level, risk can be controlled by strict adherence to Enhanced BL2 practices within a physical BL2 laboratory. Specific lab practices and experimental procedures must be outlined in a working protocol for the laboratory as the result of a specific Risk Analysis. General BL2 Enhanced working procedures are given in Appendix 2.

Biosafety Level Three (BL3)

This level identifies an inhalation exposure risk. Risk group 3 agents which are highly infectious and for which treatment may not be available are used. As examples, tuberculosis and anthrax are used in BL3 containment. Work at BL3 is allowed in some cities under separate permit from the municipal regulatory bodies. A secure and controlled laboratory environment is required. See the BMBL for specific physical laboratory requirements and practices.

Biosafety Level 4 (BL4)

This is the highest containment level as described by the CDC/NIH. Risk Group 4 agents which are extremely infectious are used at BL4 containment; examples are Ebola and Variola virus. BL4 work is prohibited in most cities. See the BMBL for specific physical laboratory requirements and practices. Work at BL4 is prohibited in Newton.

4. HUMAN MATERIALS AND OPIM

The OSHA Bloodborne Pathogen Standard defines safety requirements for working with human blood and other clinical materials, human immunodeficiency virus, and the bloodborne hepatitis viruses. Those safety requirements are described in this Biosafety Manual and Exposure Control Plan. Before working with any human materials, contact the Biosafety Officer for guidance and to schedule Bloodborne Pathogens training.

The Standard establishes the principle that blood and certain body fluids of all human beings are considered potentially infectious for bloodborne pathogens such as hepatitis B or C virus (HBV, HCV) and human immunodeficiency virus (HIV).

It further establishes that universal precautions are to be used to prevent parenteral, mucous membrane, and non-intact skin exposure to bloodborne pathogens when handling the following human materials: blood; tissues; body fluids containing visible blood; semen; vaginal secretions; cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids; HIV, HBV and HCV infected cells and animals; and saliva in dental procedures.

Universal precautions do not apply to the following human materials: urine, feces, sputum, saliva, tears, sweat, nasal secretions, and vomitus. While these materials are not covered by the bloodborne pathogens standard, they may be contaminated with infectious microorganisms and can present a potential hazard to persons working with them. Prudent handling practices are recommended for work with any human material.

Materials other than those mentioned above which should also be handled at BL2 containment using universal precautions are:

1. Human derived cell lines
2. Human cell strains
3. Human serum derived reagents

Human Cell Lines

Characterization of human cells, for inclusion or exclusion from compliance with the Bloodborne Pathogens Standard, would include screening of the cells lines for viruses characterized as bloodborne pathogens by the Standard, including human immunodeficiency viruses, hepatitis viruses and EBV, if the cells are capable of propagating such viruses. Testing may include antigenic screening for viral or agent markers, co-cultivation with various indicator cells that allow contaminants to grow, or using molecular technology such as polymerase chain reaction or nucleic acid hybridization, to identify latent viruses capable of infecting humans. These are viruses such as Herpesviruses like Epstein Barr Virus, or papilloma members of the Papovavirus group. Cell lines that are procured from commercial vendors or other sources with documented testing to be free of human bloodborne pathogens and which have been protected by the employer from environmental contamination may be excluded from the Bloodborne Pathogens Standard.

It should be noted that human cells or other transformed human cell lines are sometimes adulterated with laboratory pathogens accidentally introduced by cultivation with other cell cultures, or physically contaminated by other cell cultures handled in the same lab. In order to handle human cells, without having to comply with the requirements of the Bloodborne Pathogens Standard, human cells should be documented to be pure cells and shown to be free of Bloodborne Pathogens by testing as explained above. Even common cell lines, such as human cervical carcinoma cells, known as HeLa cells, would need documentation on purity prior to downgrading. Please note that if a cell line is proven to be BBP free, it may be removed from the requirements of the Bloodborne Pathogen Standard, but a full risk assessment would be required to also downgrade the material to BL1.

Human Cell Strains

All primary human cell **explants** from tissues and **subsequent in vitro** passages of human tissue explant cultures, also known as human cell strains, must be regarded as containing potential bloodborne pathogens and should be handled in accordance with the Bloodborne Pathogens Standard. Non-transformed, human cell strains, characterized by documented, reasonable laboratory testing as described for human cell lines, to be free of human immunodeficiency virus, hepatitis viruses, or other bloodborne pathogens may be exempted from the standard's requirements. However, if such tissue explants or subsequent cultures are derived from human subjects known to carry bloodborne pathogens, such as hepatitis viruses or human immunodeficiency viruses or are deliberately infected with bloodborne pathogens, they must be handled in accordance with the precautions noted in the Bloodborne Pathogens Standard. Likewise, animal tissues, explants or cell cultures known to be contaminated by deliberate infection with human immunodeficiency virus or Hepatitis B virus are also subject to the Standard.

Human Derived Reagents

The Centers for Disease Control cautions that all human-serum-derived reagents used in the lab, such as Human Serum Albumin (HSA), be handled at BL2 levels with universal precautions because no test method can offer complete assurance that laboratory specimens do not contain HIV, hepatitis B virus, or other infectious agents.

5. RECOMBINANT DNA (rDNA)

Research with recombinant DNA molecules is regulated typically by two organizations: the National Institutes of Health (NIH) and the local Board of Health. For facilities receiving federal funds for rDNA research, adherence to the NIH Guidelines are mandatory, even for projects at the same facility which are not funded by the NIH. For facilities that do not receive federal funding, the local Board of Health is the primary regulatory agency. Each Board of Health may have its own ordinance which requires a facility to abide by the NIH Guidelines in total, or in part. A copy of the NIH Guidelines can be found in the shared files and online at http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.pdf. The General Ordinance for the City of Newton can be found in Appendix 3.

NIH Guideline Requirements

Establish an Institutional Biosafety Committee (IBC)

Siamab shall establish an IBC and procedures that the IBC will follow in its review of project registration proposals and activities. Formal minutes of the IBC meetings will be written and kept on file at the institution. These minutes will not contain proprietary company information and therefore will be made available to the public as requested.

An IBC will be comprised of no fewer than five members with collective expertise and experience with rDNA technology, the ability to assess safety and identify potential risk to workers and the environment, and expertise in physical containment. At least one member of the committee must be from the laboratory technical staff. One member can be a consultant knowledgeable in institutional policies, applicable law, and the environment. Membership must also include:

1. The commissioner of health and human services
2. Two community representatives with expertise in rDNA research and technology and/or safety issues. One of these representatives shall be appointed by the mayor and one shall be appointed by the board of Aldermen.
3. At least three (3) members of Siamab its staff to the IBC, including the safety Biosafety Officer

The IBC will review and assess all registrations for safety and will ensure that all projects conform with the Guidelines. The initial and periodic review will include an assessment of the appropriate containment level required by the Guidelines for the proposed research and an assessment of the facilities, procedures, practices, training and expertise of recombinant DNA personnel, and will recommend emergency plans and appropriate medical surveillance for the personnel.

Project Registrations

All Principal Investigators planning to work with rDNA must complete a Project Registration document prior to beginning work. If BL2, BL2 Enhanced or BL3 containment is necessary for a project, the registration must be approved by the Institutional Biosafety Committee prior to initiation. The rDNA project registration form is given in Appendix 4.

Training for Employees

All employees involved in recombinant DNA research will be given biological safety training. In addition, project specific training will be provided by the Principal Investigator of the project before initiating work.

Medical Surveillance

Medical surveillance for each project will be decided upon by the IBC. Project specific medical surveillance programs will be included on the registration document.

Accident/Incident Reports

Any accidents, illnesses, releases, or significant problems that occur while working with recombinant DNA will be reported to the Office of Recombinant DNA Activities and the local Board of Health.

Retroviruses

Retroviral vectors are a common tool used in cell biology. Retroviruses package RNA molecules into virus particles and express a messenger RNA of interest. The retroviral genome expressed in packaging cell lines is not intact, therefore no replication competent virus (RCV) is produced. Because of this, virus particles are “infectious” for only one replication cycle. However, the possibility exists for recombination with endogenous retroviral elements, or with an exogenous retroviral infection, such as HIV. This is the primary risk when using retroviral vectors.

Another risk involved with retroviral vectors is the target cell range of the vector. For example: if RNA is packaged in particles with the envelope protein of vesicular stomatitis virus (VSV-G protein) this provides a broad target cell range because most cell types express the phospholipids to which VSV-G protein binds. Appendix 5 describes a variety of common retroviral vectors.

6. SELECT AGENTS

The Centers for Disease Control (CDC) regulation: Requirements for Facilities Transferring or Receiving Select Agents (42 CFR 72.6), was developed in response to The United States Antiterrorism and Effective Death Penalty Act. The CDC regulation was implemented to reduce the risk that terrorists, or others with illicit intentions, would gain access to, and misuse, such materials. It addresses the domestic shipment and handling of certain infectious agents and toxins. The CDC list of select agents that cause substantial harm to human health can be found in Appendix 6 of this manual. A permit must be obtained from the CDC before these agents may be shipped or received. In order to obtain a permit for Select Agents, the facility must be registered and create a Select Agents program. This manual does not cover a Select Agents program; for more details go to <http://www.selectagents.gov/>.

7. EXPOSURE DETERMINATION

The OSHA Bloodborne Pathogens Standard requires that an exposure determination be performed in laboratories where human source materials are used. A list of departments, job classifications, tasks and responsibilities must be made to identify all employees that may have exposure to human materials.

Job Classifications

Employees of the following departments may have exposure to human source materials:

Scientists

The potential for occupational exposure to blood and other potentially infectious material may occur with these job classifications:

Emergency First Aid Responders

Scientist

Director

Operations Manager

Tasks and Procedures

The following tasks or procedures may cause potential exposures to personnel listed in the above job classifications:

Work with human cell lines

Processing human tissue for assay

Generating human cell strains from explants

Shipping or receiving human source materials

Emergency First Aid response

Closing up, boxing or moving biomedical waste containers

8. ENGINEERING CONTROLS

Engineering and work practice control measures are to be used to minimize, isolate, or eliminate employee exposure for each task within the work area. Such control measures are listed below. ***Engineering controls must be the primary means of eliminating or minimizing employee exposure and include the use of safer medical devices, such as needleless devices, shielded needle devices, plastic capillary tubes and retractable scalpel/knife blades.*** When occupational exposure remains after institution of these controls, personal protective equipment is used. Engineering controls are used when there is reasonable likelihood of occupational exposure. Engineering controls are examined, and maintained or replaced, on a regular schedule by the supervisor and employee to ensure their effectiveness. Current regulations state that "safer medical devices, such as sharps with engineered sharps injury protections and needleless systems" constitute engineering controls and thus must be used where feasible.

It is important to note that each lab employee is responsible for reviewing the effectiveness of the engineering controls before use. The Biosafety Manager is responsible for ensuring biosafety cabinets are certified on an annual basis.

The Biosafety Cabinet (BSC)

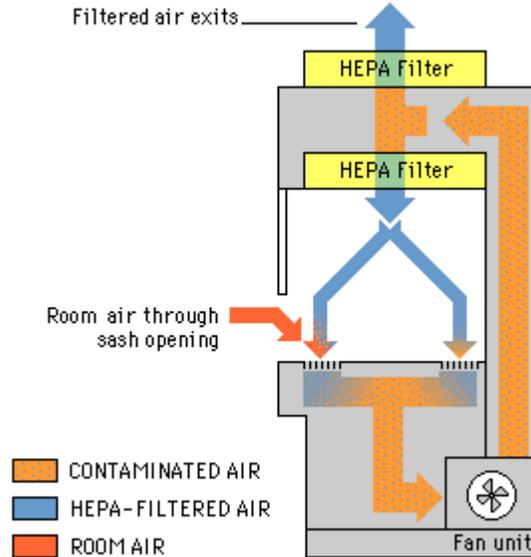
Biosafety cabinets are the primary control against potential aerosol exposure. They are primary containment devices designed to provide protection for both the worker and the environment, as well as provide a work environment free of contaminants. There are many types of BSCs available which offer various levels of protection. Information about the variety of types of biosafety cabinets can be found at http://www.cdc.gov/biosafety/publications/bmb15/BMBL5_appendixA.pdf.

Biosafety cabinets are certified once per year at a minimum, or after a cabinet has been moved within the facility or decontaminated.

Each BSC is examined and disinfected after each scientific procedure. The functionality of the HEPA filter is checked each time the BSC is used. The effectiveness of the biosafety cabinet is directly dependent on the manner in which users perform their work.

The effectiveness of the cabinet is a function of three separate directional airflows.

1. Inward airflow from the room through the front grille provides personal protection.
2. Downward airflow through a HEPA filter onto the work surface provides product protection.
3. Airflow out of the cabinet through an exhaust HEPA filter provides environmental protection.



Using the BSC

1. It is good microbiological practice to wipe down the cabinet work surface with disinfectant before beginning work.
2. Supplies needed for work should be placed into the cabinet and the cabinet allowed to run for 10 -15 minutes to establish proper airflow.
3. The vertical sash is kept below the indicated calibrated height.
4. Avoid creating turbulence in the cabinet by only placing those supplies needed for the experiment into the cabinet.
5. The work area should be set up with a workflow pattern of clean to dirty.
6. All air grates are kept clear, including the front and sides.
7. When work is finished, wipe down all surfaces with disinfectant.
8. If the BSC is not being used, keep the vertical sash down and shut the blower off.
9. Be sure to turn the blower back on, decontaminate and run for at least 10 minutes before resuming use.
10. Most biosafety cabinets use recirculated airflow; therefore hazardous chemicals cannot be used within them. A hard ducted biosafety cabinet may be appropriate for hazardous chemical use, however spark potential from the motor is still a concern for use with flammable material. No biosafety cabinets at Siamab are hard ducted.

Turbulence in the BSC

Turbulence may cause aerosols which can cross-contaminate open vessels or escape the cabinet and potentially cause exposure. Turbulence can be caused by various factors:

1. Blocking air flow grilles
2. Air current eddies caused by heat from Bunsen burners or other heat sources. (Bunsen burners should not be used in a BSC.)
3. Rapid movement of arms into or out of the cabinet
4. Rapid movement behind the worker and across the face of the cabinet

5. Down drafts from ventilation systems. BSCs should be located in areas away from ventilation intakes for this reason.
6. Cross drafts from opening doors near the BSC.

Air Flow

HEPA filters protect against particulates. Some BSCs have a digital gauge that monitors the performance of the filter and must read as stated on the certification label. If the reading varies from the certification reading, notify the Biosafety Officer so the filter can be replaced.

All BSCs at Siamab are recirculated air; no cabinets are hard ducted to roof exhaust. Therefore, use of hazardous chemicals is prohibited within the cabinet.

Motors and lights are not explosion proof, so flammables should not be used.

If the BSC alarm goes off, cap any tubes quickly and close the sash. Contact the Facility Manager and the Biosafety Officer for evaluation. Post the door with a “Do Not Enter” sign.

Other BSC Considerations

Nothing can be stored on top of the cabinet.

A biohazard label is posted on each BSC.

Sharps Containers

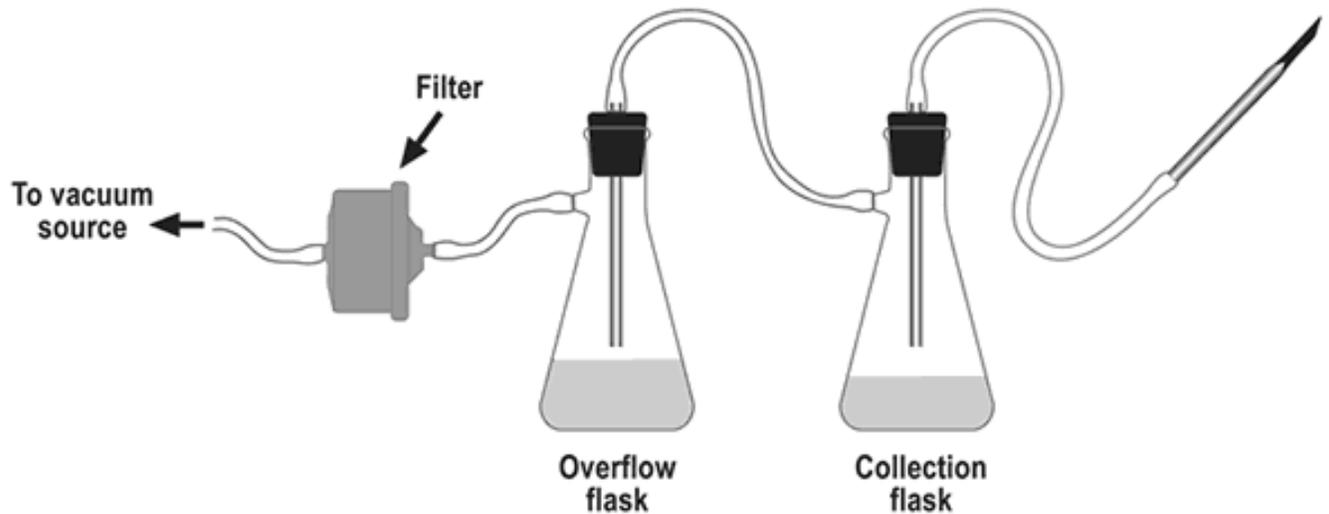
Sharps containers are made of puncture resistant material, typically polypropylene or plastic. Containers are examined and maintained after each procedure to ensure they are not compromised. When a container is full it is sealed and stored in the main lab near the rear exit until pick up by Stericycle. A new container is then put into service.

Aspiration Filters

Aspiration units used with Risk Group 2 or higher materials must be fitted with an in-line HEPA filter. This filter protects the house vacuum system, or pump, from potential contamination. The filter is checked before each procedure.

Aspiration Guideline

Protecting the vacuum line is one of the goals of proper aspiration set-up. The vacushield or other in-line filter, reduces risk of contaminating the in-house vacuum. The second line of defense is the overflow flask which is set up behind the primary collection flask. See the figure below for proper set-up, showing locations of the primary collection flask, the overflow flask, and the in-line filter.



Aspiration Work Practices

Always pre-measure disinfectant and add it to the collection flask before beginning work so that waste is disinfected as it is collected. Label the flask accordingly with biohazard waste and disinfectant name. Change the disinfectant daily, as appropriate.

If the collection and overflow flasks are on the floor, protect against breakage and use secondary containment to catch any spills.

When removing the stopper from the collection flask, work in the Biosafety Cabinet to prevent exposure from aerosols generated by splatter or splash.

Plexiglass Shielding

Plexi shielding, either in the form of a faceshield or a bench shield is used to provide protection from splash or splatter when working with materials outside of a BSC. Biohazardous work done on a bench instead of in a BSC must be reviewed and assessed by the Biosafety Officer prior to the initiation of work.

Plexi shields are examined and disinfected after each procedure.

9. WORK PRACTICES

Universal Precautions

When human source materials are used universal precautions must be adhered to. “Universal precautions” means treating material as if it is potentially infectious. When using universal precautions, one performs tasks using practices to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids are considered to be potentially infectious materials.

Non-Human Primate (NHP) Material

Due to the close genetic relationship between humans and NHP, which may lead to a greater occurrence of zoonosis, all work with NHP tissues must be handled at BL2. NHP material from Macaques may be contaminated with Herpes B Virus (aka B Virus). This potentially lethal zoonotic disease may be present in asymptomatic animals, and positive animals often do not present with circulating antibodies. For these reasons, all NHP material are handled at BL2 under universal precautions reasoning. Work with NHP material that is known to contain B Virus must undergo a full risk assessment and may be handled at a higher biosafety level. Exposures to NHP material must be cleaned immediately and medical advice sought.

Minimum Requirements for Work in a Biological Lab

1. Hands are washed immediately, or as soon as feasible, after removal of gloves or other personal protective equipment. Hand washing sinks are located in each laboratory.
2. Following contact with blood or other potentially infectious materials, hands and any other skin are washed with soap and water.
3. Contaminated needles and other contaminated "sharps" are not to be bent, sheared or broken.
4. Needle recapping is not permitted when working with human blood, body fluids or tissue. If recapping is absolutely necessary, perform a risk assessment, and use single handed recapping devices. Never bend, break, or sheer a needle. Never remove a needle from a syringe; dispose as a unit.
5. Immediately, or as soon as possible after use, contaminated sharps must be placed in puncture-resistant, labeled, leakproof containers. Sharps containers are located at each employee's lab bench. Full sharps containers are removed by the lab employee and kept by the rear door of the main lab. The medical/biohazardous waste is then shipped out for processing by a licensed medical waste transporter. The current medical waste transporter is Stericycle, Inc.
6. Eating, drinking, smoking, applying cosmetics, and handling contact lenses are prohibited in all lab work areas.
7. Food and drink are prohibited from lab and work areas including refrigerators, freezers, shelves, cabinets, countertops, and benchtops.
8. Avoid hand contact with your mouth, nose and eyes.
9. Protect wounds and dermatitis with bandages and gloves, and double glove.
10. All procedures involving blood, or other potentially infectious materials, are performed in

a manner that minimizes splashing, spraying, spattering, and generation of droplets of these substances. The following procedures have this potential and methods which will minimize these risks are given.

- a. Transfer liquid samples between containers in the biological safety cabinet or behind a benchtop safety shield.
 - b. Centrifuge liquid samples in tightly closed bottles, within covered centrifuge rotors, within covered centrifuges. Allow to settle for 10 minutes prior to opening on the bench or open in a biological safety cabinet.
 - c. Concentrate liquid samples under nitrogen pressure behind benchtop safety shields. The pressure release valve is covered with absorbent materials during pressure release.
 - d. When vortexing liquid samples, use test tube caps to cover samples. Place gauze around cap before opening.
 - e. When aspirating liquid samples, use an overflow flask and a HEPA filter for protection of vacuum lines. Remove stopper from waste flask in the biosafety cabinet.
11. Mouth pipetting is absolutely prohibited.
 12. Specimens of blood or other potentially infectious materials are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping. The container is closed prior to storing, transporting, or shipping. Specimens are labeled with the Universal Biohazard Symbol prior to transport from one location to another, both within and outside the facility. All packaging and shipping is in accordance with federal regulations.
 13. If outside contamination of the primary container occurs, the primary container is placed within a secondary container that prevents leakage during handling, processing, storage, transport, or shipping. If a specimen could puncture the primary container, the primary container is then placed within a secondary puncture-resistant container. Secondary containers are located in the lab areas and include closable, leakproof plasticware such as Tupperware® or Rubbermaid® containers.
 14. All equipment which may become contaminated with blood, or other potentially infectious materials, is examined by the employee prior to servicing or shipping and is decontaminated, as necessary, using standard disinfection methods. Appendix 7 outlines the schedule and process of equipment decontamination. If decontamination of the equipment or portions of such equipment is not feasible, a readily observable label with the Universal Biohazard Symbol is attached to the equipment stating which portions remain contaminated. This information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate prior to handling, servicing, or shipping so that the appropriate precautions are taken.

15. The use of sharps in the laboratory should be avoided as much as possible. Double edged razors are forbidden in the lab. If razors or scalpels are needed, sheaths must be used to cover the sharps when not in use. Box cutters should be used for opening packages and for cutting, when possible. If needles are used, they are never recapped, bent, sheared or broken. All needle/syringes are disposed as a unit; needles are not removed from a syringe before disposal. ALL sharps are disposed into a puncture resistant sharps container. Any sharps work with BL2 materials requires prior notification to the Biosafety Officer and documented training.
16. Substitute plastic for glass whenever possible in the lab. This reduces the sharps exposure risk.

Personal Protective Equipment (PPE)

Personal protective equipment is provided by the supervisor at no cost to the employee when there is potential for occupational exposure to biohazards. Appropriate personal protective equipment may consist of, but is not limited to, gloves, lab coats, gowns, eye protection, masks and faceshields. All personal protective equipment is to be readily accessible and available in the appropriate sizes.

Personal protective equipment will be available by the lab entrance and obtained by the employee as needed. Extra equipment is located in the lab storage area. Safety and facilities will ensure that the necessary equipment and clothing are available in these locations.

It is the employee's responsibility, when there is occupational exposure or the potential for exposure, to use the appropriate personal protective equipment and clothing.

General PPE guidelines

PPE guidelines apply to all labs, glasswash and media prep areas.

1. No open toed shoes or sandals are worn in the laboratory areas.
2. Personal attire that does not cover the entire leg area is discouraged.
3. Only low allergen, unpowdered non-latex gloves are used in the laboratories.
4. Protective eyewear will be worn in all labs and in the lab hallways.
5. PPE must not be worn out of the laboratory areas. Office areas and carpeted areas throughout the building are off limits for PPE.
6. **Never touch doorknobs with gloves, even if they are clean gloves!** This will lessen the chance of the spread of contamination.
7. If transporting material on a cart, do not touch the cart handle with gloves. Keep a box of gloves on the cart to use when touching the material.
8. Never transport or consume food or drink in the lab space. Lab space includes the laboratories themselves and the lab hallways.

BLI PPE REQUIREMENTS

Required PPE:

Safety glasses and lab coats, at all times

Gloves when working with hazardous materials, face shields for cryogenic work

Recommended PPE:

goggles when splashes or splatters can occur

BL2 PPE REQUIREMENTS

Required PPE: Safety glasses, buttoned lab coats, gloves; face shields for cryogenic work

Recommended PPE: Face shields and goggles when splashes or splatters can occur

Personal protective garments that are contaminated are to be removed immediately, or as soon as feasible, and prior to leaving the work area. Non-disposable lab coats which are visibly contaminated are placed in an autoclavable red bag or clear bag labeled with the Universal Biohazard Symbol as soon as possible by the employee. The bagged lab coat is placed in the autoclave room by the employee for disinfection and then placed in the receptacle for routine laundry pick-up by the laundry service. Unsoiled lab coats are removed and left in the work area prior to leaving the area. All lab coats will be laundered weekly. Disposable lab coats are placed in the biohazardous waste container.

Gloves are worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; and when handling or touching contaminated items or surfaces. Gloves are worn for all procedures involving blood, samples derived from blood, and other human materials. Gloves, of the appropriate type, are also worn when working with chemicals.

Disposable gloves are replaced as soon as practical when contaminated; or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Gloves are disposed of in the biohazardous waste containers located in the laboratory areas, and should not be placed in regular trash. Gloves are removed immediately after visible contamination and before leaving the work area.

Disposable gloves are not washed or decontaminated for reuse. Utility gloves (i.e. rubber household gloves) for housekeeping chores involving potential blood contact and for instrument cleaning and decontamination procedures may be used. Utility gloves may be decontaminated and re-used, but should be discarded if they are peeling, cracked, or discolored, if they have punctures or other evidence of deterioration, or if their ability to function as a barrier is compromised.

Safety glasses are required of all personnel in all laboratory areas. Chin-length face shields are worn whenever splashes, spray, splatter, aerosols or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated. The Safety Committee must evaluate situations that may require goggles in addition to a full faceshield when such operations cannot be performed behind a suitable shield or in a biosafety cabinet. Faceshields are disinfected when contaminated or disposed of in the biohazardous waste container. Non-contaminated face shields remain in the work area for future use. Safety glasses can be found near the main lab entrance. Faceshield can be found in the main lab.

Housekeeping

The worksite is maintained in a clean and sanitary condition according to a written schedule for cleaning and use of the proper methods of decontamination. The schedule and methods are based upon the location of the worksite within the facility, the type of surface to be cleaned, the type of soil present, and the tasks or procedures being performed in that area. The written schedule is located in Appendix 7.

All equipment and working surfaces are to be cleaned and decontaminated after contact with blood or other potentially infectious materials. Contaminated work surfaces are to be decontaminated with an appropriate disinfectant:

1. After completion of procedures
2. Immediately or as soon as feasible when surfaces are overtly contaminated
3. After any spill of blood or other potentially infectious materials
4. At the end of the work day

Protective coverings used to cover equipment and surfaces are removed and replaced as soon as feasible when they become contaminated. Bench paper with impermeable plastic backing or washable trays may be used to protect benchtop surfaces from contamination. If bench paper is used, once the paper is contaminated it is disposed of in the biohazardous waste container. Coverings are replaced on an as-needed basis or per the schedule in Appendix 7.

All reusable bins, pails, cans and similar receptacles, which have a reasonable likelihood of becoming contaminated with blood or other potentially infectious materials, are inspected and decontaminated on a regular basis as well as being cleaned and decontaminated immediately, or as soon as feasible, upon visible contamination. All biohazardous waste containers will be monitored, by the employee using the container, at least weekly. If contaminated or found to be leaking, they will be decontaminated and replaced, if necessary.

Disposal of all regulated waste is in accordance with the Massachusetts State Sanitary Code (105 CMR 480.000) and the waste disposal policies of Siamab.

Safer Sharps

Siamab must institute a safer sharps program for all employees that use sharps with human materials or OPIM. Since no one device will be appropriate or effective for all circumstances, employers must select devices that are based on reasonable judgment, such as

1. The sharp will not jeopardize employee safety or be medically inadvisable;
2. The sharp will make an exposure incident involving a contaminated sharp less likely to occur.

Employers must solicit input from those non-managerial employees responsible for the use of engineered controls regarding the identification, evaluation, and selection of those controls, including safer medical devices. The sharps evaluation form is located in Appendix 8. The employees selected should represent the range of exposure situations encountered in the workplace, such as those in research, safety, support staff, and others involved in the direct use of sharps.

Note: During inspections, OSHA will check for compliance with this provision by questioning a representative number of employees to determine if and how their input was requested.

Signs and Labels

Warning labels are affixed to containers of regulated biomedical waste, such as liquid or semi-liquid blood and other potentially infectious materials; refrigerators and freezers containing BL2 materials, blood or other potentially infectious materials; equipment used to manipulate BL2 materials, blood, or other potentially infectious materials; and other containers or storage areas used to collect, transport or ship this material. The biohazard symbol required by this standard is fluorescent orange or orange-red, with lettering or symbols in a contrasting color.



The required labels will be affixed as close as feasible to the container by string, wire, adhesive or any other method that would prevent their unintentional loss or removal.

Red bags must be used for the collection of biological waste. These bags must be marked with the universal biohazard symbol or the word “biohazard” in a contrasting color. Contaminated equipment should be labeled as to which part of the equipment is contaminated. Regulated waste that has been decontaminated does not have to be labeled.

Shipping

Shipping, transport and receipt of biological materials can be a complex matter if dealing with infectious or potentially infectious substances. The World Health Organization offers information for shipment of biological materials at

http://www.who.int/ihr/publications/who_hse_ihr_20100801_en.pdf. Appendix 9 lists various resources available to contact with questions about receipt and transport of regulated materials.

All biological shipments must conform to the Department of Transportation (DOT) and International Air Transport Association (IATA) requirements, as appropriate. Appendix 10 outlines such requirements for packaging and labeling of infectious materials and clinical specimen containers and can be used as guidance for preparing packages for shipment. However, any employee involved in packing, shipping, or signing manifests for these items must have DOT and IATA training as appropriate.

Cryogenics

Work with liquid nitrogen has potential safety hazards. If personnel are working with liquid nitrogen, which includes filling dewars or removing samples from deep freeze, the following precautions must be followed:

1. Work is done using a faceshield
2. Cryo gloves are used when handling liquid nitrogen
3. Employees do not change-out liquid nitrogen tanks unless trained to do so

Children in the Lab

Children under the age of 18 are not allowed in laboratories.

10. DECONTAMINATION

Laboratories are subject to contamination by infectious and non-infectious biological material. Frequent decontamination is necessary to 1) provide a work area that is suitable for good microbiological practices and 2) render contaminated material safe for handling.

There are three types of decontamination:

1. Sterilization
2. Disinfection
3. Antisepsis

Sterilization

Sterilization refers to the destruction of all forms of life on a particular item or in a particular area. Sterilization may be accomplished using steam or gas, (e.g. steam sterilizers or ethylene oxide autoclaves), radiation (e.g. ^{60}Co) or a liquid (e.g. glutaraldehyde, under certain conditions). Sterilization is used to process clean, prewrapped items in which the steam or gas can penetrate to reach all areas within the packaging. Sterilization is also used for liquids, like culture media, to ensure biological experiments are accurate. The use of sterile equipment, media, and techniques prevents unwanted microorganisms from contaminating cultures.

Most equipment, media, and sometimes waste materials, are sterilized in the steam autoclave. The autoclave can be used at various cycle lengths for different purposes. For example, the cycle time for dry goods sterilization will be shorter than for a liquid with a high protein load. As protein load increases, so does the cycle time for sterilization. Appendix 11 is a guide to autoclave use and safety.

Ethylene oxide sterilizers are also commonly used; usually in the healthcare industry for implants and other medical equipment. Ethylene oxide is a toxic gas and regulated by OSHA. There are guidelines in place to use ethylene oxide sterilizers safely and to keep exposure below the OSHA Permissible Exposure Limit.

Disinfection

Disinfection is the process of using antimicrobial agents on inanimate objects to destroy a large proportion (99.999%) of non-spore forming organisms that could pose a hazard to humans or compromise an experiment. Usually disinfection is performed with a chemical agent, but heat can also be a type of disinfection treatment for liquid materials.

There are many types of chemical disinfectants used in laboratories:

1. Chlorine based compounds, usually sodium hypochlorite solution (Bleach)
2. Alcohols, typically ethanol or isopropanol
3. Glutaraldehyde solutions
4. Iodophors, such as iodine
5. Phenol based solutions

6. Quaternary ammonium compounds

There is no universal disinfectant for all microbial agents. Some disinfectants are useful against many different types of microbes, others are used for very specific situations and agents.

Various hazards exist for each type of chemical disinfectant. A risk assessment is performed for all agents in use to determine which disinfectant is effective against the agent in question, under the conditions found in the lab or in the given solution, at the lowest hazard to the individual using it. Appendix 12 gives a broad overview of common chemical disinfectants and the types of microbe that each is effective against as well as the hazards associated with each.

Disinfectants for Work Surfaces and Reusable Items at Siamab.

The following disinfectants are acceptable for work surfaces and reusable items at the prescribed concentrations:

1. 10% solution of bleach. The shelf life of diluted bleach is only a few hours, so bleach should be diluted fresh immediately before use, or daily at a minimum.
2. 70% solution of ethyl or isopropyl alcohols. The shelf life of diluted alcohol is about a month.

Disinfectants for Waste at Siamab.

The following disinfectants are approved for liquid waste decontamination at the prescribed concentrations:

1. Bleach to a final concentration of 10% in liquid waste. This disinfectant is best for human source materials. If the protein load is high in the liquid waste that is being disinfected, a 20% final concentration is necessary.

See section 11, Regulated Waste, for specific procedures.

Disinfectants for Spill Clean-up at Saimab.

For all spill cleanup, a fresh solution of 10 to 20% bleach should be prepared. A 70% ethanol rinse solution can follow bleach when cleaning up a spill. Do not, under any circumstances substitute methanol for this step. Methanol and bleach form an incompatible mixture, which can be potentially explosive. Approximately twice the volume of disinfectant to the volume of the spill should be used. See section 15, Emergency Procedures, for more guidance on spill cleanup.

Antisepsis

Antisepsis is the application of a liquid chemical antimicrobial agent to living human or animal tissue. This chemical agent is intended to inhibit or destroy the growth of potentially infectious organisms. Handwashing with antimicrobial soap after exposure to a biological material is an example of antisepsis.

11. REGULATED WASTE

Sharps

Needles, scalpels, glass Pasteur pipettes, plastic serological pipettes, pipette tips, broken glassware, and any other material which would puncture biohazard bags are placed in a puncture resistant, rigid receptacle. There are two types in the labs: larger floor models and smaller bench-top model. All sharps containers are red in color and labeled with the Universal Biohazard Symbol.

Full sharps containers are stored in the main lab by the rear door until pickup by Stericycle.

Red Bag Medical Waste

Dry waste that is contaminated with biohazardous material is considered red bag waste. This includes all paper, plastic, petri dish cultures, test tubes and conical tubes. No loose sharps are allowed in red bag waste and only a very limited quantity of liquid is allowed. Trace chemotherapy agent waste is allowed in red bag waste, however these boxes must be labeled for incineration only. Full, sealed disposable bench-top sharps containers may be disposed of in red bag waste. All red bag waste is placed in a double-bagged cardboard Stericycle receptacle with the Universal Biohazard Symbol on it. Plastic, flip top lids are required on the boxes in the BL2 labs.

Full containers are sealed and stored in the main lab by the rear entrance until picked up by Stericycle.

Liquid Waste

For liquid waste decontamination, use the following concentration of disinfectant and allow for 30 minutes of contact time prior to sink disposal:

1. Bleach: 10% final concentration in liquid waste (sodium hypochlorite solution). This disinfectant is best for human source materials. For waste that has a high organic load, a 20% concentration of bleach is necessary.
2. Wescodyne: 0.5% final concentration in liquid waste (iodophor disinfectant / detergent). This is acceptable for tissue culture media, etc. but not for any human source materials.
3. To disinfect waste properly, a 30 minutes contact time is necessary for all liquids prior to sink disposal.

Liquid waste containing no chemical components may also be autoclaved prior to sink disposal. Each cycle and its parameters must be recorded in the biological waste log book. Quarterly challenge testing must be performed, and maintenance records kept for the autoclave.

All in-house methods of waste treatment must be approved by the Institutional Biosafety Committee. The biological waste log must be filled out for both solid and liquid waste, to be in compliance with the MA sanitary code 105 CMR 480.000.

Glass

Non-hazardous, non-contaminated intact and broken glass can be placed in the blue and white cardboard containers labeled as “CLEAN, BROKEN GLASS DISPOSAL”. Broken glassware is not to be picked up directly with the hands. Long forceps or dustpan/scrapers are utilized and these items must be decontaminated after use. **NO BIOHAZARDOUS AGENTS** are allowed in the blue and white glass bins.

Regular Trash

No biohazards, chemicals, broken glass, sharps, or gloves are allowed in the regular trash receptacles.

12. TRAINING

General Biosafety

Supervisors are to ensure that employees with occupational exposure to biological material participate in a training program that is provided at no cost to the employee. Employees are to complete the training at the time of initial assignment to tasks where occupational exposure may take place, or when there is a change in an employee's responsibilities, procedures, or work situations which places them at risk of such exposure, and at least annually thereafter.

Annual training will be carried out by the Biosafety Officer or Safety Consultant.

Training aids will consist of power-point slides, copies of in-house policies and other written materials to supplement the training.

Training materials are located in the Central Safety Files at Siamab.

Training records are maintained by the Biosafety Officer.

Copies of all policies and procedures as outlined in this manual are provided to each affected employee. These can be found in the central safety files.

Bloodborne Pathogens

All employees working with human source materials or OPIM must receive training on Bloodborne Pathogens, including specifics of Hepatitis B, HIV and Hepatitis C upon employment or assignment to tasks involving the potential for occupational exposure.

OSHA requires annual retraining.

The specifics of Bloodborne Pathogens Training is given in Appendix 13.

Training Records

All training sessions are documented in writing with training records kept in the central safety files by the Biosafety Officer for at least 3 years from the date of the training. The training record includes dates of training sessions, content of training sessions, names of persons conducting training sessions, and the name, signatures and job titles of all persons attending training sessions.

Medical Records

Confidential medical records for employees with occupational exposure are kept by Mt Auburn Occupational Health for the duration of their employment plus 30 years. Medical records include:

1. Employee's name and social security number
2. Employee's hepatitis B vaccination status, including vaccination dates and any medical records related to the employee's ability to receive vaccination
3. Results of examinations, medical testing, post-exposure evaluation and follow-up procedures
4. Written opinions of healthcare professionals
5. Copies of information provided to healthcare professionals

Sharps Injury Log

The sharps injury log will be maintained in a manner that protects the privacy of employees. At a minimum, the log will contain the date and time of the incident, the type and brand of device involved in the incident, location of the incident, and description of the incident. The Sharps injury log is contained in Appendix 14.

Safer Sharps Program

The Needlestick Prevention Act and Bloodborne Pathogens Standard require employers to evaluate safer sharps when used with human source materials (see section 10, Work Practices, for details of the program). The Safer Sharps Program will be documented with employee questionnaires and by physically evaluating newly engineered products on the market. The employer will provide the employee with the safest sharp appropriate for the job function at no cost to them.

13. MEDICAL SURVEILLANCE AND VACCINATIONS

Occupational Health Center

Siamab makes the Hepatitis B vaccination series available to all employees who may potentially have occupational exposure, and extends post-exposure evaluation and follow-up to all employees who have had an exposure incident.

All medical evaluations and procedures, including the Hepatitis B vaccine and vaccination series, post-exposure evaluation and follow-up, and prophylaxis, are made available at no cost to the employee.

Hepatitis B Vaccination

The Hepatitis B vaccination form is given in Appendix 15. All employees with anticipated exposure to blood, tissue or other OPIM must accept or decline the vaccine and sign the form.

Employees receiving the Hepatitis B vaccine will follow procedures as outlined and required by Mt Auburn Occupational Health Center.

The vaccination series is administered by a nurse or practitioner at Mt Auburn Occupational Health Center. The vaccination is safe and effective and given as a 3 shot series at no cost to the employee.

The Biosafety Officer has the responsibility to ensure that the vaccination is offered within 10 days of the employee falling under the bloodborne pathogen standard, and declinations are documented appropriately.

Post-Exposure Evaluation and Follow-Up

Mt Auburn Occupational Health will provide post-exposure evaluation, treatment, and follow-up, after the report of an exposure incident.

All exposures will be reported immediately to the supervisor and the Biological Safety Officer. In addition, an incident report must be filled out within 24 hours. Appendix 16 is the Incident Report for Occupational Exposure to Human Materials or OPIM.

The employee will wash the exposed area thoroughly with soap and water and will be transported by taxi or ambulance to Mt Auburn Occupational Health or the Emergency Room for evaluation and treatment of the exposure.

A healthcare professional's written opinion may be obtained in the following situations: 1) when employee is sent to obtain the Hepatitis B vaccine, 2) whenever the employee is sent to a healthcare professional following an exposure incident. Written opinions will follow Occupational Health Center policy.

All medical records relating to post-exposure evaluation and follow-up are confidential.

Mt Auburn Occupational Health Center will monitor post-exposure policy effectiveness and maintain records related to this policy.

Serum Storage Medical Surveillance

Mt Auburn Occupational Health will provide serum storage for those employees designated for medical surveillance. This may be required as part of a recombinant DNA registration or for those employees working at BL2 Enhanced containment with viral agents. Mt Auburn Occupational Health Center can be contacted to evaluate situations that may warrant serum storage.

14. EMERGENCY RESPONSE

It is important to summon help immediately in the event of a medical emergency or life threatening exposure incident. For any emergency that is life threatening:

1. Yell “help” to get another person to aid in the situation
2. Dial 911 to get immediate help from emergency responders

All emergencies are reported immediately to the supervisor. Biological exposure emergencies are reported to the Biological Safety Officer as well.

Resource Information

Red emergency binders include information on emergency response, evacuation response and biological spill response, among other things. The red binder should be used if there is an emergency and immediate action must be taken.

An emergency phone list is posted by all laboratory phones. The list includes the contact information for various emergency services, including:

1. Hospital emergency room information
2. Mt Auburn Occupational Health contact and fax numbers
3. Emergency Coordinator contact information
4. Safety Officer contact information
5. Safety consultant contact information, if applicable
6. Spill contractor information

Exposure Response

Immediate response to a biological exposure is necessary to prevent possible infection.

If an exposure to a biological material occurs, it is important to identify the material immediately and obtain a sample for evaluation if it has not been previously tested. If testing data is available in the safety records or from the supplier, obtain the results immediately.

In general, follow the guidelines below for immediate response to biological exposure:

<i>Eye Splash:</i>	Hold eye open at eyewash station and rinse for 15 minutes
<i>Needlestick:</i>	Use soap and wash exposed area for 15 minutes in a lab sink. Report immediately and go to Occupational Health or the ER for consultation.
<i>Skin Exposure:</i>	Use soap and wash exposed area for 15 minutes in a lab sink or safety shower.
<i>Open Wound Exposure:</i>	Massage and apply gentle pressure to force bleed cut. Rinse well with clean water and continue to force bleed cut.
<i>Mucous Membrane Exposure:</i>	Rinse area, to the best of your ability, with clean water.
<i>Exposure to Clothing:</i>	Remove clothing that has been contaminated and if material soaked through to the skin, wash exposed skin as explained above.

All overt exposures from parenteral inoculation and/or exposure to mucous membranes **MUST** be reported immediately to the supervisor and biological safety officer. Medical attention must be promptly sought for any exposures of this type, but especially for exposures to human source materials. Counseling regarding the risk of infection should be given by a medical professional, either at the emergency room, or Mt Auburn Occupational Health Center.

All exposures are reported on an incident report form with 24 hours of the incident. Incident report forms can be found in the last section of the emergency binder and on the network in the Emergency Preparedness folder within the shared safety files.

It may be suggested by the medical professional to obtain a Hepatitis B vaccination or prophylaxis following exposure to human source materials. It may also be suggested to begin a drug regimen to minimize the chance of HIV seroconversion, which must be given within a short time after exposure to known HIV positive material. A medical professional must be consulted as soon as possible after exposure to counsel the exposed employee appropriately.

Spills

Spill supplies for biological spill cleanup can be found in the spill kit in the main lab. Bleach can be found under every sink in the lab. Supplies for biological spills include the following:

1. At least 1 gallon of bleach. Periodically check the date on all bleach bottles to be used for spill cleanup to ensure that they are not expired.
2. Other appropriate disinfectant, if bleach is not a proper disinfectant for the material you are using. Bleach is not effective for every type of biological hazard, but is useful for most.
3. Paper towels, or other absorbents
4. PPE should be available in the lab, such as a lab coat, gloves, and face shield or goggles.
5. Biohazard bags must be available to contain spill materials.
6. Forceps or a dust pan and broom must be available to pick up contaminated sharps items, such as needles, broken glass or broken, rigid plastic items.

Containing biological spills, and especially aerosols produced by a spill, is extremely important to the safety of individuals cleaning a spill. Precautions must be taken to avoid spreading contamination while performing biological spill cleanup. All waste produced from the cleanup must be disposed of as biological hazardous waste.

Spills of BLI Materials

1. Wash hands and exposed skin immediately if you have been exposed to the spill.
2. Personal Protective Equipment (PPE) must be worn during spill cleanup. A lab coat, safety glasses, and gloves are required. Booties, goggles and face shields should be used as necessary, depending on the volume of the spill and the possibility for splash, splatter or formation of aerosols.
3. Assemble the spill kit materials before attempting spill cleanup.
4. Surround the spill with bleach so that the disinfectant can be mixed into the spill using paper towels. A ring of bleach around the spill will keep the spill from spreading.

5. Place absorbent materials, like paper towels, over the spill once the disinfectant has been mixed into the spill.
6. Add bleach over the paper towels to produce an estimated volume to volume concentration of 1:10, bleach to spill ratio.
7. Allow contact time of at least 30 minutes for disinfection of the spill.
8. Wipe up the spill and dispose of used clean-up materials in the biohazardous waste containers.
9. Dispose of any sharps into puncture resistance "sharps" containers. Never pick up sharps with your hands; use a dustpan and broom or tongs to handle sharps.
10. Clean the spill area with a soapy solution after all materials have been picked up and placed in the appropriate waste containers. This step is necessary to remove any protein substances left on surfaces from the spill.
11. Clean the area one more time with a freshly prepared 10% bleach solution. A 10% bleach solution can be prepared by adding 100ml of regular household bleach to 900ml of water. If using industrial strength bleach, read the label and dilute accordingly to a final concentration of 5,000 ppm chlorine. (Most household bleach is 52,500 ppm chlorine).
12. Follow with a final rinse of water or 70% ethanol to remove bleach residue.
13. Reusable items used in spill cleanup must be disinfected or autoclaved prior to returning to the biological spill kit location.

Spills of BL2 Materials

For spills of BL2 materials, or any BL1 spill that may produce aerosols, use the above listed BL1 spill procedures plus:

1. Leave the lab quickly and evacuate all personnel from the lab. Close the door and post a "no entry" sign.
2. Put any contaminated lab coats and clothing in a red biohazard bag before leaving the lab if it is safe to do so. Seal the biohazard bag and label it with your name, date and identity of the contents. Contact the Biosafety Officer about the spill and potential contamination. Contaminated clothing will need to be autoclaved before being sent to the launderer.
3. Allow 30 minutes for aerosols to settle before reentering the lab and proceeding with clean-up.
4. Contact your Supervisor, Biosafety Officer and a Safety Team Member to discuss the logistics of clean-up.
5. Always wear personal protective equipment, including a lab coat, gloves and safety glasses. Booties, a face shield or goggles may be appropriate depending on the volume of the spill.
6. While cleaning the spill, avoid splashing or splattering the materials, which can produce aerosols.
7. Pour disinfectant, preferably bleach, in a ring around the spill to stop the spread of biological contamination. Let the disinfectant flow into the spill and use paper towels to mix the disinfectant into the spill. Make sure you include any areas where aerosols may have settled.
8. Place a layer of paper towels over the spill and pour disinfectant over the center of the

towels. The paper towels will reduce any splash or splatter that may occur if you added the disinfectant directly into the spill.

9. Allow 20 to 30 minute contact time before wiping up gently. Remove any sharps or broken glass by an indirect method, such as tongs, a dustpan and broom or a scoop. Any re-usable materials must be autoclave sterilized before returning to the spill kit.
10. Once the area is cleaned of the bulk of the biological spills, clean the area with a soap and water or detergent solution to break up any protein remaining on the surfaces. Follow this with a second application of disinfectant to ensure proper disinfection of the surfaces.

Spills in a Biosafety Cabinet (BSC)

The main protection from biological spills in a BSC is the HEPA filter. If there is a spill in the BSC, check the operation of the HEPA filter by looking at the magnehelix before attempting any spill cleanup. Make sure the magnehelix indicates that the filter is operating appropriately.

1. Put on clean gloves, a lab coat and safety glasses. Proceed with decontamination while the cabinet continues to run.
2. Spray down cabinet surfaces and equipment with the preferred disinfectant and wipe all surfaces. If using bleach, follow these procedures with a water or 70% ethanol rinse to reduce corrosion of the metal surfaces.
3. If possible, lift the front exhaust grille and tray, spray with disinfectant and wipe. If you cannot lift the front grill, flood the drain pan beneath the work surface with disinfectant and allow 20 - 30 minutes contact time before draining.
4. Call the Biosafety Officer or the Emergency Coordinator if the spill is inaccessible or contaminates a filter.

Biological Mixed Spills

In general, biological mixed spills should be treated as follows:

Biological and chemical spills: use a disinfectant that is compatible with the spilled chemical to kill the biological material and then treat as chemical waste.

Consult both the Biosafety Officer and the Chemical Hygiene Officer for all mixed spills.

15. GLOSSARY OF TERMS AND ACRONYMS

AMPHOTROPIC VIRUS: An RNA tumor virus, or oncovirus, that does not produce disease in its natural host, but does replicate in tissue culture cells of the host species and in cells from other species.

ANSI: American National Standards Institute

BIOSAFETY OFFICER: also known as Biological Safety Officer or BSO, oversees and gives safety input for all biological work done in the facility. See section 2 for site specific details.

BL: Biosafety Level

BLOOD: Human blood, blood components, and products derived from blood.

BLOODBORNE PATHOGENS: Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

BMBL: *Biosafety in the Microbiological and Biomedical Laboratory*

BSC: Biosafety cabinet

CDC: Centers for Disease Control

EBV: Epstein Barr Virus

ETIOLOGIC: Cause or origin of disease

EXPOSURE INCIDENT: A specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious or biohazardous material that results from the performance of an employee's duties.

HUMAN CELL LINE: An **in vitro** or animal-passaged culture or human cells that fulfill traditional requirements of a **cell line** designation. That is, the cells are **immortalized** cells, transformed by spontaneous mutation or natural or laboratory infection with an immortalizing agent such as Epstein-Barr virus (EBV). Note: EBV is a bloodborne pathogen.

HUMAN CELL STRAINS: Cells propagated **in vitro** from primary explants of human tissue or body fluids which have finite lifetime (non-transformed) in tissue culture for 20-70 passages. Human cell "strains" must be handled as potential biohazards unless characterized by testing to be free of bloodborne pathogens.

HYBRIDOMA CELL LINES: Immortalized cell lines created by fusion of primary cells with a continuous cell line.

MURINE: Relating to, affecting, resembling or derived from a rat or mouse.

NEEDLELESS SYSTEMS: Devices, for various procedures, that provide an alternative to needles and reduce the risk of injury involving contaminated sharps. Examples include:

1. IV medication systems which administer medication or fluids through a catheter port using non-needle connections; and
2. Jet injection systems which deliver liquid medication beneath the skin or through a muscle.

NIH: National Institutes of Health

OCCUPATIONAL EXPOSURE: Reasonably anticipated skin, eye, mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious or biohazardous material that may result from the performance of an employee's duties.

ONCOGENIC: Causing or tending to cause the formation and development of tumors.

ONCOVIRUS: An RNA tumor virus.

OTHER POTENTIALLY INFECTIOUS MATERIALS (OPIM):

1. Body fluids and secretions including semen, vaginal, cerebrospinal, synovial, pleural, pericardial, peritoneal, and amniotic; saliva in dental procedures, and 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.

PI: Principal investigator

POLYTROPIC VIRUS: Infectious for both murine and nonmurine cells.

RECOMBINANT DNA MOLECULES: Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or the molecules that result from that replication.

REPLICATION COMPETENT VIRUS: Able to replicate or reproduce.

SAFETY COMMITTEE: An organizational structure where members represent all affected groups within the company to ensure that safety issues are addressed. This gives everyone a voice and should include an effective number of participants to address and enforce all issues.

SHARPS WITH ENGINEERED SHARPS INJURY PROTECTIONS: Non-needle sharps or needle/scalpel/knife devices which contain built-in safety features that are used for collecting fluids, administering medications or other fluids, or for other procedures that involve the risk of sharps injury. This description covers a broad array of devices, including:

1. Syringes with a sliding sheath that shields the attached needle after use;
2. Needles that retract into a syringe after use;
3. Shielded or retracting catheters;
4. Intravenous medication (IV) delivery systems that use a catheter port with a needle housed in a protective covering.
5. Retractable blade scalpel or Exacto knife

SOURCE INDIVIDUAL: Any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee.

UNIVERSAL PRECAUTIONS: An approach to infection control. All human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens.

XENOTROPIC VIRUS: Also known as zentropic virus. A virus that can grow in the cells of a species foreign to the normal host species, a species different from that which normally hosts it.

16. REFERENCES

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APPENDIX I SUMMARY TABLE FOR BL1 – BL4

Table 2. Summary of Recommended Biosafety Levels for Infectious Agents

BSL	Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in healthy adults	Standard microbiological practices	<ul style="list-style-type: none"> ■ No primary barriers required. ■ PPE: laboratory coats and gloves; eye, face protection, as needed 	Laboratory bench and sink required
2	<p>Agents associated with human disease</p> <p>Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure</p>	<p>BSL-1 practice plus:</p> <ul style="list-style-type: none"> ■ Limited access ■ Biohazard warning signs ■ “Sharps” precautions ■ Biosafety manual defining any needed waste decontamination or medical surveillance policies 	<p>Primary barriers:</p> <ul style="list-style-type: none"> ■ BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials ■ PPE: Laboratory coats, gloves, face and eye protection, as needed 	<p>BSL-1 plus:</p> <ul style="list-style-type: none"> ■ Autoclave available
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	<p>BSL-2 practice plus:</p> <ul style="list-style-type: none"> ■ Controlled access ■ Decontamination of all waste ■ Decontamination of laboratory clothing before laundering 	<p>Primary barriers:</p> <ul style="list-style-type: none"> ■ BSCs or other physical containment devices used for all open manipulations of agents ■ PPE: Protective laboratory clothing, gloves, face, eye and respiratory protection, as needed 	<p>BSL-2 plus:</p> <ul style="list-style-type: none"> ■ Physical separation from access corridors ■ Self-closing, double-door access ■ Exhausted air not recirculated ■ Negative airflow into laboratory ■ Entry through airlock or anteroom ■ Hand washing sink near laboratory exit
4	<p>Dangerous/exotic agents which post high individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments</p> <p>Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to redesignate the level</p> <p>Related agents with unknown risk of transmission</p>	<p>BSL-3 practices plus:</p> <ul style="list-style-type: none"> ■ Clothing change before entering ■ Shower on exit ■ All material decontaminated on exit from facility 	<p>Primary barriers:</p> <ul style="list-style-type: none"> ■ All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure suit 	<p>BSL-3 plus:</p> <ul style="list-style-type: none"> ■ Separate building or isolated zone ■ Dedicated supply and exhaust, vacuum, and decontamination systems ■ Other requirements outlined in the text

Reference: *Biosafety in Microbiological and Biomedical Laboratories*, CDC/NIH

APPENDIX III Newton Recombinant DNA Research Regulations

Newton Sec. 12-21. Regulation of recombinant DNA technology.

(a) All recombinant deoxyriboneucleic acid (DNA) research or technology in the City of Newton shall be undertaken only in strict conformity with the "Guidelines", so called, of the National Institutes of Health (NIH), by other Federal Agencies, or by Act of Congress, and in conformity also with such other health regulations as the commissioner of health and human services may from time to time promulgate or as the Newton biosafety committee (NBC) may adopt.

(b) In the context of this article the following definitions are adopted:

(1) Recombinant DNA molecules (rDNA), and organisms and viruses containing rDNA, are those defined in the NIH Guidelines promulgated in the Federal Register on July 1, 1981.

(2) An institution is any person, group of persons, business entity, association or any other organization, whether public or private, for profit or non-profit.

(3) Guidelines are defined as:

a) National Institutes of Health Guidelines for Research involving Recombinant DNA Molecules, published in the Federal Register on August 27, 1982, and any subsequent federal amendment thereto recommended by the commissioner of health and human services and approved by the NBC.

b) National Institutes of Health Physical Containment Recommendations for Large Scale Use of Organisms Containing Recombinant DNA Molecules, as published in the Federal Register of April 11, 1980, and any subsequent federal amendment thereto recommended by the commissioner of health and adopted by the NBC.

c) Administrative Practices Supplement to the NIH Guidelines for Research Involving Recombinant DNA Molecules, as issued by the Office of Recombinant DNA Activities, November, 1980, and any subsequent federal amendment thereto recommended by the commissioner of health and human services and adopted by the NBC.

(4) Large-scale means the use, for the purpose of containing recombinant DNA culture media, of any stainless steel vessel which has a volume greater than sixteen liters, or such use of any non-stainless steel vessel which has a volume greater than ten liters. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 5-26-2005)

Sec. 12-22. Newton biosafety committee.

(a) There shall be a Newton biosafety committee (NBC) which shall be comprised of nine (9) members which include the following:

The commissioner of health and human services;

Two (2) members of the Newton health advisory council, appointed by the commissioner of health;

Three (3) members appointed by the mayor, at least one of whom is a scientist knowledgeable in the

field of rDNA research and technology. The other two shall represent the fields of public health, occupational health, infectious disease or environmental health.

Three (3) members appointed by the board of aldermen, at least one of whom represents the fields of public health, occupational health, infectious disease or environmental health.

Members appointed by the mayor and the board of aldermen shall serve three (3) year terms; provided however, that of the first three members appointed to the committee by the mayor and the board of aldermen one shall serve for a term of one (1) year, one shall serve for a term of two (2) years, and one shall serve for a term of three (3) years. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-06)

Sec. 12-23. Institutional biotechnology committee.

(a) An institutional biotechnology committee (IBC) must be established for each institution conducting rDNA research or technology. The IBC shall include the commissioner of health and human services and two community representatives with expertise in rDNA research and technology and/or safety issues. One of these representatives shall be appointed by the mayor and one shall be appointed by the board of aldermen for a term of three years. The IBC shall meet at least once a year. Each institution shall name at least three (3) members of its staff to the IBC, including the safety officer.

(b) The IBC shall inspect each facility conducting rDNA research or technology annually and meet at least once annually to enforce these regulations. Each institution shall name a safety officer who shall be responsible for enforcing the policies of the IBC. In addition, the IBC shall immediately notify the commissioner of health and human services and the NBC upon discovery of non-compliance by the institution with any section of this ordinance or the NIH guidelines. (Ord. No. R-237, 3-15-82; Ord. No. T319, 12-20-93; Ord. No. X-175, 05-26-05)

Sec. 12-24. Permit requirement.

(a) All institutions planning to conduct rDNA research or to use rDNA technology must obtain a permit from the commissioner of health and human services with the prior approval of the NBC, before commencing said research or technology. Institutions receiving such permits shall conduct research or technology only as specifically set out in its permit application and supporting documents filed with such application.

(b) All institutions requesting a permit from the commissioner of health and human services to commence rDNA research or technology in the Limited Manufacturing Zoning District (Sec. 30-12), the Manufacturing Zoning District (Sec. 30-12), and the Mixed Use 1 and 2 Zoning Districts (Sec. 30-13), must also receive a special permit from the board of aldermen pursuant to section 30-24 prior to the original issuance, but not the renewal, of said permit. Institutions seeking such permit from the commissioner of health and human services must first submit the following to the NBC:

- (1) A completed application form obtained from the Newton health and human services department.**
- (2) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.**
- (3) A listing of all organisms, including containment levels, to be employed in rDNA research or technology, and including the screening process to be performed by institutions conducting rDNA research or technology in order to insure the purity of the strain of host organisms used in the experiments and to test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics. Host organisms obtained from independent laboratories shall undergo the same screening process.**
- (4) A plan for systematic monitoring of waste to assure that surviving rDNA organisms will not be released into the environment.**
- (5) Establish a training program of safeguards and procedures for personnel using rDNA;**
- (6) The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the IBC for all persons engaged in the use of rDNA. Such programs shall include, but shall not necessarily be limited to:**
 - a) A pre-employment medical examination for employees. Facilities using rDNA research or technology requiring BL2 or BL3 as defined in the National Institutes of Health (NIH) guidelines published in the Federal Register, as amended, physical containment, or large scale use, shall take employee serum samples at the time of employment and maintain said samples to permit future testing for at least ten years.**
 - b) Prompt reporting of significant or potentially related employee illnesses to the IBC.**
 - c) Retention of medical and health records for at least ten years. Medical or employee health records shall be made available for inspection and may be used for public health studies.**
 - d). Effective rodent and insect control programs must be in place.**
- (7) The name of the safety officer who shall be responsible for enforcing the policies of the IBC.**
- (8) A plan for orienting representatives of the Newton health and human services, fire and police departments to the physical plant and to procedures to be utilized in the event of an emergency.**
 - (c) The NDC shall review the institution's application for a permit and supporting documents and make its recommendation of the same to the commissioner of health and human services.**
 - (d) Not later than sixty (60) days after an institution has commenced rDNA research or technology as determined by the commissioner of health and human services, the institution shall file with the commissioner:**
 - (1) The names and qualifications of members of IBC.**
 - (2) Copies of Newton building department and Newton fire department certification.**
 - (3) Evidence of certification, as necessary, from the Massachusetts Department of Environmental Quality Engineering and the Massachusetts Department of Public Health.**
 - (e) Permits granted by the commissioner of health and human services shall be renewed**

annually.

(f) The fee for a permit granted by the commissioner of health and human services, or annual renewal thereof, shall be \$250. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No.X-175, 05-26-05)

Sec. 12-25. Inspection and review.

(a) The institution shall allow inspections and review of the procedures and practices of rDNA use for compliance with this ordinance.

(b) The Newton health and human services department shall retain a competent professional person, agency or institution to perform inspections and review. The results shall be reported to the commissioner of health and human services, the NBC and the institution involved.

(c) Inspections will be conducted at least annually.

(d) The institution shall reimburse the city for the direct expense of inspections and review. (Ord. No. R237, 3-15-82; Ord. No. X-175, 05-26-05 Sec. 12-26. Procedure for requesting and holding a hearing.

Institutions denied a permit, or the renewal thereof, or any person aggrieved by the granting of a permit, may request a hearing by filing a written petition with the commissioner of health and human services within ten (10) days from the denial or grant of a permit. Upon receipt of such petition the commissioner of health and human services shall set a time and place for such hearing and shall so inform the petitioner, and the institution if other than the petitioner, in writing. At the hearing the petitioner shall be given an opportunity to be heard and to show why the permit should be granted or denied. (Ord. No. R-237, 3-15-82; Ord. No. X-175, 05-26-05)

Sec. 12-27. Appeal.

Any institution or person aggrieved by the final decision of the commissioner of health and human services with respect to the denial or grant of a permit may seek relief therefrom in any court of competent jurisdiction, as provided by the laws of this commonwealth. (Ord. No. R-237, 3-15-82)

Sec. 12-28. Restrictions.

Recombinant DNA use requiring physical containment greater than the BL3 level shall not be permitted in the City of Newton. (Ord. No. R-237, 3-15-82)

Sec. 12-29. Violations.

An institution which violates any provision of this article shall be subject to a fine of three hundred dollars (\$300.00) per offense, each day of violation constituting a separate and distinct offense. The commissioner of health and human services shall be empowered to enforce this ordinance in any court of competent jurisdiction. In addition to a fine, an institution which violates any provision of this ordinance or whose continued conduct of recombinant DNA technology poses an immediate threat to the public health or environment may be closed by the commissioner of health and human services. Any institution aggrieved by such action of the commissioner of health and human services shall appeal the same under the provisions of Sections 12-25 and 12-26. (Ord. No. R-237, 3-15-82; Ord. no. X-175, 05-26-05)

Sec. 12-30. Severability.

If any provision(s) or portion(s) of this article or the application of any provision(s) or

portion(s) thereof to any person or circumstance is/are held to be invalid, such invalidity shall not affect the validity of the remainder of said provision or other provisions of this article. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-06) Secs. 12-31—12-39. Reserved.

APPENDIX IV RECOMBINANT DNA REGISTRATION FORM -



Institutional Biosafety Committee
90 Bridge St. Suite 100
Newton MA 02458
(800) 513-1569

Recombinant DNA (rDNA) Project Registration Form

Protocol Number:

Title:

Principal Investigator:	
Address:	
Phone:	
Fax:	
Email:	
Home Phone:	

The signatures below represent the acceptance of responsibility for completeness of this project registration form, and compliance with all local, state and federal regulations and laws pertaining to the use of rDNA covered under this protocol. Copies of this protocol must be provided to the individuals working under it and to other Siamab staff as requested or required.

Principal Investigator's Signature: _____ **Date:** _____

Program Director Signature: _____ **Date:** _____

This protocol has been reviewed and accepted by the Siamab Institutional Biosafety Committee (IBC). Please note that approval is not final until the principal investigator receives written confirmation of the approval.

IBC Chairman: _____ **Date:** _____



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A. Project Classification

Please review the NIH Guidelines for Research Involving Recombinant DNA Molecules and then check the appropriate level for this project registration in the chart below.

Check	Level	Approval/Review	Examples
	III-A	NIH Director, RAC, IBC	A drug resistant gene transferred into a (new) microorganism.
	III-B	NIH/OBA, IBC	The cloning of toxin molecules with LD ₅₀ < 100 ng/kg of body weight.
	III-C	RAC, IRB, IBC	Recombinant DNA (or DNA or rDNA derived from rDNA) transferred into humans.
	III-D	IBC [†]	Recombinant DNA transferred to or from whole animals, whole plants, transgenic rodents, experiments involving >10 Liters of culture, or agents listed in Risk Groups 1, 2, 3, or 4 (see below) at the appropriate Biological Safety Level (BSL).
	III-E	IBC [§]	Recombinant DNA involving no more than 2/3 eukaryotic virus agents, whole plants, arthropods, or transgenic rodents.
	III-F	Exempt	Recombinant DNA not found in organisms or viruses, single monochromal or viral DNA sources, or host DNA transferred to the same host or related species.

[†] Approval required before initiation.

[§] Notify IBC when project is initiated. IBC approval still required.

B. Project Goals

Please give a brief summary of project goals stated in non-technical terminology.

C. Technical Description of Experiments

Provide a technical description of experiments. Include enough detail that referencing other documents or scientific papers would not be necessary.

C.1. What is the source of the DNA/RNA?

Include gene names and organism of origin.

C.2. What is the nature of the DNA/RNA segment to be inserted?

Does the insert code for a toxin, what percentage of viral genome is eukaryotic, etc?

C.3. What hosts and/or vectors will be used?

List all prokaryotic and eukaryotic hosts.

C.4. Will non-recombinant microorganisms be used?

Describe other potential sources of microorganisms, such as etiologic agents, blood, tissues, etc.

C.5. What is the scale of work?

Bench scale <9.9 liters, or production scale >9.9 liters

C.6. Will animals be used under this project registration?

Outline procedures animals use is required for. IACUC review will be necessary for any experiments involving animals.

If yes, specify:

Host

Vectors

Inserted DNA

What fraction of eukaryotic viral genome is contained in the recombinant molecule?

C.7. Will plants be used under this project registration?

If yes, specify:

Host

Vectors

Inserted DNA

What fraction of eukaryotic viral genome is contained in the recombinant molecule?

D. Occupational Health and Safety

Please check off the categories below that apply to this protocol. Discuss in detail below what procedures will be followed to assure proper protection of personnel.

D.1. Please state biosafety level work will be conducted at and include a justification for choosing this level.

All work included in this project registration will be conducted according to the policies and procedures outlined in the Siamab biosafety manual and exposure control plan, including but not limited to general handling, equipment use and waste procedures.

PI INITIALS: _____

D.2. Other safety considerations

Check	Safety Considerations
	Radioisotopes (may require changes to MA radiation materials license)
	Chemical Hazards
	Controlled Substances
	Primary Human Tissue (requires BBP training)
	Other

D.3. Use as much space as necessary to fill in fields below.

Specific Hazard	Category	Precautions

E. Personnel

Provide below the names, titles and training each person working under this protocol has received. Include number of years working with rDNA and specific details of experience. Use as much space as is necessary. A copy of each individuals CV must also be on file.

Name	Title

F. Location of rDNA Use

Please list room numbers or names where work will take place.

G. Transfer of Materials

Will any of the materials be shipped between facilities? Please copy chart for each co-investigator.

Name	
Address	
Phone	

APPENDIX V RETROVIRAL VECTORS

Retrovirus	Genus	Receptor	Type	Function	Tropism
MoMLV	Gammaretrovirus	CAT-1	TM14	Amino acid transport	Ecotropic, mouse
X-MLV	Gammaretrovirus	XPR1	TM8	Unknown	Xenotropic, human, others
P-MLV	Gammaretrovirus	XPR1	TM8	Unknown	Polytropic. mouse and human
A-MLV	Gammaretrovirus	Pit-2	TM10-13	Phosphate transport	Amphotropic, mouse and human
GALV	Gammaretrovirus	Pit-1	TM10-13	Phosphate transport	Primate and human
HERV-W	Gammaretrovirus	RDR	TM9-10	Amino acid transport	Human
SRV-1-5	Gammaretrovirus	RDR	TM9-10	Amino acid transport	Primate
HIV-1, HIV-2	Lentivirus	CD4, CCR5/CXCR4	TM1, TM7	MHCII binding, Chemokine receptor	Human
SIV-1	Lentivirus	CD4, CCR5, Others	TM1, TM7	MHCII binding, Chemokine receptor	Primate, Human
FIV-1	Lentivirus	CXCR4, HS	TM7	Chemokine receptor	Feline, Human

Abbreviations:

MoMLV is Moloney Murine Leukemia Virus; X-MLV is xenotropic MLV; P-MLV is polytropic MLV; A-MLV is amphotropic MLV; GALV is gibbon ape Leukemia virus; HERV-W is human endogenous retrovirus group W; SRV 1-5 is simian retroviruses 1-5; HIV is human immunodeficiency virus; SIV is simian human immunodeficiency virus; FIV is feline immunodeficiency virus; CAT-1 is cationic amino acid transporter 1; XPR-1 is xenotropic, polytropic receptor 1; PIT ½ is phosphate transporter 1 or 2; RDR is RD-114 and D-type retrovirus receptor; CCR5 is C-C chemokine receptor 5; CXCR4 is CXC chemokine receptor 4; HS is heparin sulfate; TM is transmembrane.

This table was reproduced from *Safety Considerations for Retroviral Vectors: A Short Review*, page 5, prepared by Donald E. Mosier, TSRI Institutional Biosafety Committee Chair with the assistance of Carolyn Keierleber, TSRI Biosafety Officer and Associate Director of Environmental Health & Safety and Richard Gulizia, TSRI BL-3 Facility Director.

APPENDIX VI SELECT AGENTS LIST

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. The list of excluded agents and toxins can be found at:

<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html>.

HHS AND USDA SELECT AGENTS AND TOXINS 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS	OVERLAP SELECT AGENTS AND TOXINS
Abrin	<i>Bacillus anthracis</i> *
Botulinum neurotoxins*	<i>Bacillus anthracis</i> Pasteur strain
Botulinum neurotoxin producing species of <i>Clostridium</i> *	<i>Brucella abortus</i>
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X ₁ CCX ₂ PACGX ₃ X ₄ X ₅ X ₆ CX ₇) ¹	<i>Brucella melitensis</i>
<i>Coxiella burnetii</i>	<i>Brucella suis</i>
Crimean-Congo haemorrhagic fever virus	<i>Burkholderia mallei</i> *
Diacetoxyscirpenol	<i>Burkholderia pseudomallei</i> *
Eastern Equine Encephalitis virus ³	Hendra virus
Ebola virus*	Nipah virus
<i>Francisella tularensis</i> *	Rift Valley fever virus
Lassa fever virus	Venezuelan equine encephalitis virus ³
Lujo virus	
Marburg virus*	USDA SELECT AGENTS AND TOXINS
Monkeypox virus ³	African horse sickness virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)	African swine fever virus
Ricin	Avian influenza virus ³
<i>Rickettsia prowazekii</i>	Classical swine fever virus
SARS-associated coronavirus (SARS CoV)	Foot-and-mouth disease virus*
Saxitoxin	Goat pox virus
<u>South American Haemorrhagic Fever viruses:</u>	Lumpy skin disease virus
Chapare	<i>Mycoplasma capricolum</i> ³
Guanarito	<i>Mycoplasma mycoides</i> ³
Junin	Newcastle disease virus ^{2,3}
Machupo	Peste des petits ruminants virus
Sabia	Rinderpest virus*
Staphylococcal enterotoxins A,B,C,D,E subtypes	Sheep pox virus
T-2 toxin	Swine vesicular disease virus
Tetrodotoxin	
<u>Tick-borne encephalitis complex (flavi) viruses:</u>	USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS
Far Eastern subtype	<i>Peronosclerospora philippinensis</i> (<i>Peronosclerospora sacchari</i>)
Siberian subtype	<i>Phoma glycinicola</i> (formerly <i>Pyrenochaeta glycinis</i>)
Kyasanur Forest disease virus	<i>Ralstonia solanacearum</i>
Omsk hemorrhagic fever virus	<i>Rathayibacter toxicus</i>
Variola major virus (Smallpox virus)*	<i>Sclerophthora rayssiae</i>
Variola minor virus (Alastrim)*	<i>Synchytrium endobioticum</i>
<i>Yersinia pestis</i> *	<i>Xanthomonas oryzae</i>

*Denotes Tier 1 Agent

- ¹ C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α -M1 and α -G1 (shown above) as well as α -G1A, Ac1.1a, α -Cn1A, α -Cn1B; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.
- ² A virulent Newcastle disease virus (avian paramyxovirus serotype 2) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.
- ³ Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies *Mycoplasma capricolum* except subspecies *capripneumoniae* (contagious caprine pleuropneumonia), all subspecies *Mycoplasma mycoides* except subspecies *mycoides* small colony (Mmm SC) (contagious bovine pleuropneumonia), any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, and Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3, provided that the individual or entity can verify that the agent is within the exclusion category.

9/10/13

APPENDIX VII SCHEDULE OF CLEANING AND DECONTAMINATION

Below is the routine cleaning schedule for equipment used with bloodborne pathogens. As noted in the exposure control plan, all equipment is immediately cleaned after a spill occurs.

<u>EQUIPMENT</u>	<u>FREQUENCY</u>	<u>DISINFECTANT</u>	<u>PROCEDURE</u>
Incubators	Monthly	70% ethanol	Wipe down surfaces, autoclave shelves
BSC	Daily, as used	10% bleach followed by 70% ethanol	Wipe down surfaces. Lift grates and clean under work area as needed.
Biowaste lids	When boxes are closed for disposal	70% ethanol	Wipe all surfaces (top and underneath)
Centrifuges	Monthly	10% bleach followed by 70% ethanol	Wipe down surfaces, including centrifuge buckets and caps.

APPENDIX VIII SHARPS EVALUATION FORM

The federal Needlestick Safety and Prevention Act requires the investigation and use of sharps with engineered injury protections or needleless systems whenever possible. An example of this would be the use of a self-sheathing needle.

Input from researchers using sharps with human materials is required for the selection and use of safer medical devices. Complete the following initial survey form and return to the Biosafety Officer (BSO).

1. I work with human materials, or other potentially infectious materials (OPIM), such as blood, serum, tissue, bodily fluids or human cell lines.
 YES NO
2. I use sharps, such as needles, razor blades, or scalpels in my work with human materials or OPIM.
 YES NO

If you answered no to question #2, skip the rest of the form, sign and return to the BSO.

3. The tasks that involve the use of needles or sharps are (briefly describe):
4. Have you seen devices on the market that may make your work safer or reduce the risk of sharps injury?
 YES NO
5. If yes, indicate the vendor and part number, as well as the vendor phone number or website link below.
6. Are you interested in participating on an informal committee to select and evaluate sharps with engineered sharps injury protections and needleless systems when more become available to the market?
 YES NO

NOTE: If you come across a new engineered device that can be used in your work, bring it to the attention of the BSO for evaluation immediately.

Print Name: _____

Signature: _____

Date: _____

Department: _____

APPENDIX IX RECEIPT AND TRANSPORT OF BIOLOGICAL MATERIALS

General Guidelines for Receipt of Delivered Biological Materials

1. Do not handle the package directly if the packaging looks compromised.
2. If the package is damaged or leaking, put the package in a secondary container and call the Biological Safety Officer.
3. Handle the package as a biological spill.

General Guidelines for Transport of Biological Materials

1. Transport all BL2 and above materials in a labeled, sealable, unbreakable secondary container. This can be a zip-lock bag, tupperware container, or biocarrier.
2. Packages of infectious or potentially infectious agents must be labeled with the universal biohazard symbol.

<u>Regulated Material</u>	<u>Permit Application/Regulating Agency</u>
Recombinant DNA Materials	Compliance with the NIH guidelines for rDNA work. USDA PPQ 1001 if plant, animal or soil material is infective.
Certain Human/Animal pathogens and all foreign human specimens (Receipt of human specimen from some areas is prohibited. Consult with the USDA/CDC as early as possible.)	CDC 0.753 Center for Disease Control Biosafety Office 1600 Clifton Road, N.E. Atlanta, GA 30333 (404) 639-3883 http://www.cdc.gov/od/ohs/biosfty/imprtper.htm
Foreign animal cell cultures, foreign derived products, sera, hormones, milk, etc. Domestic pathogens and all foreign source material from animals, plants and soil.	USDA VS 16-3 + 7-R MA Department of Food and Agriculture State Office Building 100 Cambridge Street Boston, MA 02202 (617) 565-7030 Boston office must approve before they forward request to Hyattsville office. Inspectors may visit.

For information, advice
and forms:

U.S. Department of Agriculture
Animal and Plant Inspection Service
6505 Belcrest road
Federal Building, Room 42
Hyattsville, MD 20782
(410) 436-8226

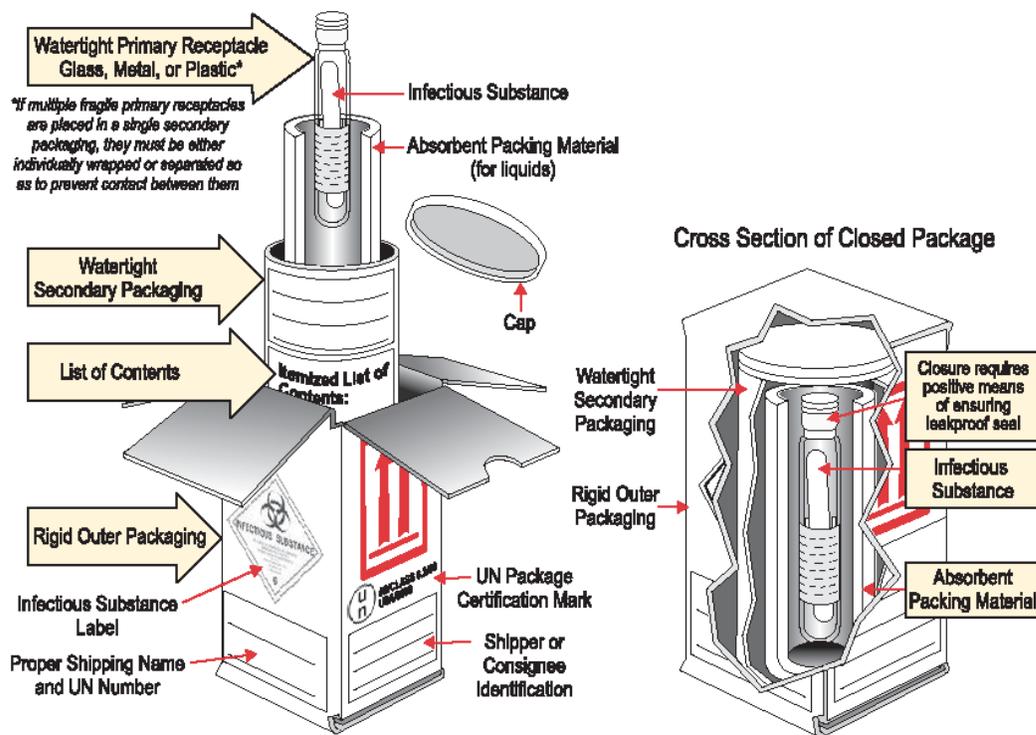
APPENDIX X SHIPPING BIOHAZARDOUS SUBSTANCES

Department of Transportation (DOT) and International Air Transport Association (IATA) regulations must be followed for all shipments. Anyone who ships hazardous materials must be trained in DOT and IATA regulations.

Packaging and labeling requirements for interstate shipment of infectious substances (etiologic agents) and clinical specimens.

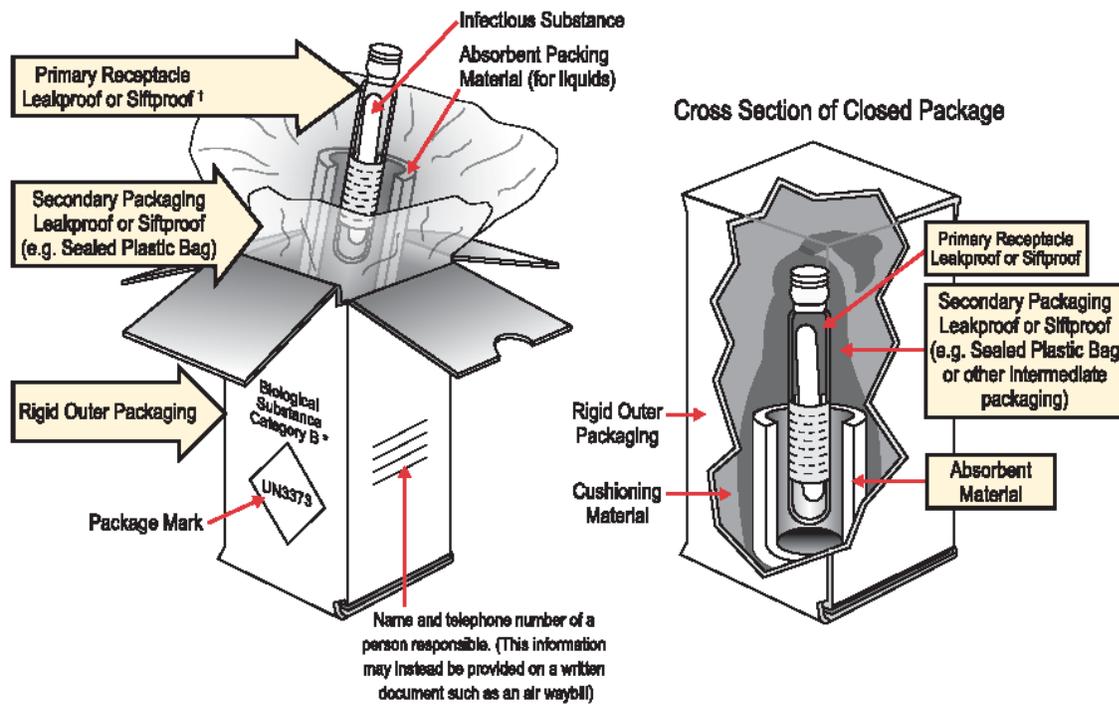
Note that the shipper's name, address and telephone number must be on the outer and inner containers. Refer also to additional provisions of the Department of Transportation (49 CFR Parts 171-180) Hazardous Materials Regulations.

Category A - Infectious Substance



- Note 1:** The smallest external dimension of the outer packaging must not be less than 100 mm (3.9 inches)
- Note 2:** The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa
- Note 3:** Follow package manufacturer's closure instructions

Category B - Biological Substance



* The proper shipping names "Biological Substance, Category B"; "Clinical Specimen"; and "Diagnostic Specimen" are authorized until December 31, 2006. From January 1, 2007 only the proper shipping name "Biological Substance, Category B" will be authorized.

† If multiple fragile primary receptacles are placed in a single secondary packaging they must be either individually wrapped or separated to prevent contact

Note: Follow package manufacturer's closure instructions

APPENDIX XI. AUTOCLAVE SAFETY

Every autoclave is different, so refer to the operator's manual for specific instructions on operation of the autoclave.

Procedure

There are several practices that will minimize the chance of a serious accident occurring, but also increases the functionality of the autoclave.

1. Before using the autoclave, check to make sure no items were left inside by the previous user that could pose a hazard.
2. Clean the drain strainer before loading the autoclave
4. Load the autoclave properly as per manufacturer's recommendations.
5. Before loading containers of liquids into the autoclave, the caps must be loosened to avoid having the bottles shatter during pressurization.
6. Individual glassware pieces should be in heat resistant plastic trays on a shelf or rack and never placed directly on the autoclave bottom or floor.
7. Use a tray with a solid bottom and walls to contain the contents and catch spills.
8. Add ¼ to ½ inch of water to the tray so the bottles will heat evenly.
9. Make sure plastic materials are compatible with being autoclaved.
10. Make sure the autoclave door is fully closed and latched and the correct cycle is selected before starting the cycle.
11. Wear heat resistant gloves when operating the autoclave door after a cycle.
12. If the door must be opened prior to the "cool down" cycle being completed, stand behind door when opening and beware rush of steam. Be sure to wear eye and face protection.
13. For non-liquid glassware loads allow the material to cool for 15 minutes prior to touching it with ungloved hands. If the material is waste wear at least latex or equivalent gloves to place the waste in the proper medical waste container.
14. For liquid loads allow the material to cool for one (1) hour before touching with ungloved hands. Inform others in the area that a heat hazard is present.
15. When removing items from the autoclave, wear heat resistant gloves. A rubber apron is also recommended.

Prohibited autoclave activities

NEVER put solvents, volatile or corrosive chemicals (such as phenol, chloroform, bleach, etc.) or radioactive materials in an autoclave. Call the Chemical Hygiene Officer if you have questions about proper disposal of these materials.

APPENDIX XII DISINFECTANTS

SUMMARY OF PRACTICAL DISINFECTANTS

	Quaternary ammonium compounds	Phenolic compounds	Chlorine compounds	Iodofors	Ethyl alcohol	Isopropyl alcohol	Formaldehyde	Glutaraldehyde
Inactivates								
Vegetative bacteria	+	+	+	+	+	+	+	+
Lipoviruses	+	+	+	+	+	+	+	+
Nonlipid viruses	-	a	+	+	a	a	+	+
Bacterial spores	-	-	+	+	-	-	+	+
Treatment requirements								
Use dilution	0.1-2.0%	1.0-5.0%	500ppm^b	25-1600 ppm^b	70-85%	70-85%	0.2-8.0%	2%
Contact time (min)								
Lipoviruses	10	10	10	10	10	10	10	10
Broad spectrum	NE	NE	30	30	NE	NE	30	30
Important characteristics								
Effective shelf life >1 week ^c	+	+	-	+	+	+	+	+
Corrosive	-	+	+	+	-	-	-	-
Flammable	-	-	-	-	+	+	-	-
Explosive potential	-	-	-	-	-	-	-	-
Inactivated by organic matter	+	-	+	+	-	-	-	-
Skin irritant	+	+	+	+	-	-	+	+
Eye irritant	+	+	+	+	+	+	+	+
Respiratory irritant	-	-	+	-	-	-	-	-
Toxic ^d	+	+	+	+	+	+	+	+
Applicability								
Waste liquids	-	-	+	-	-	-	-	-
Dirty glassware	+	+	+	+	+	+	+	+
Equipment, surface decon.	+	+	+	+	+	+	+	+
Proprietary products ^e	CDQ	Hil-Phene	Chloramine T	Hy-Sine			Sterac	Cidex
	End-Bac	Matar	Clorox	Ioprep				
	Hi-Tor	Mikro-Bac	Purex	Mikroklene				
	Mikro-Quat	O-Syl		Wescodyne				

+ = Yes; - = No; NE = Not effective

^a Variable results depending on virus

^b Available halogen

^c Protected from light and air

^d By skin or mouth or both. Refer to manufacturer's literature or Merck Index.

^e Space limitations preclude listing all products available. Individual listings (or omissions) do not imply endorsement (or rejection) of any product by the National Institutes of Health or the U. S. Environmental Protection Agency.

Source: Van Houten, J., 1989. New Frontiers in Biosafety: The Industrial Perspective. *In* Biohazard Management Handbook, Liberman, D.F. & Gordon, J.G. (Eds), pp.199-200, New York, Marcel Dekker, Inc.

ACTIVITY LEVELS OF SELECTED DISINFECTANTS		
Class	Use-Concentration of Active Ingredient	Activity Level
GAS		
Ethylene oxide	450-500 mg/L*	High
LIQUID		
Glutaraldehyde, aqueous **	2%	High
Formaldehyde + alcohol	8% + 70%	High
Stabilized hydrogen peroxide	6-10%	High
Formaldehyde, aqueous	3-8%	High to intermediate
Iodofors	30-50 mg/L free iodine / 20-150 mg/L available iodine***	Intermediate
Iodine + alcohol	0.5% + 70%	Intermediate
Chlorine compounds	0.1 - 0.5% free chlorine	Intermediate
Phenolic compounds, aqueous	0.5 - 3%	Intermediate to low
Quaternary ammonium compounds	0.1 - 0.2% aqueous	Low
Mercurial compounds	0.1 - 0.2%	Low

* In autoclave-type equipment at 55° to 60° C.

** There are several proprietary formulations on the U.S. market, i.e., 4% glutaraldehyde and 3% formaldehyde; glutaraldehyde 2% and 7% buffered phenol; and glutaraldehyde 2%, low pH and normal and raised temperatures.

*** There are semantic problems associated with iodofors, available iodine, and free iodine.

PREPARATION AND STABILITY OF CHLORINE SOLUTIONS

	Desired chlorine concentration			
	5000 ppm	1000 ppm	500 ppm	100 ppm
Dilution of bleach (5.25% NaOCl) prepared fresh for use within 24 hr	1:10*	1:50	1:100	1:500
Dilution of bleach (5.25% NaOCl) prepared fresh and used for 1-3 days	1:5†	1:25	1:50	1:250

* To achieve a 1:10 dilution, add one part bleach to nine parts water.

† To achieve a 1:5 dilution, add one part bleach to four parts water.

Reference: Rutala, W.A., APIC Guidelines for selection and use of disinfectants, Am J Infect Control, 24:326,1996.

INACTIVATION OF HBV AND HIV BY DISINFECTANTS

Disinfectant	Concentration inactivating 10 ⁸ HBV in ST, 10 min, 20° C*	Concentration inactivating 10 ⁵ HIV in ST, ≤ 10 min, 25° C †
Ethyl alcohol	ND	50%
Glutaraldehyde	2%	ND‡
Glutaraldehyde-phenate	0.13% glutaraldehyde-0.44% phenate	ND
Hydrogen peroxide	ND	0.3%
Iodophor	80 ppm	ND
Isopropyl alcohol	70%	35%
Paraformaldehyde	ND	0.5%
Phenolic	ND	0.5%
Sodium hypochlorite	500 ppm	50 ppm

ST - Suspension test; ND - No data

* Data from Bond *et al.*⁹²

† Data from Martin *et al.*⁹⁵ Also see Sattar and Springthorpe⁹⁶ for data concerning activity of other disinfectants HIV.

From: APIC Guidelines for Selection and Use of Disinfectants, Rutala, W.A., Am J Infect Control. 24:322,1996.

APPENDIX XIII BLOODBORNE PATHOGENS TRAINING OUTLINE

- A. Occupational Safety and Health Administration (OSHA): Bloodborne Pathogen Standard
 - 1. Purpose: To minimize or eliminate occupational exposure to blood or other potentially infectious materials (human blood and body fluids, tissues, cell lines, etc.) since an exposure could result in transmission of bloodborne pathogens which could lead to disease or death.
 - 2. Scope: Covers all employees who could be “reasonably anticipated” as a result of performing their job duties to have contact with blood and other potentially infectious materials.
- B. Training Requirements
 - 1. Employees receive training upon employment or assignment to tasks involving the potential for occupational exposure.
 - 2. Annual retraining is required.
- C. Bloodborne Pathogens and Occupational Transmission
 - 1. Definition: Bloodborne pathogens are microorganisms (virus, bacteria, etc.) found in human materials that may cause disease in humans.
 - 2. Current epidemiology, exposure and symptoms data are discussed for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV).
 - 3. Occupational routes of transmission:
 - a. Needlestick or cut/puncture with sharp object
 - b. Splash or splatter to face or exposed skin
 - c. Contact with non-intact skin (i.e. chapped skin)
 - 4. Other transmission routes
- D. Exposure Control Plan
 - 1. Review of job titles and specific job tasks where there is reasonably anticipated exposure.

2. Review of Universal Precautions and Standard Operating Procedures (SOP's):
 - a. engineering and work practice controls
 - b. safer sharps initiatives
 - c. personal protective equipment
 - d. housekeeping (cleaning/decontamination schedule)
 - e. labels and signs

E. Hepatitis B Vaccine

1. Safe and effective vaccine available for immunization against HBV.
2. A series of 3 vaccinations.
3. Vaccination against HBV is made available free of charge to all employees who have occupational exposure to blood and other potentially infectious materials.
4. Employees must sign a declination form if they choose not to be vaccinated, but may later request and receive the vaccine at no cost.

F. Exposure Management

1. Review of exposure incidents (needlesticks, etc.)
2. Procedure to follow in the event of an exposure:
 - a. wash the exposed area with soap and water
 - b. notify your supervisor immediately
 - c. go to the designated occupational medicine provider
3. Medical assessment, treatment, follow-up and counseling:
 - a. confidential
 - b. no cost to the employee
4. Limitations of protection devices

G. Recordkeeping Requirements

1. Training Records
2. Medical Records

APPENDIX XIV. SHARPS INJURY LOG

If an OSHA recordable sharps injury occurs, this form must be completed in addition to the OSHA 300 form. Complete the form below for all occupational exposures to blood or OPIM that occur from a sharps injury.

<u>OSHA Log Reference #</u>	<u>Device Involved in Incident</u>	<u>Brand of Device Involved in Incident</u>	<u>Location of Incident</u>	<u>Description of Incident</u>



APPENDIX XV HEPATITIS B VACCINATION FORM

The OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030, requires that the hepatitis B vaccination be made available to all employees who are occupationally exposed to human source materials including blood, serum, plasma and all other potentially infectious materials (OPIM). The vaccine is offered after the employee has received bloodborne pathogens (BBP) training as required by the standard and within 10 working days of initial assignment. Vaccination is encouraged unless, 1) the employee has already had the hepatitis B vaccination series; 2) antibody testing has revealed that the employee is immune; or 3) the vaccine is contraindicated for medical reasons. The employee is given the option to accept or decline the vaccination after being told of the benefits and risks of the vaccine during BBP training.

The availability of the Hepatitis B vaccine is part of the company's compliance to the BBP standard, which also includes:

1. An exposure control plan
2. New employee and annual training
3. A safer sharps program
4. A sharps injury log

The attached hepatitis B vaccine form must be completed by all employees during bloodborne pathogens training. If the hepatitis vaccine is declined initially, the employee can choose to receive it at any time during employment at no cost to them, including post-exposure, change of assignment or at any other time.

CHECK AND SIGN **ONE** OF THE FOLLOWING BOXES:

DECLINATION

- I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring a hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with the hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with the hepatitis B vaccine, I can receive the vaccination series at no charge to me.

PRINT NAME

SIGNATURE

DATE

CONSENT FOR VACCINE AND TITER

- I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring a hepatitis B virus (HBV) infection. I understand the risks and benefits of the hepatitis B vaccine and that I will need to receive a series of three shots followed by a scheduled titer to complete the vaccine. I would like to participate in the hepatitis B vaccination program as offered by Siamab. The vaccination series and titer are offered at no cost to me. I agree to go to the occupational health center to participate in this program.

PRINT NAME

SIGNATURE

DATE

STATEMENT OF PREVIOUS IMMUNIZATION

- I attest that I have previously been immunized against hepatitis B virus (HBV) infection. Please list the dates (month/year) of the three shots.
- I have previously received the hepatitis B vaccination, but I would like to have my titer evaluated and a booster administered if necessary.

PRINT NAME

SIGNATURE

DATE

APPENDIX XVI. INCIDENT REPORT

Date of Injury: _____

Employee Name: _____ Employee Signature: _____

Describe the incident in a detailed manner. Explain what the injury was, where it occurred, how it happened and, if a sharp was involved, what type of sharp it was. Include the manufacturer of the sharp, if possible.

Was the employee exposed directly to human source materials or OPIM? YES NO

If yes, is serological, PCR or similar data available for the material? YES NO

Was the employee referred to Occupational Health for counseling on the exposure?
If yes, attached physician's written opinion to this form. YES NO

Did Occupational Health review the data for the source material, if it was available? YES NO

Does the employee require follow-up medical evaluation at Occupational Health?
If yes, attached physician's written opinion to this form. YES NO

Describe any corrective actions and/or preventative measures to be taken to avoid this type of accident in the future.

Safety Officer Signature: _____ Date: _____

APPENDIX XVII ANCILLARY PERSONNEL CAUTION

Ancillary personnel are only to wash floors and remove universal trash and recycling containers from labs. Red bins and sharps containers should not be handled by ancillary personnel. Counter tops should not be touched or cleaned by ancillary personnel. Access is restricted to BL1 labs only.

If scientifics are working in the lab ask before entering

Dress code must be complied with and required PPE must be worn.

- No open toed shoes
- Covered legs recommended
- Safety glasses required in all labs