BIOSAFETY MANUAL
&
BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

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1.0 Objective

Tuoro University of California's (TUC) Biosafety Manual includes the university's Bloodborne Pathogens Exposure Control Plan, and provides a framework and operational guidelines, for safely handling biologically hazardous materials, potential human pathogens, and biohazardous waste.

This Plan is intended to provide information and guidelines to help reduce and eliminate the risks from occupational exposure to biohazardous materials, including human blood, cells and cell lines, tissues, and other body fluids.

This document will be modified, as necessary, to reflect significant changes in work practices and operations at TUC.

2.0 Regulatory Basis

The guidelines for Biosafety set forth in this manual are consistent with those established in the biomedical and medical research industry, which are based on the following publications.

Biosafety in the Microbiological and Biomedical Laboratory (BMBL). The Centers for Disease Control and Prevention.

NIH Guidelines for Research Involving Recombinant DNA (NIH Guidelines). The National Institutes for Health.

The Bloodborne Pathogens program is a requirement under the California Occupational Safety and Health Administration (Cal/ OSHA), presented in *Title 8 California Code of regulations, Section 5193*.

Waste handling procedures described in this document follow the requirements of the *California Medical Waste Management Act*.

These documents can be found on the Internet, or made available from TUC's Biosafety Officer.

3.0 Safety Policy

TUC is committed to providing a safe and healthy work environment for its employees and its policy is to comply with all applicable laws and regulations, and standards pertaining to Biosafety and Bloodborne Pathogens. The university strives to provide written documents and training for employees who work with biohazards, and expects employees to follow and comply with the policies, procedures, and safety guidelines set forth in this Plan.

4.0 Responsibilities

Each employee is required to work in a manner that minimizes and reduces risks to human health and safety by protecting themselves and fellow employees from risk of exposure or contamination from biohazardous materials. Therefore each employee has a role in safety. Specific responsibilities under the Biosafety program are defined below.

4.1 Provost

The Provost/ Chief Operating Officer is ultimately responsible under the Occupational Safety and Health Act for providing a safe work place. Responsibilities include:

- Authorizing and promoting the Plan as an operational requirement for those affected by the program.
- Providing the resources necessary to comply with enforceable regulations and procedures.
- Requiring managers and Principal Investigators (PIs) to adopt the policies, procedures, and guidelines appropriate to their area of responsibility.
- Review injury reports and help resolve the conditions which led to injuries and accidents.

4.2 Institutional Biosafety Committee

TUC receives funding from the National Institutes of Health (NIH), which requires following the provisions of the *NIH Guidelines for Research Involving Recombinant DNA (the Guidelines)*. Among the requirements of the Guidelines is the establishment of an Institutional Biosafety Committee (IBC) and appointment of a Biosafety Officer. The role of the committee is to review NIH-funded projects to ensure that protocols follow the provisions for biosafety detailed in the Guidelines.

Operating and administrative parameters for the IBC are provided in Appendix D.

4.3 Principal Investigators & Managers

Managers and PIs have more direct contact with lab staff and students, and are responsible for their safety. These responsibilities include:

- Providing the necessary resources to effectively implement the safety standards spelled out in this Plan.
- Provide the Biosafety Officer and Human Resources the names of employees who work with human blood or other potentially infectious materials.
- Promoting and advancing safety awareness in their respective department.
- Ensuring that workplaces and equipment are maintained, and in compliance with regulations, internal policies, guidelines, and procedures.

- Providing that employees attend required safety training classes.
- Reporting hazards to biohazardous materials to the Biosafety Officer, in order to resolve and mitigate them.
- Participating in injury and incident investigations.

4.4 Biosafety Officer

- Chairing the Institutional Biosafety Committee (IBC).
- Corresponds with the NIH on the activities of the IBC.
- Implementing the Biosafety program and Bloodborne Pathogens.
- Providing Biosafety/ Bloodborne Pathogens training.
- Investigating and evaluating incidents and injuries involving biohazardous materials.

4.5 Employees

- Understanding and abiding by all applicable rules, policies, and procedures applicable to biosafety.
- Participating in training programs applicable to the activities in which training is required.
- Using safe work practices in all operational aspects of a job or task.
- Promptly reporting injuries and accidents.
- Reporting immediate and potential hazards in the workplace.

5.0 Principles of Biosafety

The CDC and NIH classify infectious agents into Risk Groups 1 - 4 based on their virulence, pathogenesis, and infectivity. These four Risk Groups (RGs) are assigned corresponding biosafety levels (BSL), which identify safe work practices and proper containment levels applicable to each of the four Risk Groups. A summary of all Biosafety levels is presented in Appendix F.

The general theme in Biosafety is containment of the pathogens and organisms in a manner where no risk is posed to human health or the environment. Therefore containment will increase with increase in pathogenicity or virulence of the material or organism.

Risk Group 1 agents are not associated with disease in healthy adult humans while Risk Group 2 agents are associated with human disease which is rarely serious under occupational settings, and for which preventive or therapeutic interventions are often available.

TUC labs operate at either BSL-1 or BSL-2, depending on the specific agents and materials handled in the lab. Labs handling lab strains of bacteria and in some cases, attenuated viruses that pose no risk of infection may be handled under BSL-1 practices. Labs handling human blood, cells, tissue, or other potentially infectious materials must function under BSL-2 containment levels.

5.1 Biosafety Level 1 (BSL-1)

BSL-1 represents a basic level of containment where well-characterized agents are routinely handled in the lab bench. BSL-1 containment relies on standard microbiological practices and includes the following safety practices and containment practices.

- Safe sharps handling procedures are implemented.
- All procedures should be performed to minimize aerosols.
- Work surfaces must be decontaminated regularly.
- Biological waste must be handled in leak-proof containers, labeled with the international biohazard symbol.
- Biohazard symbol must be posted at the entrance to the lab.
- A pest control program must be in effect.
- Lab PPE (lab coat, gloves and safety glasses).
- Class I or II Biosafety cabinets.

5.2 Biosafety Level 2 (BSL-2)

Similar to BSL-1 this is a suitable level of containment for most microbiological labs. The agents handled under BSL-2 containment practices pose moderate risks and accommodates the handling of agents known to cause disease in humans including human-derived fluids, tissue, and cells. Therefore the containment measures are increased from those of a BSL-1 lab.

In addition to the safety rules stated in above for BSL-1 the following safe laboratory practices must be applied to BSL-2 labs.

- The laboratory manager establishes rules and procedures by limiting access only to people who have fulfilled all entry requirements (i.e. training, immunizations, PPE).
- Lab employees receive appropriate immunizations or tests for specific agents, where they exist, such as the Hepatitis B virus vaccine.
- A Biosafety Manual is required for labs that handle BSL-2 agents. The Biosafety Manual and its procedures will be integrated into standard operations in the lab and are considered lab safety policy.

- The lab manager ensures that all employees have attended the required training and implement safe lab practices as defined in this manual and in training classes.
- A sharps handling program must be in place to ensure that handling needles and other sharps immediately after use. Sharps must be disposed of after each use and needles must never be handled after use. Dispose of all contaminated sharps immediately. Do not bend, remove, or otherwise place hands near the needle after use.
- A biohazard label is posted at the entrance with the names of the agents listed and the name and phone number of the lab manager posted.
- Biosafety cabinets of at least a Class II design are maintained and certified at least annually by a qualified vendor.
- Face shields, dust/ mist respirators, and other appropriate protections are offered where the potential for aerosol generation is increased.
- Double gloving may be appropriate for handling BSL-2 agents. Employees are instructed to wash their hands after removing gloves and before leaving the lab.

Labs handling human cell lines, human blood, or human pathogens must operate under BSL-2 containment practices, because most human blood, cells, and tissue are considered capable of harboring pathogens. In addition, some non-human primate samples are subject to scrutiny due to pathogens, which can be transmitted to humans.

TUC is not equipped to operate under BSL-3 practices.

Personnel who work with Risk Group 1 agents are expected to be proficient in microbiological techniques in order to ensure proper handling of biological agents. Personnel working with Risk Group 2 agents in a BSL-2 setting must additionally attend training in handling those specific agents, and be familiar with the hazards, and safety provisions of each specific agent.

The common bloodborne pathogens, HIV, hepatitis B virus, and hepatitis C virus are typically transmitted in an occupational setting through bloodborne exposures, such as breaks in the skin, exposure to the eyes, or exposure to open wounds. The medium by which these agents are transmitted is typically human blood, serum, and plasma (including buffy coats) and body fluids These media can harbor airborne viruses, such as influenza or tuberculosis, so BSL-2 practices strive to protect against exposure to these materials.

An Exposure Control Plan as required by Cal/ OSHA for handling human-derived agents is presented in Section 11.

TUC does not have the facilities to handle Risk Group 3 or 4 agents. Refer to the CDC handbook ***"Biosafety in Microbiological and Biomedical Laboratories"*** for additional discussion of BSL-3 and BSL-4 labs and agents.

6.0 Safe Laboratory Practices

Employee behavior and attitude toward safety form the first, and most important, line of defense against injury or exposure in the biological lab. Safe behavior is an innate part of each individual's personal approach to working safely in the laboratory environment, and relies on an individual's laboratory experience, personal work habits, technical knowledge and attitude toward safety. The principles of infection control need to be kept in mind to use the appropriate precautions.

Good microbiological technique is also important in and scientists are expected to be knowledgeable in appropriate microbiological techniques. Training, familiarity with safety procedures, and implementing those procedures and practices in the lab are used to help employees recognize hazards and personal safety risks. The following are basic tenets of biosafety, and are the basis of laboratory safety:

- Use only mechanical pipetting or suction devices.
- Manipulate infectious fluids carefully to avoid spills and minimize the production of aerosols and droplets.
- Restrict the use of needles and syringes to those procedures for which there are no alternatives; use needles, syringes and other "sharps" carefully to avoid self-inoculation; and dispose of sharps in leak-proof and puncture-resistant containers immediately after use.
- Wear personal protective equipment that is appropriate to the agents being handled.
- Do not eat, drink, store food, apply cosmetics or lip balm, chew gum, or other hand-to-face activities, which may transfer contaminants to one's face.
- Personal hygiene should not be overlooked. Wash hands following all laboratory activities, following the removal of gloves, and immediately following contact with infectious materials.
- Decontaminate work surfaces before and after use and immediately after spills.

Employees are expected to apply safe work practices appropriate for the agents handled and the biosafety level of the lab. If unsure of the risk or the appropriate containment measures, consult with the Biosafety Officer or consult the CDC's handbook *Biosafety in the Microbiological and Biomedical Laboratory*, which is available on the Internet.

Each potentially biohazardous agent has the capacity to infect a host and cause disease, therefore unsafe practices or behaviors provide opportunities for infectious agents to potentially expose employees, and also contribute to the potential contamination of the laboratory.
Risk assessments should be considered when there is uncertainty about handling a pathogen or microorganism.

Risk assessments evaluate the following factors:

- The route of transmission
- The inherent hardiness of the agent
- Susceptibility of the host to infection
- Medical predispositions of employees
- Prior immunity
- Personal and medical predispositions

6.1 Containment

The principles of Biosafety include a hierarchical approach in preventing exposure and contamination from biohazardous agents. Biosafety levels establish a containment regimen by incorporating the use of engineering controls, administrative controls, and personal protective equipment (PPE). These control measures are applied in the form of primary and secondary containment.

6.1.1 Primary Containment

Primary containment refers to containment practices and devices that contribute toward the prevention of exposures and the release of contaminants inside the lab. In effect, primary containment includes control measures inside the lab. These containment measures include engineering controls, work practice controls, and PPE.

The BSC is the principal device used to provide containment of infectious droplets or aerosols generated by many microbiological procedures. TUC uses mostly Class II Type A biosafety cabinets, which are defined in the following section.

Engineering Controls - Includes Biological safety cabinets (BSCs), enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials.

Biological Safety Cabinets are designed to contain aerosols generated during work with biological material, by using laminar airflow and high efficiency particulate air (HEPA) filters, and are distinguished as Class I, II and III, each providing different levels of protection.

Class I biological safety cabinets are partial containment devices that provide a primary barrier protecting the work and the material being manipulated. These are enclosed on three sides with a HEPA filter on the back and an open front face.

The Class II biological safety cabinets are enclosed on all sides, with a front sash that provides splash protection to the user, and produces an air curtain across a

front grill. Class II BSCs protect the product (e.g., cell cultures, microbiological stocks) from external contamination, and protect the employee from aerosols and mists produced inside. Class II BSCs filter air through HEPA filters and air is circulated back into the room, therefore Class II BSCs are not suitable for handling hazardous chemicals, because of the risk of exposure to the employees working at the hood. TUC's biological safety cabinets are certified at least annually to ensure that the units operate properly.

Class III BSCs are fully contained with 100% exhausted air. These include Glove Boxes and other isolation devices used to handle sterile materials or for handling particularly infectious material.

Other engineering controls include:

- Chemical fume hoods
- Aspiration systems for liquid wastes
- Filtered pipette tips

Administrative Controls – These include procedures and work practices intended to reduce an employee's potential for exposure. For example, the direct disposal of contaminated sharps is a procedure that eliminates recapping needles, or otherwise placing oneself at risk of accidental self-inoculation. Other administrative controls may include, but are not limited to:

- Limiting access to certain labs, especially during sensitive operations
- A medical surveillance program
- A decontamination program
- Spill cleanup procedures
- Good housekeeping practices

Employees are required to be familiar with all written procedures, policies, and guidelines having to do with personal safety and biological containment.

Personal Protective Equipment (PPE) - Personal protective equipment includes protective clothing, often used in combination with engineering and work practice controls. In some situations, protective clothing may be the most effective barrier between personnel and infectious materials and pathogens.

The type of PPE used should be appropriate for the type of procedures being performed and the type of exposure anticipated. For example, when working with a vacutainer tube of whole blood, lab safety glasses are appropriate for preventing exposure to droplets. If handling bags of pooled blood from a blood bank, or large volumes of aspirated liquids, then a face shield may be better to provide an additional level of protection against splatters and spills.

PIs and managers are required to train employees when new or additional PPE is issued. This is to ensure compliance with applicable OSHA regulations and helps employees understand the uses and limitations of PPE.

Personal protective equipment must be provided by the employer and meet the following criteria.

- Must properly fit employees
- Laundering and repair or replacement must be provided by the employer
- Proper disposal containers for contaminated equipment must be provided
- Employees must be trained in the use and limitations of PPE

Standard laboratory PPE includes:

- **Lab coats** – The primary barrier that prevents aerosols, sprays, mists, or spills from contaminating employee's clothing. Employees are issued cotton lab coats that require laundering by a vendor. Disposable lab coats may be purchased for use under special or unique circumstances.
- **Gloves** – At least two kinds of gloves are available in labs; nitrile and latex. Latex gloves are typically used when handling biological materials, whereas nitrile gloves offer greater protection for handling chemicals. Gloves must be impervious to the material being handled and cover all exposed skin.

  Latex gloves have been implicated in causing allergic responses in some people. Employees who believe they may have an allergy to latex should talk to their supervisor or biosafety officer.
- **Eye and face protection** – Safety glasses are recommended when working in the lab, because this is considered a route of exposure. Safety glasses provide side shields and a brow guard that protect the eyes from errant droplets and small splashes. These can be purchased from the lab supply catalog.

  Face shields are commonly used when working with liquid nitrogen freezers or Dewars.
- **Closed-topped shoes** – Protect all exposed skin when working in the lab. It is recommended that all exposed skin be covered when working in the lab.

6.1.2 Secondary Containment

Secondary containment refers to the design and infrastructure of a facility that supports safety and provides a barrier to protect people working inside and outside the laboratory, including the surrounding community from accidental releases from labs.

Secondary barriers in these laboratories include:

- Separation of the laboratory work area from public areas, such as food handling and administrative work areas.
- Availability and use of effective decontamination equipment (e.g., autoclave, chemical disinfectants, etc.),
- Hand washing facilities and safety shower/ eyewash stations
- HEPA-Filtered ventilation.

As the risk for aerosol transmission increases, higher levels of secondary containment using multiple containment devices may become. The most important consideration of secondary containment is to reduce the risk to employees and the public.

7.0 Emergency Procedures

Emergencies include spills and releases, exposures to biologically hazardous agents, and injuries involving biological hazards. Exposure and post-exposure procedures are discussed in the Bloodborne Pathogens Exposure Control Plan in Section 10.

The greatest concern with responding to emergencies is to ensure that human health and safety is the top priority, followed by preventing exposure to others.

7.1 Exposure to Employees

Exposure from pathogens to employees may occur from several exposure pathways. Contact a supervisor and Human Resources immediately following an exposure. The eyes present a pathway for pathogens to enter one's body, therefore if a splash or spill gets in the eyes, immediately proceed to a safety eyewash fountain and flush the eyes for a minimum of 15 minutes. Do not worry about flooding the floor for it can be mopped up later.

Exposures can occur through open wounds, or skin punctures from contaminated materials. Employees in a clinical or residency setting must also be aware that bites and scratch wounds may penetrate the skin and pose a risk of exposure to pathogens.

Exposures to airborne pathogens may require medical surveillance, depending on the circumstances. Employees suffering such exposures are provided post-exposure follow-up by a physician, which is described further in the Bloodborne Pathogens Exposure Control Plan, Section 10.

Employees who have suffered an exposure incident will be offered medical attention. TUC sends injured and exposed employees to the local Kaiser Permanente Occupational Health clinic.

7.2 Biological Spills

Biological spills commonly involve liquids containing potentially pathogenic materials, such as spilled filtration flasks from tissue culture labs, infectious cultures, or spilled blood or other human fluids. Recognize the hazards of the spilled material and clean up the spill following these procedures.

a. Make sure that you are not contaminated and that your clothing is not contaminated. Call for help if contaminated, and avoid contaminating any surfaces while getting out of the spill area.

b. Put exposed clothing in a red biohazardous waste bag if the material is known to be potentially infectious. The Biosafety Officer will help find a clean dry change of clothing for the interim if personal clothing is contaminated.

c. Alert and inform others of the spill. When other employees are exposed or contaminated, then provide assistance in with people before proceeding.

d. Isolate the spill by one of two methods.

    i. Place physical barriers around the spill to prevent people from entering the contaminated area. Use items such as caution tape, chairs, or close the lab door.

    ii. Simply tell others to leave the area until the spill is cleaned up.

e. Don the appropriate personal protective equipment. At a minimum wear safety goggles, thick gloves, lab coat, and closed shoes, with no exposed skin showing.

f. Remove broken glass or contaminated sharps with tongs, and place these in a red sharps container.

g. Place absorbent towels (paper towels are appropriate) on top of the spill and continue to add absorbent until the material is sufficiently and completely absorbed. Absorbent pads are stocked in spill kits located in each lab.

h. Pour a 10% household bleach solution on top of the absorbents and let it stand for 30 minutes to kill any biologically viable agents. Low hazard agents can simply be cleaned up with a mop or paper towels.

i. Place all solid clean up material in a red biohazardous bag and dispose of it as biohazardous waste.

j. Decontaminate all affected surfaces with a soap and water solution.

Care must always be taken to protect open wounds and the eyes, because spill clean up can disturb and spread contaminants across the lab.

8.0 Disinfection and Decontamination

Viable biological agents must eventually be inactivated before disposal, which is accomplished by killing the organism, or destroying cellular proteins of the organism, rendering it inactive.

The term disinfection refers to the use of germicidal chemical agents, which destroy the potential for an agent to be pathogenic, using the assumption that not all of the microbial agents have been inactivated, even though the material no longer poses a risk to healthy adults. Each biologically active agent has a different susceptibility to disinfectants. The specific disinfectant depends on parameters such as:

- The nature and properties of the agents
- Sensitivity of equipment to chemical disinfectants
- Contact time on contaminated surfaces

Sterilization, on the other hand, is defined as the use of physical or chemical means to destroy all microbial life including highly resistant bacterial or fungal spores. Sterile is an absolute term and there are no degrees of sterility. Autoclaves are the most common sterilization technology. An autoclave is used in Research for sterilizing reusable supplies and other materials, as necessary.

All contaminated equipment, materials, or apparatus should be disinfected or sterilized before being stored or reused. All work surfaces where biohazardous agents are used must be disinfected after each use, and at least daily.

8.1 Liquid Disinfectants

Disinfection of equipment material uses a chemical agent, each with a recommended effective contact time. Liquid disinfection is normally applicable for inactivating cell culture media, liquids aspirated into filtration flasks, and for inactivating spilled materials including blood or body fluids. The most common liquid disinfectants include:

- **Chlorine Compounds** - Household bleach, with the active ingredient being sodium hypochlorite, is the most common chlorine compound. A 1:10 dilution of household bleach provides sufficient strength for most laboratories needs and is recommended as an effective general use disinfectant for most TUC labs. A diluted bleach solution is effective for up to 5 days, while commercial disinfectants with stabilizers may last longer.
- **Alcohols** - These are typically used in 60% - 90% aqueous solutions, which means that these compounds evaporate quickly from surfaces, limiting the contact time to effectively inactivate most microorganisms. A 70% isopropyl alcohol solution is more appropriate as a cleaner than as a disinfectant.
- **Quaternary Ammonium Compounds -** Quaternary ammonium compounds, or "Quats," include many commercially available products and are acceptable as general use disinfectants that are effective for use in most BSL-2 laboratories.

- **Phenolic Compounds** - These are effective for killing most bacteria, including spore-producing and lipid-containing viruses. Phenolic disinfectants can pose a chemical exposure risk if not used properly, and for this reason its use is discouraged.

9.0 Waste Disposal

Biological waste, also called biohazardous waste, which potentially contains biologically viable materials, and materials that came in contact with potentially biohazardous materials. Biohazardous waste is regulated under the CA Medical Waste management Act, and enforced by the California Department of Public Health.

9.1 Solid Waste

Solid waste usually consists of cell culture plates, gels, plastic, paper, and other supplies and equipment that may have come in contact with potentially viable material. California law requires that biohazardous waste be generated only in red waste bags bearing the biohazard symbol. Solid waste must be collected in rigid leak-proof waste containers bearing the international biohazard symbol and must be covered when not in use. The inside surface of the waste container lid must also be cleaned periodically in order to prevent the spread of contaminants.

When waste bags fill approximately ¾ full, employees are instructed to close the bag with tape or the rubber bands provided. Using a cart lined with absorbent bench paper underneath the waste bag, dispose of the bag in a vendor's drum in the nearest waste accumulation room. Red bags are disposed of in Room G15, serving both Anatomy and Research and Development.

State law requires that vendor's waste drums be picked up weekly, regardless of how much has accumulated in the drum. TUC schedules weekly waste service with the waste vendor, Stericycle.

9.2 Liquid Waste

Liquid waste generally consists of media, filtrate from aspiration flasks, and blood or other potentially infectious human fluids. Standard laboratory practices require that liquid biological wastes be disinfected prior to sink disposal. Add enough household bleach to the liquid vessel until it comprises 10% of the total volume and allow the liquid to stand for at least 15 minutes in order to effectively deactivate viable material. After 15 minutes dispose of the liquid down the lab sink, flushing the materials with running water as the liquid is poured out.

9.3 Sharps Disposal

Sharps may include razor blades, needles and syringes, Pasteur pipettes, glass vials, or other breakable disposable equipment that is capable of cutting or puncturing a red bag. All sharps must be disposed of immediately after use into a rigid sharps container, and in a manner that prevents handling the sharp end of the object. For example, razor blades should only be handled from the safe side, and syringes should never be recapped. In both cases, simply dispose of the entire object in the sharps container. Other waste handling guidelines include:

- Sharps must not protrude from the opening of the container. Use sharps containers that will effectively hold the materials being disposed.
- When a sharps container is ¾ full, close the lid firmly and dispose of the filled sharps container in a vendor's drums in the waste accumulation Room.

10.0 Bloodborne Pathogens Exposure Control Plan

The procedures in this Plan are designed to minimize the potential for exposure to blood and the potential pathogens associated with human-derived agents. The Plan introduces the important concept of Universal Precautions, and describes acceptable storage and disposal practices related to TUC's Bloodborne Pathogens program. The OSHA Standard requires that the Exposure Control Plan be in writing and contains the following elements:

1. Exposure determination of at-risk employees
2. Implementation of each of the applicable subsections:
    a. Methods of Compliance
    b. HIV, HBV and HCV Research Laboratories
    c. Hepatitis B Vaccination
    d. Post-exposure Evaluation and Follow-up
    e. Communication of Hazards to Employees
    f. Recordkeeping related to this standard
3. Procedures for investigating exposure incidents
4. Use of a Sharps Injury Log for injuries sustained by a percutaneous exposure.
5. An effective procedure for evaluating engineering controls, particularly engineered sharps, in an effort to reduce their use.
6. A procedure for reviewing and updating the exposure control plan with respect to the procedures performed in each respective work area or department.

TUC must also insure that a copy of the Exposure Control Plan is accessible to all affected employees at all times of the workday. This will be accomplished through publication of the Plan on the campus website (site location).

The Bloodborne Pathogens program applies to all employees whose work has the potential to expose them to:

- Human blood and blood components
- Other human fluids
- Unfixed tissue or organ (other than intact skin) from human (living or dead)
- Cells or tissue cultures, including culture media, containing HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), or from experimental animals inoculated with HIV, HBV or HCV.
- Waste generated from labs handling any of these agents

The Biosafety Officer and Safety Committee members will review and authorize all changes to the program and to this Plan, which will be modified for the following reasons:

- Changes in regulatory requirements
- Changes in procedures
- Changes in the agents handled in the lab.

10.1 Exposure Determination

Employees who are identified as potentially at-risk of exposure must participate in the Bloodborne Pathogens program. The two primary methods of determining an employee's participation include the individual's job definition and work locations.

All job classifications and locations in which employees may be expected to have occupational exposure to blood or other potentially infections materials, based on the nature of the job and collateral duties, which shall be identified and evaluated by the TUC Human Resources Department. These fall into the following two classifications.

- **Category I** - Employees are exposed to blood or other potentially infectious materials on a regular basis, and in which such exposures are considered normal course of work. These include the following job titles.
    - Research Scientists including Principal Investigators
    - Research Associates or Post-doctoral Employees
    - Patient Care Providers in the Student Health Center or Off-Campus Clinical Sites, i.e. physicians, nurses, physician assistants, medical assistants.
- **Category II** - Employees may have an occasional exposure to blood or other potentially infectious materials, and in which such exposures occur only during certain tasks or procedures that are collateral to the normal job duties. These include the following job titles.

- Administrative Staff
- Facilities Personnel (custodians, maintenance workers)
- IT Staff
- Vendors, Service personnel, and Contractors

All Category I and II employees will receive Bloodborne Pathogen training within 30 calendar days of appointment. The Hepatitis B vaccination shall be made available to Category I employees within the same 30 day time period. This will ensure compliance with regulations requiring employee protection from the hepatitis B virus.

Exposure determinations to identify potentially at-risk employees must consider the following.

- An employee's job description and job title
- Job duties potentially involving bloodborne pathogens
- The work locations and labs that the employee must enter.

10.2 Universal Precautions

Complying with the requirements of the OSHA Bloodborne Pathogens Standard requires that employees understand and the concept known as Universal Precautions. Universal precautions are defined as a set of work practices, procedures, and techniques for preventing exposure to potentially pathogenic agents. The concept of Universal Precautions treats all human blood and certain human body fluids as if infected with HIV, HBV, HCV, or other bloodborne pathogens. The following describe methods for implementing Universal Precautions.

- **Use Engineering Controls Whenever Feasible** – Engineering controls incorporate mechanical means of containing and controlling contaminants at the source, and is the most effective control measure. Examples of engineering controls include:
  - Biosafety cabinets and other specialized ventilation devices
  - Shielding
  - Sealed centrifuge tubes and cups
  - Pipetters
  - HEPA filters.
- Administrative Controls – If engineering controls are not completely effective, then employees are trained in specific safe work procedures to help reduce the risk of exposure. Examples include the following.
  - **Good Personal Hygiene** - Wash hands and exposed skin when leaving the lab and when removing gloves. Wash exposed skin immediately if exposed to blood or other potentially infectious materials (OPIMs).

- **Sharps Handling Techniques** – Sharps of all kinds must be used **one time only**, and disposed of in a labeled biohazardous sharps waste container after use. Do not recap, bend, cut, or otherwise handle needles or other sharps. Never place your hand in proximity to the sharp edge or tip of any potentially contaminated object. OSHA requires using engineered sharps protection when drawing blood samples or delivering an injection.
  - OSHA requires that the entire assembly used to draw blood, including the needle and tube holder, be disposed of after each use. Thus, a new assembly must be used for each blood draw.
- **Clean up Spills and Splashes** – Clean up spills and accidents as soon as they occur. Section 7.2 discusses spill cleanup procedures.

➢ **Personal Protective Equipment (PPE)** - PPE is considered primary containment and is intended to prevent exposure to pathogenic material when engineering controls and other preventive measures are not fully effective.

Standard Lab PPE includes the following:

- Lab Coat
- Protective gloves
- Safety eyewear (safety glasses or face shield)
- Closed-topped shoes

The level of protection must be appropriate for the type of procedures being performed and the type of exposure possible. If unsure whether the level of protection is adequate, ask the Bioafety Officer for recommendations.

10.3 Identifying and Evaluating Engineered Sharps

The Student Health Center handles needles and sharps systems when providing vaccinations, drawing blood or assisting students with diabetic episodes. Health Center nurses who potentially handle sharps use engineered sharps devices and to comply with OSHA requirements and therefore participate each year in evaluating sharps and the use of potentially safer products available to perform these duties.

This small staff gathers informally each year and reviews records such as Sharps Injury Logs and Accident Investigations to identify if the current products are the safest available. The group evaluates alternative devices from reviewing supplier's catalogs, checking OSHA websites for guidance, or consulting with vendors on new products.

Criteria for evaluating new products include the following.

- A safety feature is built into the device as an integral part of the device and cannot be removed.
- If there are no devices with an integrated design currently available in the marketplace for a particular procedure, accessory or “add-on” designs may be considered an appropriate engineering control.
- If the safety feature has a passive design that remains in effect before, during, and after use. This is preferred to an active design.
- If an active design, or one that employees must manually activate, can be replaced with a passive design.

If new and safer products are available, they are evaluated and tested for ease of use, functionality, cost, and effectiveness.

10.4 Good Laboratory Practices

The principles of infection and primary safe work practices need to be kept in mind when appropriate safety precautions are selected. Motivation and good judgment are essential in the protection of human health and the environment, therefore building safe work practices into one’s daily activities are encouraged. Plan ahead and stage the materials in a manner that follows the procedures and guidelines presented in this document to ensure the safety of everyone in the lab.

At a minimum, the Seven Basic Rules of Biosafety presented in Section 6.0 should be the basis of any personal laboratory work ethic.

Personal hygiene should not be overlooked as a means to enhancing personal protection in the laboratory. Scrubbing immediately after removing gloves ensures that contamination of the hand from micropunctures and contact with contaminated surfaces is minimized. The lab is not an appropriate location for applying makeup, cleaning or trimming fingernails, or brushing hair. These activities provide unnecessary opportunities for exposure but also contribute to potential contamination of the laboratory environment.

10.5 HBV Vaccinations

New employees will be provided access to HBV titers and vaccines within 30 calendar days of appointment. After completing the HBV series of immunizations, employees will have their titer tested to insure antibody protection. Up to 10% of the adult population does not develop antibody protection, so it is important to check the titer after completing the vaccination series.

Employees who do not develop a surface antibody to HBV may be reassigned or may require special provisions in the workplace. They may also choose to continue working

in their original position with the knowledge they do not have antibody protection. TUC's process for providing the HBV vaccination series follows.

- An HBV vaccination or titer test must be offered to an employee before the employee handles blood or blood products.
- HBV vaccinations include three shots; the first is given upon an employee's introduction to the program, another shot follows a month later, and the final immunization five months after the second.
- Employees who have previously received the series of shots may have titer tests at Kaiser Permanente Vallejo, or provide verification of their antibody from a previous employer.
- HBV vaccinations and titer tests must be provided at no cost to employees.
- Personnel may decline the Hepatitis B Vaccine by signing the Declination Form in Appendix B. An employee who declines the HBV vaccination may, at any time thereafter, change his or her mind and receive the vaccine.
- Titer tests are provided after completion of the series to verify conversion of a surface antibody. Titer tests may be requested by employees to learn their immunity status.

Human Resources will maintain employee vaccination records, which can be obtained by the employee upon request.

10.6 Hazard Communication

All employees working with bloodborne pathogens or working in those locations where bloodborne pathogens are handled are provided this document to read and are trained in the program within 15 days of appointment.

Methods for informing employees of the hazards of bloodborne pathogens, and safe work precautions are provided in the following manner.

- The front and top of waste containers are labeled with the universal biohazard symbol.
- Biohazard labels are affixed to storage equipment (e.g. freezers and refrigerators, incubators, etc) or any other area where potentially infectious materials are stored or handled.
- Biohazard signs are posted on the entrance of labs handling bloodborne pathogens. BSL-2 labs are required to post the entrance with a sign that includes the biohazard symbol, name of the agent(s) handled in the lab, special entry requirements, and the telephone number for a 24-hour contact.
- Initial and annual training, which is discussed in the next section

The Biosafety Officer may also send communications via email, or post warning signs and posters to help clarify policies and procedures.

10.7 Training

New employees who are enrolled in this program are provided with a copy of this Plan and a short orientation to the Bloodborne Pathogens Program at the time of appointment. This orientation may include a video *or online* presentation, followed at a later date with a training class dedicated to the Bloodborne Pathogens Program. Employees who work with human blood, tissue, or other potentially infectious material must attend all required training programs including an annual refresher course on bloodborne pathogens.

When procedures change, or a project involves a newly introduced pathogen, the supervisor or principal investigator will conduct informal safety discussions with lab staff. At a minimum, all personnel working with bloodborne pathogens must be trained in the following areas as soon as possible after starting work at TUC.

- The components of the TUC Laboratory Hygiene Plan and Exposure Control Plan.
- Uses and limitations of, and procedures for, using personal protective equipment.
- A discussion of the HBV vaccination series including the benefits of vaccinations and efficacy of the vaccine in preventing disease.
- Safe handling methods for potentially infectious or viable agents.
- The vaccination/ prophylaxis program
- Proper methods for transporting biohazardous materials
- Emergency procedures involving blood exposure or contamination
- Post-exposure follow-up procedures
- Hazard communication
- Evaluation of employee understanding of the Plan

Annual training classes are conducted within 12 months of the previous training class, and are best used to update employees on changes to the TUC program and to inform employees of changes in regulatory requirements. Supervisors are responsible for ensuring that their direct reports attend all applicable training programs and that employees are formed of their responsibility for safety.

Student Health Center employees will also participate in the initial and annual training programs, which will include discussion on transmissible airborne pathogens, as described in Section 11.

10.8 Incident Reporting

An incident report must be completed for all injuries and exposures. If the incident involves a puncture from a sharp, then according to OSHA requirements, a Sharps Injury Log, or similar means of investigating the injury, must be maintained. Human Resources enters these injuries on the OSHA 300A log.

The injured employee must report the incident immediately to the area supervisor and Human Resources. In the event of an exposure to blood or other potentially infectious materials by needlestick puncture or through an open wound use the following procedures.

- Wash the wound with soap and running water for at least 15 minutes. Meanwhile have a co-worker call TUC's health care provider.
- Inform the receptionist on the phone about the nature of the injury, the time it happened, the severity, and most importantly the source agent of exposure.
- Take a sample of the source agent, if requested, to the health care provider.
- It is suggested that injured employees be driven to the health care provider as opposed to having them drive while injured.

10.9 Medical Surveillance

All injuries related to exposures to bloodborne pathogens must be reported immediately and treated by a physician as soon as possible afterwards. Such exposures may include medical monitoring and surveillance.

All exposure incidents are investigated and documented, as described in the Injury and Illness Prevention Plan, and the exposed employee(s) must be provided medical attention immediately after exposure. Incidents involving exposures via the percutaneous route, via mucous membranes, or to the eyes must be reported immediately. This is important in providing exposed employees with the fastest and most appropriate medical treatment possible.

Injury investigations strive to determine the primary and contributing causes of an injury, preventive actions necessary to avert similar incidents, and identify responsible parties for each preventive action. Injury investigations can be completed after seeking medical treatment. Personal information obtained during the investigation and subsequent medical treatment will remain confidential and TUC will ensure that the physician – patient relationship remains confidential.

10.10 Post-Exposure Follow-up

Post-exposure follow-up is available to all employees who have had an exposure incident. Employees exposed to human blood or other bloodborne pathogens will be provided serologic testing, post-exposure prophylaxis if appropriate, and counseling by a physician for the duration of the injury and resulting treatment.

All subsequent counseling, guidance, monitoring and health services will be provided at no expense to the employee, and held in the strictest of confidence. Human Resources maintains confidential employee exposure records for at least the duration of employment plus 30 years

10.11 Recordkeeping Requirements

The employer shall establish and maintain an accurate record for each employee participating in the Bloodborne Pathogens program, and include the following.

- A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and titer test results
- A copy of all results of examinations, medical testing, and follow-up procedures as required
- The employer's copy of the healthcare professional's written opinion from adverse exposures
- Rosters and copies of handouts from training classes

11.0 Aerosol Transmissible Diseases

The Student Health Center is subject to complying with Cal/ OSHA's Aerosol Transmissible Disease standard, written in 2010 to address exposures in the health care industries to prevent exposure to airborne and aerosol pathogens. These include the potential for exposure to influenza, tuberculosis, and other disease-causing agents spread by respirable aerosols. Many of the elements to this requirement are covered elsewhere in this Plan, so the following describes procedures as outlined in the OSHA standard.

The Director of Student Health Services is responsible for managing this program, and for following the guidelines set forth in this section. The exposure potential to all medical and nursing staff arises from assisting students with managing existing illnesses, and administering vaccinations to students who may have been exposed to respirable illnesses in a clinical setting, or who are at risk due to international travel.

At-risk staff will evaluate each patient to determine what protective measures are necessary by using the following criteria.

- Have a cough for more than three weeks that is not explained by non-infectious conditions.
- Exhibit signs and symptoms of a flu-like illness during the months outside of the typical period for seasonal influenza, or exhibit these signs and symptoms for a period longer than two weeks at any time during the year. These signs and symptoms generally include combinations of the following: coughing and other respiratory symptoms, fever, sweating, chills, muscle aches, weakness and malaise.
- State that they have a transmissible respiratory disease, excluding the common cold and seasonal influenza.
- State that they have been exposed to an infectious ATD case, other than seasonal influenza.

In addition to using engineering and procedural controls, employees may also determine that respiratory protection is appropriate. Respiratory protection will consist of disposable N-95 dust/ mist respirators or N-95 mask, unless the Director determines that a higher level of protection is needed.

Employee exposures resulting in illness to pathogens other than seasonal flu or colds will be treated as described in the Biosafety and Bloodborne Pathogens programs, with all the attendant provisions for confidentiality and duration of treatment as any other exposure incident.

Employees will be trained annually in the provisions of this standard as part of Bloodborne Pathogens training.

Appendix A – Definitions

Biological Safety Cabinet (BSC) - A device designed to draw air inward by means of mechanical ventilation and in which pathogens are handled and manipulated. Biological cabinets are classified as:

Class I: A ventilated cabinet for personnel protection with an inward airflow away from the operator, and with high-efficiency particulate air (HEPA) filtered exhaust air lining the back. These typically protect the product and not the employee

Class II: A ventilated cabinet intended to protect personnel, product, and the environment having an open front with inward airflow, HEPA filtered laminar airflow for product protection, and HEPA filtered exhaust air for environmental protection.

Class III: A total enclosed, ventilated cabinet of gas-tight construction. Operations in the cabinet are conducted through attached protective gloves.

Blood - Includes human blood, human blood components, and products made from human 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).

Contaminated - The presence, or the reasonably anticipated presence, of blood or other potentially infectious materials on a surface or an item.

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

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

Engineering Controls – Mechanical devices that control, isolate, or remove pathogens from the workplace at the location at which they are generated. (e.g., sharps disposal containers, needleless systems and sharps with engineered injury protection).

Engineered Sharps Injury Protection

1. A physical attribute built into a needle device used for withdrawing body fluids, which effectively reduces the risk of an exposure incident by a mechanism such as barrier creation, encapsulation, withdrawal or other effective mechanism.
2. A physical attribute built into any other type of needle device, or into a non-needle sharp, which effectively reduces the risk of an exposure incident.

Exposure Incident – Contact with blood or other potentially infectious materials that results from the performance of an employee's work activities resulting in exposure to the eyes, mouth, other mucous membrane, non- intact skin, or parenterally.

Licensed Healthcare Professional - A person whose scope of practice includes an activity licensed by the State of California to provide heath services (e.g. physician, phlebotomist, nurse).

Needle or Needle Device - A needle of any type, including, but not limited to, solid and hollow-bore needles.

Needleless System - A device that penetrates the skin that does not utilize needles

Occupational Exposure – Exposure with blood or other potentially infectious materials to the skin, eye, mucous membrane, or parenteral contact resulting from the performance of work duties.

OPIM - Means other potentially infectious materials.

Parenteral Contact – The piercing of mucous membranes or the skin from such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment (PPE) - Clothing or equipment worn or used by employees for protection against a hazard. The employer must provide appropriate and adequate PPE for the work being performed.

Regulated Waste - Waste that meets any of the following descriptions and is defined in the California Medical Waste Management Act:

1. Liquid or semi-liquid blood or OPIM
2. Contaminated items that contain liquid or semi-liquid blood, or are caked with dried blood or OPIM; and are capable of releasing these materials when handled or compressed.
3. Contaminated sharps.
4. Pathological and microbiological wastes containing blood or OPIM.

Research Laboratory - A laboratory producing or using research-laboratory-scale

amounts of HIV, HBV or HCV. Research laboratories may produce high concentrations of HIV, HBV or HCV but not in the volume found in production facilities.
"Sharp" means any object used or encountered in the industries covered by subsection (a) that can be reasonably anticipated to penetrate the skin or any other part of the body, and to result in an exposure incident, including, but not limited to, needle devices, scalpels, lancets, broken glass, broken capillary tubes, exposed ends of dental wires and dental knives, drills and burs.

Sharps Injury - Any injury caused by a sharp, including, but not limited to, cuts, abrasions, or needlesticks.

Sharps Injury Log - A written or electronic record satisfying OSHA requirements of subsection (c)(2) in the Bloodborne Pathogens Standard.

Source Individual - Any individual whose blood or OPIM may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinical patients; some human remains; and individuals who donate or sell blood or blood components.

Universal Precautions - An approach to infection control. According to the concept of Universal Precautions, all human blood tissue, cell lines and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens.

Work Practice Controls - Controls that reduce the likelihood of exposure by defining the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique and use of patient-handling techniques).

Appendix B - Hepatitis B Immunization Declination Form

Under the Occupational Safety and Health Administration's (Cal/ OSHA) Bloodborne Pathogens Standard, employers are required to provide vaccinations against the hepatitis B virus (HBV). Employees who handle human-derived material, such as blood, tissue, cells, clinical samples, and other human bodily fluids are required to participate in the vaccination program. Employees who enter work areas and laboratories where human-derived materials are used must also be included in the program and offered vaccinations.

An employee's job title and work location indicate whether they must participate in the HBV vaccination program. Job titles and duties are discussed in Section 11.4.

Human Resources offers new employees HBV vaccinations or a titer test within 10 days of being hired, will provide employees with locations where these can be performed. If an employee knows they had the immunization, and choose to decline further, they must sign the following statement and return it Human Resources. All new participants in the Bloodborne Pathogen program will be offered this declination upon hire.

I understand that due to my occupational exposure to blood or other potentially infectious material (OPIM), I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine at no charge. However, I decline the 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 I continue to have occupational exposure to blood or OPIM and wish to be vaccinated with hepatitis B vaccine in the future, I can receive the vaccination series at no charge.

Employee

_____ _____

Printed Name **Date**

_____

Signature

Appendix C - Sharps Injury Log

The following information, if known or reasonably available, is documented within 14 working days of the date on which each exposure incident was reported.

1. Date and time of the exposure incident:
   _____
2. Date of exposure incident report: _____
3. Report written by:
   _____
4. Type and brand of sharp involved:
   _____
5. Description of exposure incident:

Job classification of exposed employee:		
Department or work area where the incident occurred:		
Procedure being performed by the exposed employee at the time of the incident:		
How the incident occurred:		
Body part(s) involved:		
Did the device involved have engineered sharps injury protection?	☐Yes	☐No
Was engineered sharps injury protection on the sharp involved?	☐Yes	☐No

If Yes	If No
Was the protective mechanism activated at the time of the exposure incident? Yes ____No ____	Does the injured employee believe that a protective mechanism could have prevented the injury? Yes ____No ____

6. Did the injury occur before, during, or after the mechanism was activated?_____

   Comments:
   _____
7. Does the exposed employee believe that any controls (e.g., engineering, administrative, or work practice)could have prevented the injury? Yes (3) _____ No (3) _____

Employee's Opinion:

_____

_____

8. Comments on the exposure incident (e.g., additional relevant factors involved)

_____

_____

9. Employee interview summary:

_____

_____

10. Picture(s) of the sharp(s) involved (please attach if available).

Appendix D – Operating Guidelines for the Institutional Biosafety Committee

At the core of the NIH Guidelines is the Institutional Biosafety Committee (IBC), charged with reviewing all research projects involving recombinant DNA (rDNA) in order to ensure safe containment of potentially pathogenic agents. An Institutional Biosafety Committee (IBC) represents collective expertise, and research experience, in managing recombinant DNA research, and implementing biological safety in experiments which may pose potential risks to human health or the environment. The IBC is responsible for ensuring that research conducted at TUC is in compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (the Guidelines), and is responsible for drafting biosafety policies and procedures, and reviews safety provisions for related research projects.

Membership of the IBC is comprised of the Safety Committee which includes the Biosafety Officer, as well as a community member with no TUC affiliation other than membership on the IBC. Community members are appointed to represent the interests of the surrounding community with respect to human health and environmental protection. The IBC appoints a Biosafety Officer to administer and manage the Biosafety Program in accordance with the NIH Guidelines. The collective expertise of the IBC is integral in ensuring a safe and compliant program.

Under NIH requirements, select projects may also require review and approval by the NIH's Office of Biotechnology Activities (OBA) or the Recombinant DNA Advisory Committee (RAC). Projects requiring agency approval include:

- The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally.
- Deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD_{50}.
- For an experiment involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants (human gene transfer).

TUC does not currently engage in projects requiring RAC or OBA approval, and it will be the responsibility of the Biosafety Officer to inform the IBC of these reporting requirements in advance of initiating such projects.

NIH Guidelines require that other projects involving Risk Group 2 agents have a project registration form completed. This form is referred to as the Biological Use Authorization (BUA) form, and is presented in Appendix E. Before the research project is initiated the principal investigator completes a BUA and submits it to the IBC for review and approval. This is intended to identify the potential risks and safety measures appropriate for each project.

IBC approval is required before the initiation of an experiment for the following projects.

- Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems.
- Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents are cloned into nonpathogenic prokaryotic or lower eukaryotic Host-Vector Systems.
- Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.
- Experiments involving whole animals.
- Experiments involving whole plants.
- Experiments involving more than 10 liters of media culture.

All research projects require completion of a BUA prior to initiation of the project. Experiments or research which is designated Biosafety Level 1 are exempt from Committee review and the BUAs can usually be reviewed and approved solely by the Biosafety Officer (BSO).

Researchers using any of the following should complete and submit a BUA application form for review and approval:

- Recombinant DNA
- Infectious Agents
- Toxins
- Human blood, body fluids, or unfixed tissue
- Tissues, organ or cell cultures of human origin
- Human Gene Therapy

Committee review includes an assessment of the containment levels for the proposed research, an assessment of the laboratory facilities, procedures and practices, training, appropriate medical surveillance, and experience of personnel.

Appendix F - Summary of Biosafety Levels

Biosafety Level	Agents	Safe Work Practices	Primary Barriers	Secondary Barriers
1	Not known to consistently cause disease or infection to healthy adults	Standard microbiological techniques and practices	None required	1. Facility design accommodates lab work. 2. Hand washing sink
2	Capable of causing disease, but not by standard laboratory routes of exposure. Potentially infectious only by percutaneous, ingestion, or mucous membrane exposure pathways.	BSL-1 Practices plus: • Limited access to lab. • Biohazard warnings • Sharps handling • Biosafety manual	• Biosafety cabinets – (Class 1 or II) • Physical containment devices to minimize aerosols and potential exposures. • PPE – lab coat, gloves, safety glasses	BSL-1 plus: Autoclave available
3	Agents capable of causing disease by aerosol transmission. The disease may have serious or lethal consequences.	BSL-2 Practices plus: • Controlled access • Decontamination of all waste • Decontamination of lab clothing • Baseline serum samples	• Biosafety cabinets – (Class II or III) • Physical containment devices to minimize aerosols and potential exposures. • PPE – lab coat, gloves, safety glasses	BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhausted air filtered and not circulated • Negative airflow into lab
4	Dangerous and exotic agents with a high risk of life-threatening disease via aerosol transmission. Related agents with unknown risk of transmission.	BSL-3 Practices plus: • Clothing change before entering • Shower on exiting • All materials decontaminated before	All procedures in Class III Biosafety cabinet or Class I or II with full-body positive pressure suit and supplied air.	BSL-3 plus: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum and decontamination system

Biosafety Level	Agents	Safe Work Practices	Primary Barriers	Secondary Barriers
		leaving the facility.		