



**BELLARMINE  
UNIVERSITY**

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**Bellarmino University**  
**Biosafety Committee Handbook**

July 1, 2015

## Preface

This document defines the composition, role, and function of the Institutional Biosafety Committee at Bellarmine University. Additionally, the handbook serves as a resource that outlines best practices or guidelines associated with learning and research in the biological, medical, and related fields. As such the document provides an overview of critical lab safety issues, underscores the importance of lab safety training, and articulates the broader, but limited, role of the IBC chair.

## 1. Purpose & Mission

Bellarmino University is committed to the safety of all faculty, staff, students and visitors by ensuring that the environment is free of undue risks to their health and well-being. The Institutional Biosafety committee (IBC) of Bellarmine University was designed, in part, to help meet this goal. The IBC is designed to oversee all university activities that involve: 1.) recombinant DNA and 2.) potentially infectious materials to ensure that it is conducted in compliance with the National Institutes of Health Guidelines (<http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>). While the guiding principles and regulatory authority of IBC are defined by rules established by NIH, the University recognizes that the BU IBC plays an important advisory role in broader laboratory safety domains as they relate to both teaching and research. To that end, the Handbook includes details on required and recommended training. Ultimately, though, laboratory safety is the responsibility of the individual faculty members and/or employee.

## 2. Composition & Quorum

The IBC will be composed of no fewer than five members including the Chair and Vice-Chair. To ensure compliance with federal regulations and ensure broad representation of the campus community, the BU committee will include at least one regular member from the following constituencies: 1) Natural Sciences, and 2) Health Sciences; and no less than two unaffiliated members from the community at large. Please note, one member may be able to satisfy more than one of these constituency requirements. As required by governing regulations, the community member (and/or any of their immediate family members) must not have a formal affiliation with the institution. The committee will appoint alternates to ensure a quorum can be achieved in situations where one or more members may identify a potential conflict of interest.

**Quorum** will be defined as no less than three participating members with at least one of the attendees being an unaffiliated member of the community. In limited and extra-ordinary situations, IBC members may, with prior approval of the Chair and consent of the majority of members in attendance, participate via teleconference to obtain a quorum. A passing vote shall be defined as one receiving a simple majority of those members present. The Chair and Vice-chair are voting members of the committee.

## 3. Appointment Procedures & Terms

The Office of Academic Affairs will solicit volunteers annually and membership will ordinarily be selected from the obtained pool of volunteers. Members and alternates will be appointed for three -year terms by the Provost (or designee). To ensure consistency, the terms will be staggered with 50% of the members and/or alternates appoint annually. Should a permanent member resign or be removed from the committee, the Provost (or designee) will consult

with the IBC Chair prior to appointing a replacement. The Chair and Vice-Chair of the IBC will be appointed by the Provost (or designee).

#### **4. Meeting Schedule**

The committee will meet at-least once per year to assess the status of biosafety training, essential planning documents, protocols, and research on campus. Additionally, the committee may meet to review and approve relevant research protocols. When and where electronic resources can be used to increase the efficiency of the review process, technology shall be used at the discretion of the Chair insofar as the principles of committee composition and quorum are preserved and all regular members (or designated alternates, if appropriate) have the means to participate. Additionally, the Academic Safety Officer will call an annual meeting with chairs and the IBC to discuss biosafety issues and concerns—as well as to provide any critical updates to the BU community.

#### **5. Functions, Responsibilities, & Authority**

This manual is designed to be used in concert with department and laboratory specific manuals and procedures that specifically address the scope of work of the individual lab. The IBC will review and approve investigator protocols as well as exercise continuing review of ongoing research, laboratory safety, and associated training. As part of its review process, the IBC has the authority to recommend modifications prior to approval to ensure the safety of the public. Likewise, the IBC may vote to not approve proposed research as the risks may be deemed unacceptable. Additionally, the IBC is obligated to investigate non-compliance issues and has the authority to suspend research activities and may recommend sanctions related to research performance and/or misconduct to the Office of Academic Affairs.

The IBC must review any and all research protocol type associated with Section III-B of the NIH Guidelines prior to active research commences. All investigators must prepare a descriptive and detailed “proposal” using the structure outlined in Appendix A.

The Chair has responsibilities for scheduling and chairing meetings of the IBC and may delegate duties to the Vice-chair, as needed. Additionally, the Chair will coordinate compliance with University and OSHA expectations for BBP training faculty and students, as well as staff when requested to do so (see Section 3).

It is the responsibility of Deans, Program Directors, and Department Chairs to be familiar with and implement University biosafety guidelines or designate a person with the authority to carry out these requirements. The IBC Handbook will be annually distributed to all faculty, staff (including temporary employees), students, visitors, volunteers, and students electronically using campus email and other appropriate means. Hard copies of the IBC Handbook will be available in human resources. All supervisors must direct individuals within their labs or department to obtain any required safety and health training before working with hazardous chemicals, biohazardous agents, and/or other physical/mechanical hazards found within their working or learning environments. They must also determine and ensure that safety needs and equipment for departments are met (e.g., training, protective equipment, etc.) and that items of noncompliance, identified during facility inspections, are corrected promptly. In addition, they must ensure college and departmental procedures are established and communicated to identify and respond to potential accidents and emergency situations and encourage college and departmental laboratory participation in self-inspection process as a means to regularly check performance against regulatory requirements and identify opportunities for improvement

The ultimate responsibility for health and safety within laboratories rests with each individual who works in the laboratory; however, it is the responsibility of the Faculty and laboratory supervisors to ensure that students and employees (including visitors, volunteers, temporary employees, and student employees) have received all appropriate training, and have been provided with all the necessary information to work safely in laboratories under their control. Faculty and Lab Supervisors have numerous resources at their disposal for helping to ensure a safe and healthy laboratory that is compliant with state and federal regulations, including Dr. Jay Gatrell and all members of the Biosafety Committee.

## 6. Training, Lab Safety, & Annual Inspections<sup>1</sup>

The IBC is committed to ensuring compliance with NIH rules and regulation. Further, the committee is committed to ensuring the overall safety of students in laboratory research and learning environments. This document provides information on registration, training, recommended work practices, and safety equipment. However, it is the responsibility of the Program Director, Department Chair, Supervising Faculty, or appointed designee to appropriately assess and mitigate the risks associated with individual research protocols. Additional guidance is provided in *Biosafety in Microbiological and Biomedical Laboratories*, published by the Centers for Disease Control/ National Institutes of Health ([BMBL](http://www.cdc.gov/biosafety)). To ensure safety and compliance, the IBC requires the following:

**Lab Safety Training:** The IBC requires all students enrolled in laboratory courses complete a formal lab safety curriculum. The IBC recommends completing the NIH Division of Occupational Health & Safety online training (<https://www.safetytraining.nih.gov/Main.aspx>). Individuals (students, faculty, or staff) actively engaged in research involving recombinant or synthetic nucleic molecules must complete the NIH online training. Please note the NIH modules cover advanced biosafety content and may or may not be appropriate for the specific course or content level. For that reason, academic departments may deliver their own lab safety curriculum as long as it covers all of the relevant materials in the NIH course and they have consulted with the IBC chair. Additionally, all BU employees and students are expected to agree to adhere to BU lab safety guidelines and practices outlined in this handbook. A sample and recommended lab safety statement is included in Appendix C. All instructors are required to provide students enrolled in laboratory sessions with a safety statement at the first assigned meeting. It is the responsibility of Faculty and laboratory supervisors to ensure that staff and students working in laboratories under their supervision have obtained the required health and safety training and have access to MSDS (and other sources of information) for all hazardous chemicals used in laboratories under their supervision. MSDS must be accessible at all times.

**Bloodborne Pathogens (BBP) Training:** The IBC recognizes that the NIH online course for lab safety includes a basic overview of BBP issues. However, the IBC requires students enrolled in selected health science and biomedical majors to complete additional formal training. These majors include: Nursing, Physical Therapy, Biology, Biochemistry & Molecular Biology, Medical Laboratory Science, Respiratory Therapy, and Exercise Science. These majors may have established BBP training modules as part of existing courses for enrolled students that meet the minimum expectations of OSHA as outlined in 29 CFR Section 1910. All faculty assigned to laboratory and/or clinical environments are required to have completed an OSHA approved course on BBP and it is expected that faculty renew their regularly. Bellarmine University does not plan to implement a single uniform training structure given the varied nature of positions,

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<sup>1</sup>Lab safety is not governed by the IBC per se except in cases of: 1.) recombinant DNA and/or 2.) potentially infectious materials; or in learning & research environments where it is reasonable to believe students, staff, or faculty may be at risk for exposure to biohazards. As such, individual programs have primary responsibility for ensuring their programs meet the safety requirements of the University within the context of the professional expectations and best practices of their disciplines.

curriculum, and clinical experiences. BBP online training is provided by BU for all employees (faculty, instructors, staff, and student workers). To enroll in this training, supervisors and employees should contact the IBC chair ([dgolemboski@bellarmine.edu](mailto:dgolemboski@bellarmine.edu)).

In addition to the training outlined above, all researchers, instructors, and employees engaged in learning, working, or research environments where exposure might reasonably be anticipated to occur (such as public safety, residential life, and so on) are required to have completed advanced training and have access to safety equipment appropriate for the Biosafety level of the research conducted, teaching activity, and/or workplace exposure risk. The capacity and infrastructure at Bellarmine University is limited such that no research or laboratory activities above Biosafety Level 2 will be permitted. Additionally, Bellarmine University does not currently have an operational animal research facility and campus based protocols requiring approval of an approved IACUC cannot be approved at this time. Please note, the IBC and university recognize that Bellarmine faculty and researchers may be active in collaborative research at another institution and this document does not govern off-site labs.

Finally, the IBC expects all academic departments to maintain safe research and learning environments. To ensure compliance, academic department chairpersons (or their designee) are required to report and document any identified safety concerns in primary classrooms, labs, and adjoining hallways to the Academic Safety Officer. In addition to academic units, intercollegiate athletics<sup>2</sup>, the university health services, and other campus units are expected to adopt and implement standard training practices. The summary documents will be housed in the Office of Sponsored Projects. While facilities management has primary authority over buildings and must perform annual inspections, any observed deficiencies associated with the building should be noted and brought to the attention of the AVP for Facilities Management and electronic copies of concerns or deficiencies should be documented using the laboratory inspection checklist forms in Appendix C. The form should be forwarded to the Academic Safety Officer via email.

## 7. Planning & Reporting: Required Documentation

IBC and Bellarmine University (BU) required documentation are contained in Appendix B. In the following paragraphs, the IBC expects compliance, benefits, and policies afforded employees to be extended all students and visitors, as necessary.

*Plans.* All departments with faculty, staff, or students engaged in biological research, standard teaching laboratory activities, or required undergraduate research activities are required to review and forward any and all updates associated with the approved BU “Occupational Exposure to Bloodborne Pathogens” plan. Each department is required to review the basic plan in this document and forward any revisions to the IBC biennially and no later than September 1, beginning in 2016. All departments are required to confirm that a current plan exists, is consistent with the plan contained in this handbook, and is being implemented. As part of the planning process, all departments are required to perform an internal biological risk assessment of their facilities beginning with the CDC’s risk assessment worksheet. The worksheet is available online at:

<http://www.cdc.gov/biosafety/publications/BiologicalRiskAssessmentWorksheet.pdf>. See Appendix C.

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<sup>2</sup> Intercollegiate athletics has primary authority and responsibility for biosafety issues pursuant to NCAA regulations. The IBC will provide technical support, as needed. The IBC has reviewed NCAA documents and thus finds them generally consistent with the expectations, policies and practices in this handbook—and as such their internal athletics compliance officers are solely responsible for training, reporting, responding, and record keeping.

*Training Records.* The university maintains a record of all employees including student workers who have completed required BU BBP training. Units using other training frameworks should maintain a training log that includes the training record form.

*Incident Reports.* Any adverse events or laboratory incidents must be reported using the approved form with copies sent to the IBC chair and the university's primary risk management official, the Assistant Director of Facilities (x8117). If immediate safety issues are a concern, local authorities and first responders should be contacted immediately.

*Laboratory Safety Documentation.* Instructors are required to distribute a lab safety statement to all students at the first meeting of the lab and/or course. The instructor is required to review the sheet with the students and provide safety instruction at the initial meeting of all courses and students should complete lab safety statements for 100-level or general education labs and/or courses only. However, basic lab safety is expected to be reviewed in all 200-level and above courses. Finally, the statement should be signed by the students and maintained by the instructor through the end of the enrolled semester.

*Live Material.* Live material is defined as living organisms (excluding animals) that may pose a potential biosafety risk. Faculty, instructors, students, and other campus based researchers using live material are required to provide the IBC chair with a comprehensive list of all material annually and no later than September 1, each year. Faculty can submit the list of material via email to the IBC Chair. When appropriate, the list should be amended throughout the year, specifically if additions to the list are made. Failure to provide and update lists of live material constitutes non-compliance with BU Biosafety guidelines.

## **8. Human Subjects & Informed Consent**

Any and all protocols involving human subjects must also be approved by the Institutional Review Board (IRB) and the IRB protocol application can be substituted for an Appendix B proposal in consultation with the IBC chair. Pursuant to IRB requirements, informed consent is required in all situations.

## **9. Investigations of Non-Compliance, Reporting, and Actions**

The IBC has a duty to investigate all cases of noncompliance associated with biomedical research governed by the NIH Guidelines. Notification of suspected noncompliance may occur during the review of submitted protocols, community reports, inadvertent disclosures, or report of an adverse event. Once the IBC has been made aware of potentially noncompliant research, the Chair must determine if noncompliance has occurred. If the chair determines noncompliance with NIH Guidelines has occurred, the chair must report the incident to the NIH in all situations where extramural grants or contracts are supporting the activity associated with the incident. Pursuant to the NIH Guidelines, "Noncompliance may result in: (i) suspension, limitation, or termination of NIH funds for recombinant or synthetic nucleic acid molecule research at the institution, or (ii) a requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid molecule projects at the institution. As such, noncompliance in the area of research may result in penalties to the individual researcher, lab, and/or university depending on the severity of the incident or concern. Noncompliance concerns or safety incidents associated with teaching activities and/or unfunded research should be reported to the IBC chair and academic safety officer. Following a formal investigation, instructors, students, and other participants associated with an adverse event and broader non-compliance with handbook guidelines may be barred

from university laboratory facilities, have their laboratory activities limited, required to attend additional training, and/or, in situations of willful neglect or intentional acts, subjected to disciplinary action pursuant to existing University policies and procedures.

## **10. Responsible Institutional Representatives**

While the IBC has authority over maintaining general policies and the chair of the IBC plays a critical leadership role on campus, the following individuals have primary authority over components of the biosafety and lab safety of all Bellarmine University employees, students, and guests:

Academic Safety Officer (ASO) refers to a designee of the Provost housed in the Office of Academic Affairs. The ASO will serve as the primary liaison with between the faculty as represented by the IBC and the University Compliance Officer, Facilities Safety Officer, and Chemical Safety Officer

University Compliance Officer (UCO) refers to a designee of the Vice President of Administration & Finance and is responsible for maintaining all employee records housed in human resources associated with required OSHA training. The UCO resides in the Human Resources department.

Facilities Safety Officer (FSO) refers to a designee of the AVP for Facilities with responsibilities for all employee risk management issues, building/structural issues, and all facilities management concerns. The FSO also has primary responsibilities for all university risk management concerns.

Chemical Safety Officer (CSO) refers to the chair of the Department of Chemistry or his or her designee. The CSO has formal academic training in chemistry or a related field and oversee safety of the chemistry lab environments.

Academic Department Chairpersons or Program Directors are responsible for ensuring that proper lab safety training instruction is provided to all students and that, where appropriate, advanced training occurs (i.e., BBP). Chairpersons are also responsible for regular safety inspections of all research facilities assigned to faculty and/or labs and classroom where students engage in learning activities, as well as maintaining all documentation surrounding safety inspections. When and where facility related safety concerns associated are identified, facilities and the academic safety officer should be immediately notified and deficiencies documented using the lab checklists in Appendix C. Annually, all department chairs will participate in a biosafety meeting called by the Academic Safety Officer. Forms and documents are located in Appendix C.

Faculty have primary responsibility for ensuring student safety, reporting safety concerns to Facilities and the Chairperson, in a timely fashion, and properly training all enrolled students, visitors, and/or employees in their labs or courses. Faculty will be expected to review the IBC handbook annually to ensure compliance. Faculty are expected to require all enrolled students to complete the laboratory safety statement and prepare a classroom checklist for each class. The checklist and statements should be maintained by the faculty member until the end of each semester (see Section 7).

## **11. Research Protocols**

Faculty and student researchers engaged in funded research are expected to submit proposals to the IBC for approval. Faculty are required to submit proposals when performing independent research when and where the *NIH Guidelines* warrant submission. Faculty are encouraged to contact the IBC to clarify this requirement. Standard teaching laboratory activities, required undergraduate research activities, activities that involve only the in vitro use of nucleic acids (i.e., PCR, synthetic double stranded RNA) and that which does not involve the cloning and propagation of recombinant or synthetic nucleic acid molecules in cells, organisms or viruses, and other educational activities are exempted.

## **12. Changing this document & Associated Forms**

Changes to this document may be made provided the suggestions are disseminated to all current members for their review and comment. Changes shall be passed by a simple majority of the Committee members. The date of the latest revision should be noted in the footer.



## **Appendix A: Documentation & Forms**

The documents in this appendix include:

1. Occupational Exposure to Bloodborne Pathogens Exposure Control Plan
2. Bloodborne Pathogens Training Record
3. Declination of HBV Vaccination
4. Post-Bloodborne Pathogen Exposure Incident Report form
5. Sharps Injury Report
6. Post-Exposure Evaluation & Follow-up Declination .

Upon completion, copies of these forms should be maintained in the main office of the responsible academic unit. In the case of exposures and/or other incidents (#2-6) electronic copies should be sent to the Academic Safety Officer in the Office of Academic Affairs.



Department \_\_\_\_\_

Prepared by \_\_\_\_\_

## Occupational Exposure to Bloodborne Pathogens Exposure Control Plan

In accordance with the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030

### Purpose

The Exposure Control Plan is designed to eliminate or minimize work-related exposure by identifying potentially exposed employees, to human blood or other infectious body fluids.

In 1992, the Occupational Safety and Health Administration (OSHA) enacted the Bloodborne Pathogens Standard codified as 29 CFR 1910. 1030. The purpose of the standard is to protect workers from anticipated exposures to bloodborne pathogens including Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV).

### Review and Update of the Bloodborne Pathogens Exposure Control Plan

This Exposure Control Plan will be reviewed and updated at least annually by the IBC in consultation with the Academic , Facility, and Chemical Safety Officers, and when necessary to reflect new or modified tasks and procedures.

#### 1. Exposure Determination

OSHA requires employers to determine which employees may incur occupational exposure to blood or other potentially infectious materials. Exposure determination is made without regard to the use of personal protective equipment.

Job Classifications in which **some** employees have occupational exposure and the tasks or procedures that would cause occupational exposure:

#### 2. Method of Implementation

Institutional Biosafety Committee, in consultation with the Faculty, Chemical Safety, and Academic Safety Officers, have developed this Occupation Exposure Control Plan.

The IBC, Academic Safety Officer, Facility Safety Officer, and Chemical Safety Officer are responsible for the following:

- Implementing the plan and developing site specific policies and procedures and ensuring compliance.
- Reviewing and updating the Exposure Control Plan at least annually, and when necessary to reflect new or modified tasks and procedures, and to reflect new or revised employee positions that affect occupational exposure.

- Monitoring exposure control in their respective areas.
- Application of universal precautions
- Appropriate work practices and engineering controls

The Chemical Safety Officer is available to assist with development of the exposure control plan, employee training and other consultative roles as related to the OSHA standard.

A copy of this plan will be accessible to all employees via myBellarmine. Copies of the plan are also available online at the Institutional Biosafety website.

### 3. Compliance Methods

#### A. Universal Precautions:

Universal Precautions were developed by the Centers for Disease Control to help prevent the transmission of bloodborne diseases in the work place. Under universal precautions, all human blood and other potentially infectious materials (OPIM) are considered infectious for HIV, HBV, and other bloodborne diseases. Therefore, all human blood and OPIM are treated as though they are infectious and precautions are taken accordingly.

#### OPIM includes:

1. The following body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids
2. Any unfixed tissue or organ (other than intact skin) from a human (living or dead)
3. HIV containing cell or tissue cultures, and HIV or HBV containing culture medium or other solutions, and blood, organs and other tissues from experimental animals infected with HIV or HBV.
4. Included are human cells, tissue cultures, and blood products and blood components containing known or suspected bloodborne diseases, unless documented to be free of human bloodborne pathogens.

#### B. Engineering Controls

Engineering and work practice controls will be used to eliminate or minimize exposure to employees. Where occupational exposure remains after institution of these controls, personal protective equipment will be used.

- *Hand washing facilities* are readily available in the work area, such as the laboratory, procedure room, or patient care area.
- *Sharps containers* are available where sharps are used. Appropriate containers are puncture resistant, labeled with a biohazard label or color coded, and leak proof on the sides and bottom. Sharps containers are located as close to the point of use as possible.
- *Biological Safety Cabinets* (Class II) will be used when necessary to provide worker protection during aerosol generating procedures with human blood and OPIM (including human cells, tissue cultures, and blood products and blood components). Class II Biological Safety Cabinets,

while providing laminar airflow to protect research material, are designed with inward flow to protect personnel, and filtered exhaust air for environmental protection as well

- *Infectious Waste* is discarded into red plastic bags. If the waste will puncture the bags, a biohazard box with a red plastic bag liner is used.
- *Mechanical Pipettes* are used, mouth pipetting is prohibited.
- *Containers* for blood or OPIM will be constructed to prevent leakage during handling, processing, storage or transport. If universal precautions are used, additional labeling is not necessary as long as the containers are recognizable as containing blood or OPIM and do not leave the facility. If the primary container leaks or outside contamination occurs, the primary container will be placed within a second container which prevents leakage and is properly labeled.
- *Contaminated Equipment* will be decontaminated prior to servicing or shipping. Equipment that cannot be decontaminated will be labeled with a biohazard label.
- Nearest location of emergency showers and eyewash stations

### C. Work Practice Controls

The following protocols should be followed:

- *Hand washing* with soap and water for at least ten seconds is required immediately after any exposure, and as soon as possible after removal of gloves or other personal protective equipment. If employees incur exposure to skin, those areas will be washed with soap and water. When soap and water are not available employees shall use a sanitizing hand cleaner (e.g., Purell, and other materials containing 60-70% ethanol). Exposures to eyes or mucous membranes require flushing with water.
- *Needles and Sharps* will not be bent, recapped, removed, sheared or purposely broken. Needles and other sharps will be discarded into approved sharps containers. Recapping is permitted only if no other means are feasible and a mechanical device or one handed technique is used.
- *Personal Protective Equipment* will be removed immediately upon leaving the work area. Disposable gloves and other items can be discarded in the regular trash. Grossly contaminated items that meet the definition of Regulated waste (see Section F, Waste Disposal) are to be disposed in infectious waste containers.
- *Eating, drinking, applying cosmetics, and handling contact lenses* are prohibited in work areas where there is a possibility of occupational exposure. Food and beverages will not be stored in refrigerators, freezers, counters or bench tops where blood or OPIM are present.
- *Mouth Pipetting* or suctioning is prohibited.
- All procedures involving blood or OPIM will be conducted in a manner minimizing spraying, splashing or generation of droplets.

### D. Personal Protective Equipment

All personal protective equipment (PPE) used will be provided by the department, at no cost to the employees. PPE is chosen based on the anticipated exposure. The PPE will be considered appropriate only if it does not permit blood or OPIM to pass through or reach the employee's clothing, skin, eyes, mouth, or mucous membranes under normal conditions of use and for the duration of time the PPE will be used. Employees exhibiting sensitivity to latex gloves will be provided hypoallergenic, powder-free nitrile or vinyl or gloves.

The Resident Life Office is responsible for ensuring that PPE in appropriate sizes is readily accessible to all employees under their supervision.

The following list indicates the required PPE for tasks and procedures in which occupational exposure may occur.

- Contaminated PPE will be removed as soon as possible.
- All PPE, whether contaminated or not, must be removed prior to leaving the work area. This is especially important for gloves, since they are generally assumed to be contaminated. When disposable gloves are removed, they must be discarded.
- Gloves are worn when employees may have hand contact with blood, OPIM, mucous membranes or non-intact skin, or contaminated items or surfaces.
- Gloves must be replaced as soon as possible if they are torn, punctured, or when their ability to function as a barrier is compromised.
- Disposable gloves are not to be washed or decontaminated for re-use.
- Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are torn or punctured.
- Appropriate face and eye protection (i.e., safety glasses and face shields) whenever the potential for splashes exists

#### **E. Housekeeping**

The academic department in consultation with facilities/custodial services will ensure work areas will be maintained in a clean and sanitary condition. A written schedule for cleaning and methods of decontamination based on the location, type of surface to be cleaned, type of soil present, and the tasks or procedures done in the area will be implemented.

- Work surfaces and equipment will be cleaned and decontaminated at the completion of procedures, as soon as possible after contact with blood or OPIM, and at the end of the work shift if they may have been contaminated during the shift.
- Appropriate disinfectants include chlorine bleach (5.25% sodium hypochlorite or household bleach, in a 1:10 dilutions). Commercial disinfectant labeled with the EPA Classification: Hospital Disinfectant with Tuberculocidal Activity. Look for the terms "tuberculocidal" and "hospital disinfectant" on the label of the chemical
- Protective coverings such as imperviously backed absorbent paper, plastic wrap or aluminum foil used to cover equipment and environmental surfaces will be removed and replaced as soon as feasible after contamination.
- All bins, pails, cans and similar receptacles intended for reuse, which have a reasonable likelihood for becoming contaminated, will be inspected regularly. Receptacles will be cleaned and decontaminated immediately or as soon as feasible upon visible contamination.
- Broken glassware that may be contaminated must never be picked up by hand. Mechanical means such as forceps, tongs, or dust pan and broom must be used.

#### **F. Regulated Waste Disposal**

Regulated waste is defined as liquid or semi-liquid blood or OPIM; contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that are caked with dried

blood or OPIM capable of releasing these materials during handling; contaminated sharps; all needles and syringes regardless of their use; pathological and microbiological wastes.

- Immediately after use, sharps will be disposed of in closable, puncture resistant containers that are leak proof on sides and bottom in addition to labeled or color coded.
- Sharps containers will be replaced routinely and not allowed to overfill.
- Reusable sharps containers will not be opened, emptied, or cleaned manually in a manner which would expose employees to the risk of percutaneous injury.
- All regulated waste must be segregated, packaged and discarded in accordance with the policies outlined in the Bellarmine University Guidelines for Disposal of Infectious Waste (Appendix D, p. 47). It is the responsibility of the department, or laboratory generating regulated waste to comply with these guidelines, and provide the appropriate packaging material (i.e. sharps containers and orange/red Biohazard bags).

#### **G. Contaminated Laundry**

Laundry contaminated with blood or OPIM will be handled as little as possible. Such laundry will be placed in appropriately marked bags at the location where it is used.

- All employees who handle contaminated laundry will use appropriate personal protective equipment.
- Disposable articles will be used whenever feasible to reduce the generation of contaminated laundry.

The department in which the facility is housed is responsible for providing laundry services for their contaminated lab coats and contaminated re-usable garments. Should employee owned clothing be contaminated, laundry services will also be provided. Home laundering of personal protective equipment or contaminated clothing is not permitted.

#### **4. Hepatitis B Vaccination Program**

***All employees are strongly encouraged to be vaccinated against Hepatitis B virus if their work may expose them to blood or OPIM including human cells, tissue cultures, blood products and blood components.***

The vaccination program is made available through the **Bellarmino University Health Services**. Call **452-8219** for scheduling information. All employees occupationally exposed are to report to Health Services where they will be provided with information about the vaccine. The employee will then sign a consent form, and be provided the vaccine. Employees who decline the Hepatitis B vaccine must sign the Hepatitis B Declination form. A copy of these records will be maintained by Dr. Daniel Golemboski.

The vaccine will be offered within 10 working days of their initial assignment involving the potential exposure to human blood and OPIM, unless the employee has previously received the complete Hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

The University will insure all employees identified as having occupational exposure blood or OPIM are offered the Hepatitis B vaccine, at no cost to the employee if approved by their department. Furthermore, the

university will assure that if an employee initially declines the Hepatitis B vaccine, but at later date, while still covered under the standard, decides to accept it, the vaccine will be made available at that time, if previously the department had agreed to pay. Finally, the university, through either the Academic Safety Officer or other divisional designate will assure employees who decline the Hepatitis B vaccine must sign the prescribed Declination Statement.

## 5. Post-Exposure Evaluation and Follow Up

Any Bellarmine University employee who sustains an occupational exposure (needle/instrument stick, splash exposure to mucous membranes, or exposure to cut or non-intact skin) will be provided post exposure evaluation and follow-up at no cost to the employee.

Health Services currently recommends that evaluation be undertaken immediately, so that treatment prophylaxis, if indicated, can be started preferably within 1-2 hours post exposure.

Employees who experience a needle-stick or other occupational exposure are to do the following:

- Clean the area involved thoroughly with soap and water. For splash to eyes, mouth or nose, flush with copious amounts of water.
- Notify their supervisor immediately.
- Complete the **Exposure Incident Report**.
- Employees must then take the completed form with them for medical evaluation to their immediate Supervisor as well as a copy to the Academic Safety Officer in the Office of Academic Affairs.

### A. Health Services

The selected offsite care facility will provide a confidential medical evaluation and follow-up including:

- Documentation of the route of exposure and circumstances related to the incident and HBV and HIV antibody status of the source (if known).
- If the source person can be determined and permission is obtained, collection and testing of the source person's blood will be done to determine the presence of HIV or HBV. These results will be forward the results to the Physician.  
In laboratories, most sources will not be individuals. Potential sources include tissue samples, pooled blood, cell cultures, blood products and blood components unless documented to be free of human bloodborne pathogens.
- The employee will be offered the option of having their blood collected for testing of HIV/HBV status. Testing may be done at the time of exposure, or the blood sample will be preserved for up to 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline tested, such testing will be done as soon as feasible.
- The employee will be offered post exposure prophylaxis in accordance with the current recommendations of the U.S. Public Health Service. Health Services will follow an approved protocol for evaluation, testing, treatment, counseling, and follow-up.
- The employee will be given appropriate counseling concerning precautions to take during the period after the exposure incident. The employee will be advised to report to the physician any febrile illness, flu-like symptoms, rash, lymphadenopathy, or other illness within 12 weeks of the incident.

- During the follow-up period after the exposure, exposed persons will be advised to follow the Health Services recommendations for preventing transmission of infectious agents.
- The employee should contact the Health Services or the physician with any questions or concerns.
- Documentation of each incident and associated records will be kept in a central location by the Institutional Biosafety Committee with limited access and strict confidentiality maintained.
- During all phases of the follow-up, confidentiality of the employee will be protected.

#### **B. Healthcare Professional's Written Opinion**

After the consultation, the attending physician or Health Care Provider (HCP) provides Health Services with a written opinion. Health Services, in turn, will furnish a copy of this opinion to the exposed employee within 15 days of the evaluation.

The written opinion will be limited to:

- Whether the Hepatitis B vaccination is indicated for the employee
- Whether the employee has received the Hepatitis B vaccination
- Confirmation that the employee has been informed of the results of the evaluation.
- Confirmation that the employee has been told about any medical conditions resulting from the exposure incident which require further evaluation or treatment

All other findings or diagnoses will remain confidential and will not be included in the written opinion.

#### **6. Labels and Signs**

- Labels shall be affixed to containers of regulated waste, sharps containers, refrigerators, freezers, or other containers used to store, transport, or ship blood or OPIM.
- Red bags or containers may be substituted for labels as appropriate.
- Contaminated equipment will be labeled and also indicate which portions are contaminated.
- The required labels will include the International Biohazard Symbol and BIOHAZARD written under the symbol.
- The labels will be fluorescent orange or orange-red with the letters and symbols in a contrasting color.
- Labels will be affixed as close as feasible to the container, in a way that prevents their loss or unintentional removal.

#### **7. Information and Training**

The hiring department is responsible for assuring that all employees with occupational exposure receive the link to University-required Bloodborne Pathogen training.

Training will be provided at the time of initial assignment to tasks where exposure may occur and at least annually thereafter. If changes occur in tasks or procedures that may affect the employees' exposure, additional training will also be provided.

The training program will consist of the following elements:

- Availability of the Bloodborne Pathogens Standard and explanation of its contents
- A general explanation of the epidemiology and symptoms of bloodborne diseases
- An explanation of the modes of transmission of bloodborne pathogens
- An explanation of this individualized Exposure Control Plan including location and availability of copies



- Appropriate methods for recognizing tasks and other activities that may involve exposure to blood or OPIM.
- An explanation of the use and limitations of exposure controls including engineering controls, work practices, and personal protective equipment
- Information on the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment
- An explanation of the basis for the selection of personal protective equipment
- Information on the Hepatitis B vaccine including its efficacy, safety, method of administration, benefits and how to receive the vaccine at no cost to the employee
- Actions to take and persons to contact in case of a spill or other emergency involving human blood or OPIM
- The procedures to follow if an exposure incident occurs, including procedures for reporting and the medical follow-up that will be made available
- Information of the post exposure evaluation and follow-up that will be provided following an exposure incident
- Explanation of the signs, labels, and color coding

An opportunity for interactive questions and answers with the person conducting the training program will be provided.

The person conducting the training must be knowledgeable in the OSHA Bloodborne Pathogens Standard, the unit's Exposure Control Plan and the elements contained in the training program as they relate to the unit

The Institutional Biosafety Committee is available to assist with University and regulatory aspects of the training program upon request. Requests for assistance should be made by contacting the Institutional Biosafety Committee.

## **8. Recordkeeping**

Medical records will be established and maintained for each employee who has an occupational exposure incident. These records will be maintained by the Institutional Biosafety Committee.

Training records will be retained for 3 years. These records will be established at the time of training and maintained by the hiring department and chair of the IBC.

The records will include:

- The dates of the training
- The contents or summary of the training
- The name and job title of the people attending the training
- The name and job title of the trainer

## **9. Terms and Definitions:**

**Blood** means human blood, human blood components, and products made from human blood.

**Bloodborne Pathogens** means 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) and human immunodeficiency virus (HIV).

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

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

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

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

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

**Engineering Controls** means controls (e.g. sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.

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

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

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

**HBV** means hepatitis B virus.

**HIV** means human immunodeficiency virus.

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

**Other Potentially Infectious Materials (OPIM)** means:

- A. The following human body fluids:
- Semen
  - Vaginal Secretions
  - Cerebrospinal fluid
  - Synovial fluid
  - Pleural fluid
  - Pericardial fluid
  - Peritoneal fluid
  - Amniotic fluid
  - Saliva in dental procedures
  - Any body fluid that is visibly contaminated with blood
  - All body fluids in situations where it is difficult or impossible to differentiate between body fluids
- B. Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- (a) 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.
  - (b) Included are human cells, tissue cultures, and blood products and blood components containing known or suspected bloodborne pathogens, unless documented to be free of human bloodborne pathogens.

**Parenteral** means piercing mucous membranes or the skin barrier through such events as needle-sticks, human bites, cuts, and abrasions.

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

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

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

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

**Source Individual** means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol

treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

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

**Universal Precautions** is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV and other bloodborne pathogens.

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

## Bloodborne Pathogens Training Record

Bloodborne pathogens training will be provided at the time of initial assignment tot tasks where occupational exposure may occur and at least annually thereafter. If changes occur in tasks or procedures that may affect the employees' or students' exposure, additional training will also be provided.

The Training Objectives will enable an employee or student to:

- Identify the types of bloodborne pathogens that may be present in the workplace
- Understand the types of disease that are transmitted through blood and how they are transmitted
- Determine whether they have been potentially exposed to bloodborne pathogens (BBPs) in the workplace
- Protect themselves from exposure through prevention and by following certain procedures if exposed
- Understand their right to medical evaluations

Additionally, the training will provide:

- An explanation of the Departmental Exposure Control Plan
- Information on Hepatitis B vaccine
- Procedures to follow and the name of a contact person in the case of exposure to BBP
- Explanation of post-exposure follow-up after an exposure incident
- Explanation of signs, labels, and color coding

\_\_\_\_\_  
Employee/Student signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Supervisor/Faculty signature

\_\_\_\_\_  
Date

Date Online Training Completed \_\_\_\_\_

**Bellarmino University Declination of HBV Vaccination**

I understand that due to my occupational exposure to blood or other potentially infectious materials 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 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.

If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

\_\_\_\_\_  
Signature – Employee or Student Declining Vaccine

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature – Witness

\_\_\_\_\_  
Date

## Post-Bloodborne Pathogen Exposure Incident Report

An individual who has a parenteral, cutaneous or mucous membrane exposure to blood or any other potentially infectious material must immediately notify his or her supervisor. The exposed individual must assist his/her supervisor in the completion of the following report. The supervisor shall submit the report to the Academic Safety Officer within 24 hours of the exposure incident.

Name: \_\_\_\_\_

Date incident occurred: \_\_\_\_\_ Time: \_\_\_\_\_

Route(s) of exposure: \_\_\_\_\_

List the activity(s) in which the exposed individual was involved at the time of the exposure. \_\_\_\_\_

Was the exposed individual wearing protective clothing/gear? \_\_\_\_\_

Describe: \_\_\_\_\_

What other precautionary measures in the work practice were employed? \_\_\_\_\_

Provide a brief description as to how the exposure occurred: \_\_\_\_\_

Is the source known? \_\_\_\_\_

Has the exposed individual been vaccinated against Hepatitis B? YES NO

If yes, give date of last core antibody test: \_\_\_\_\_

Signature of exposed individual: \_\_\_\_\_

Signature of exposed individual's supervisor: \_\_\_\_\_

Date that this incident report was received by the Institutional Biosafety Committee: \_\_\_\_\_

Has the exposed individual accepted post-exposure treatment? YES NO

If no, has the individual completed the Post-Exposure Evaluation and Follow-up Declination Form ? YES NO

If yes, has blood been drawn from the exposed individual? List the date of the blood draw. \_\_\_\_\_

Has the source material been collected for testing of human pathogens? YES NO

If the source was human, has consent been obtained from the source individual?

If the source was human and consent has been obtained from the source individual, have all privacy laws been reviewed with the exposed individual? YES NO

List all follow-up actions taken on behalf of the exposed individual \_\_\_\_\_

## Sharps Injury Report

Please complete all applicable fields. Some fields are required to be completed. These are marked with an asterisk (\*).

Employee Last Name\*: \_\_\_\_\_

Employee First Name\*: \_\_\_\_\_

Date of Incident\*: \_\_\_\_\_

Department: \_\_\_\_\_

Building\*: \_\_\_\_\_

Type and/or Brand of Device\*: \_\_\_\_\_

Please provide a brief description of how the injury occurred, including the task which was being performed as well as any protective equipment worn or utilized\*: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Was an animal or human involved?    Yes    No

Was immediate treatment sought? If so, where: \_\_\_\_\_

Recommendation for preventing recurrence: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Supervisor's Name: \_\_\_\_\_

Supervisor's Signature: \_\_\_\_\_



**Post-Exposure Evaluation and Follow-up Declination**

I understand that due to the occupational incident in which I was exposed to blood or other potentially infectious material, I may have been exposed to HBV and/ or HIV. A confidential medical evaluation, blood tests for HBV and HIV and a vaccination for HBV have been recommended to me and would be provided to me by my employer free of charge.

At this time, I would like to decline:

\_\_\_\_\_ the confidential medical evaluation

\_\_\_\_\_ the blood tests for HIV

\_\_\_\_\_ the blood tests for HBV

\_\_\_\_\_ the vaccination for HBV

I understand that by declining the Hepatitis B vaccine, I continue to be at risk for acquiring HBV.

---

Printed Name

---

Signature

Date

---

Witness's Printed Name

---

Witness Signature

Date

## Appendix B: Research Protocols

### Research/Teaching requiring IBC approval

1. Recombinant or Synthetic Nucleic Acid molecules activities as required by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
2. Infectious Microorganisms – Excluding those considered low risk to healthy humans and that are contained at Biosafety Level 1 (which is determined through a Risk Level 1 assessment determination)

The charts in Appendix C from *CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL)* can be used to assess the risk level and biosafety level of the agent(s) being used

Faculty and student researchers engaged in any campus based research covered under the *NIH Guidelines* are required to prepare a proposal with the following required elements that should be accessible and understandable to lay reviewers. Undergraduate research associated with course or degree requirements that do not involve the cloning and propagation of recombinant or synthetic nucleic acid molecules in cells, organisms or viruses are excluded; however compliance with the *NIH Guidelines* is expected and required. All extramurally funded research must be reviewed by the IBC. All elements must be address even if “not applicable” (i.e., N/A). Researchers are required to follow up with the IBC chairperson prior to submitting a protocol for approval. The required elements include:

1. Contact Information
2. Project Title
3. Proposed Project Start and End Dates
4. Abstract
5. Research Design & Objectives
6. Description of Essential Research Elements
  - A. Recombinant DNA
    - Vector
    - Microbes
    - Assessment of Biosafety Level Required
    - Organ, Tissue, or Cell Cultures
    - Vertebrates, Invertebrates, or Plants (Note: Vertebrate research cannot be performed at this time on campus)
  - B. Non-recombinant Research Elements
    - Microbes
    - Organ, Tissue, or Cell Cultures
    - Vertebrates, Invertebrates, or Plants (Note: Vertebrate research cannot be performed at this time on campus)
  - C. Chemicals Used to Elicit a Biological Response
7. Disposal of Waste
8. Potential Environmental Impact
9. List Laboratory & Administrative Personnel
10. Description of Lab Facilities, Safety Practices, & Equipment

## Appendix C: Laboratory Safety

Faculty have primary responsibility for ensuring student safety and properly training all enrolled students, visitors, and employees in their labs, or courses. Faculty will be expected to comply with the IBC Handbook guidelines and practices. Any failure to comply with the guidelines for laboratory safety guidelines may pose an unwarranted to risk to students, staff, and faculty. The following forms have been created to document compliance:

- Lab Safety Statements
- Laboratory Inspection Checklists

In addition to forms, this appendix serves as a resource and provides critical information on lab safety, material handling, material disposal, and provides an overview of NIH defined risk levels and risk assessment practices.

Academic Department Chairpersons or Program Directors are responsible for

- Ensuring that proper lab safety training instruction is provided to all staff, faculty, and students and that, where appropriate, advanced training occurs (i.e., BBP)
- Regular, preferably annual, safety inspections of all research facilities assigned to faculty and/or labs and classroom where students engage in learning activities
- Forward a comprehensive list of all live material being used, to the IBC Chair, annually and no later than September 1; when appropriate, the list should be amended throughout the year

## Laboratory Procedures and Work Practices

Laboratory personnel should seek to utilize laboratory practices that are the most effective, but limit exposure to potentially infectious material. Consider the availability of safer, alternative procedures or non-infectious or less infectious organisms that could be substituted, and yet provide the desired outcome. While there is a wealth of acceptable procedures that have been performed in the laboratory for many years, the inherent safety of an activity is not always implied from its long-term usage. Consider the example of mouth pipetting, commonly used for many years, which is now considered a high-risk practice.

### Generally Acceptable Laboratory Practices

- Outer street clothing (coats, hats, etc.) should be kept in an area where accidental contamination with infectious or other hazardous materials is unlikely to occur.
- Long hair, beards, and loose-flapping clothing are potentially dangerous when working near biohazardous materials that could be inadvertently spilled, or moving laboratory equipment. Tying back hair or employment of hairnets should be encouraged in all laboratories.
- Keep jewelry to a minimum. Do not wear dangling jewelry in the lab.
- Consideration must be given to whether a person should be permitted to work alone on a biohazardous laboratory operation. Emergency situations often necessitate actions by others if someone is contaminated in the incident, such as a spill, in order to prevent injury and avoid additional contamination away from the spill site. The Faculty or lab supervisor must evaluate and establish lab guidelines in this regard.
- Protection of the eyes is a matter which should be given high priority in every laboratory. Signs indicating "Eye Protection Required" should be prominently displayed in all areas where a hazardous exposure may exist. Infection can occur through the eyes if a pathogenic microorganism is splattered into the eye, and many chemicals commonly employed in the laboratory can cause serious damage if similarly deposited. Safety glasses, goggles, or a face shield should be worn when necessary.
- Every laboratory that uses materials that are irritating to the eyes must have an eyewash fountain. These eyewash fountains must be ANSI approved.
- Laboratory bench tops must be impervious to water and chemically and thermally resistant. Laboratory chairs must be covered with non-porous material that facilitates cleaning and decontamination with an appropriate disinfectant. Substitute plastic ware for glassware wherever possible.

## Standard Microbiological Work Practices

The overall use of standard microbiological practices can minimize and even prevent exposure to biohazardous materials. Standard practices are based on the primary need to protect the worker, coworkers, community and environment while assuring product integrity. Faculty or laboratory supervisor should limit or restrict access to the laboratory when experiments that involve infectious agents or biohazardous materials are conducted. Additionally, special entry requirements, such as personal protective equipment or immunizations might be required.

### Standard practices should include:

- Wash hands with soap and water after exposure to potentially infectious materials, after removing gloves and other personal protective equipment, after completion of any procedure in which biohazardous material is used, and before you leave the laboratory. If a sink with water and soap is not available or accessible, alcohol-based hand sanitizers (e.g., gels or foams) can be substituted.
- DO NOT eat, drink, smoke, apply cosmetics or lip balm, brush teeth, or handle contact lenses in work areas where biohazardous materials are stored or used.
- Storage of food in refrigerators or freezers used for infectious materials or chemical carcinogens is strictly forbidden.
- Use mechanical devices when pipetting. Mouth pipetting is expressly forbidden.
- Policies for the safe handling of sharps such as:
  - Securing unused hypodermic syringes and needles, and log their distribution
  - Utilizing one sharps item at a time. Do not leave sharps unattended
  - Having readily accessible sharps disposal containers close to work area
  - Incorporating engineered sharps injury protection systems (e.g., safer needles) when practical
  - Use sharps only when no other alternatives are available
- Activities that are likely to produce aerosols, splashing, or splattering of infectious or biohazardous materials (e.g., procedures such as vortexing, grinding, blending, sonicating, centrifuging, and cutting or slicing of infectious or biohazardous materials) should be performed in a certified Biological Safety Cabinet (Class II)
  - A Biological Safety Cabinet will be used when necessary to provide worker protection during aerosol generating procedures with human blood and OPIM (including human cells, tissue cultures, and blood products and blood components).
  - Class II Biological Safety Cabinet is recommended for manipulations of infectious agents that are likely to create aerosols (e.g., aspirating with a syringe, removing caps from tubes after centrifugation, vortexing of open tubes, sonication).
  - Class II Biological Safety Cabinets, while providing laminar airflow to protect research material, are designed with inward flow to protect personnel, and filtered exhaust air for environmental protection. HEPA filters (High Efficiency Particulate Air) inside the cabinet remove 99.97% of airborne particles that are 0.3 $\mu$ m, and higher efficiencies(99.99%) with particles above and below 0.3 $\mu$ m. Some laminar flow hoods direct HEPA filtered air horizontally across the work surface towards the operator and the open

laboratory environment. These hoods are not safety devices and must never be used with infectious, toxic, or sensitizing materials.

- Biological safety cabinets must be routinely inspected and certified by an independent contractor who is trained to National Sanitation Foundation Standard No. 49.
- Decontaminate work surfaces at least once a day and after any spill of infectious or biohazardous materials with a disinfectant that has been proven to be effective against the agent/ material used. Appropriate disinfectants include:
  - Chlorine bleach (5.25% sodium hypochlorite or household bleach, in a 1:10 dilution). At these concentrations, sodium hypochlorite exhibits broad-spectrum activity against vegetative bacteria, fungi, lipid, and non-lipid viruses. Higher concentrations and extended contact time can be used to inactivate bacterial spores. The efficacy of hypochlorite as a disinfectant is reduced in the presence of organic materials, high pH, and exposure to light. Solutions should be prepared weekly.
  - Ethyl and isopropyl alcohols, in concentrations of about 60% to 95%, which are effective against vegetative forms of bacteria, fungi, and lipid-containing viruses. Alcohols are less effective against non-lipid viruses, and completely ineffective against bacterial spores and *Mycobacterium tuberculosis* (TB).
  - Chlorine dioxide gas effectively kills pathogenic microorganisms such as fungi, bacteria and viruses. It also prevents and removes biofilms. Chlorine dioxide is efficacious against protozoan parasites (*Giardia*) and spore forming bacteria.
  - Formalin (37% solution of formaldehyde) diluted to 5% is effective against vegetative bacteria, spores, and viruses. Formaldehyde should not be used since it is a human carcinogen and creates respiratory problems at low levels of concentration.
  - Glutaraldehyde (2-5%) displays a broad spectrum of activity, but because it is toxic and damaging to the eyes it should not be used
  - Hydrogen peroxide exhibits bactericidal, virucidal, tuberculocidal, sporicidal, and fungicidal properties.
  - Iodophors show a wide spectrum of antimicrobial and antiviral activity. they have variable effect on hepatitis B virus, and do not inactivate bacterial spores.
  - Phenol and Phenol derivatives (in concentrations of 0.5-5%) inactivate vegetative bacteria including *Mycobacterium tuberculosis*, fungi, and lipid-containing viruses, but are not active against bacterial spores or non-lipid viruses.
  - Quaternary ammonium compounds (0.5-1.5%) are effective against many bacteria and lipid-containing viruses, but are not active against bacterial spores, non-lipid-containing viruses (e.g., hepatitis B), and *Mycobacterium tuberculosis*. Organic materials and salts found in water can inactivate quaternary ammonium compounds.
- Segregate biohazardous waste in red biohazard bags or sharp disposal containers, and dispose as regulated medical waste (see **Appendix D: Guidelines for Disposal of Infectious Waste** for more specific information).
  - Biohazardous waste (whether autoclaved or not) should not under any circumstances go into the regular trash.
  - Red bags with Biohazard symbols do not go into regular trash under any circumstances. Placing these bags in the regular trash puts both Bellarmine University and the regular trash removal contractor in violation.

- Biohazardous waste that imposes minimum risk (e.g., risk group 1 organisms, recombinant DNA materials) generated in the laboratory should be autoclaved in **clear autoclave bags** before disposal as regular solid waste.
  - Only bacterial cultures of non-pathogenic, environmental (soil or plant) organisms, lab strains of genetically-modified organism which are non-pathogenic and specifically engineered to limit survival, and cell lines of non-human origin (which have been described in the literature as being free of association with any zoonoses, and have been treated with bleach to eliminate any transmission of viruses) may be autoclaved for regular trash disposal.
  - Environmental bacterial waste autoclaved for regular trash disposal should NOT be placed in a biohazard bag – it should go in a clear bag.
  - If such waste is autoclaved, spore-containing sterility controls should be periodically used. Records of those sterility controls should be maintained and should be available for periodic review by the personnel on the Biosafety Committee responsible for biohazardous waste disposal. Chemical or physical indicators can be routinely used to ensure that the correct temperature has been achieved and maintained for the specified amount of time needed to ensure sterilization. For example, chemical indicators, such as those used in autoclave tape, use a color change to indicate that the appropriate temperature and pressure have been reached.
  - Any waste that is autoclaved would need to be retained until the sterility controls are checked.
  - Even acceptable non-hazardous cultures, that are autoclaved properly for disposal, should be placed in trash containers in existing secured labs and not in public or unsecured spaces (i.e., hallways).
  
- Use the universal biohazard warning symbol to indicate areas and equipment where infectious agents and biohazardous materials are handled and stored.
  
- Report any insect/ rodent problems to Facilities Management.
  
- Persons working with infectious material should avoid touching the face, eyes or nose with gloved or unwashed hands. The use of Kleenex rather than cloth handkerchiefs is recommended for personal hygiene in laboratories handling infectious materials.
  
- Gloves must be worn when working with an infectious agent. Gloves must also be worn when one anticipates hand contact with blood, potentially infectious materials, mucous membranes, or non-intact skin. Vinyl, latex, and nitrile single-use, disposable gloves should be replaced as soon as possible if contaminated, torn, punctured or damaged in any way. Never wash or decontaminate gloves for reuse. Faculty and lab supervisors should be aware of the possibility that employees may have allergies to latex. When chemical hazards are also present more extensive consideration of the many available types of glove materials is necessary.
  
- Laboratory clothing should be routinely laundered at work. When clothing is overtly contaminated with infectious materials decontaminate by steam sterilization (autoclaving) or other proven effective means (e.g., soak in bleach solution) before laundering. Avoid laundering at home unless the clothing can first be decontaminated. Disposable clothing (coats, gowns, etc.) must be decontaminated by steam sterilization before discarding. In exceptional circumstances, the Institutional Biosafety Committee may recommend alternative treatment of laboratory clothing worn in certain BSL-2 facilities prior to laundering.

- All biohazardous materials must be placed in rigid, leak proof containers labeled with a biohazard symbol for intra-campus transport between buildings or from one laboratory to another located in the same building. The primary container must be a sealed non-breaking container and must be enclosed in a non-breakable, sealable, secondary container. Both containers must be decontaminated prior to removal from the laboratory. Containers of viable materials may be opened only in facilities having an equivalent or higher than the biosafety level than the biosafety level of the laboratory of origin.



## Biological Risk Assessment

To ensure overall lab safety and OSHA compliance, all lab instructors are encouraged to complete a “Biological Risk Assessment” for their courses and/or research activities. The IBC suggests using the CDC generic example for the purpose of assessing risk. The worksheet is located at:

<http://www.cdc.gov/biosafety/publications/BiologicalRiskAssessmentWorksheet.pdf>

An effective risk assessment process adequately identifies characteristics of microorganisms as well as host and environmental factors that influence the potential for exposure and balances this against expensive or burdensome safeguards that may prove ineffective. An effective initial risk assessment will identify hazards; determine how to manage laboratory hazards; determine the appropriate biosafety level and select additional relevant precautions; evaluate integrity of equipment and the proficiencies of staff work practices; and review risk assessments with a representative of the Institutional Biosafety Committee

Faculty and laboratory supervisors are encouraged to consult with the IBC to ensure that the laboratory is in compliance with established guidelines, regulations, and the proper work practices and containment requirements for work with biohazardous materials as applies to individual laboratories.

Microorganisms are assigned to one of four risk groups. The NIH Guidelines contain a comprehensive list of risk group 2-4 agents. However, those agents not listed in Risk Groups 2, 3, and 4 are not automatically or implicitly classified in Risk Group 1; a risk assessment must be performed on the known and potential properties of the agent, and consider the relationship to agents on the list. The risk group classification and the types of laboratory activities being conducted are used as a starting point to estimate the appropriate containment for working with a biohazardous agent and assignment to one of four biosafety levels (BSL1-4). The assigned biosafety level takes into consideration characteristics of the agent such as its infectivity, severity of any associated disease, transmissibility and the nature of the work being conducted. Generally, organisms of a particular risk group are handled at the corresponding biosafety level (e.g., RG2 at BSL2). The fundamental principle of biological safety is containment. A thorough understanding of containment includes knowledge of acceptable practices and techniques, components of primary barriers, protective clothing, mechanical devices, and secondary facility design.

The risk assessment for the use of recombinant organisms should include the following considerations: the properties of the organism derived by recombinant DNA (rDNA) techniques, either through deliberate or accidental means; the potential for deliberate release or accidental escape of some of these microorganisms in the workplace and/or into the environment; the subsequent multiplication, genetic reconstruction, growth, transport, modification and die-off of these micro-organisms in the environment, including possible transfer of genetic material to other microorganisms; the establishment of these microorganisms within an ecosystem niche, including possible colonization of humans; and the subsequent occurrence of human or ecological effects due to interaction of the organism with some host or environmental factor.

See [http://www.cdc.gov/biosafety/publications/bmbl5/BMML5\\_sect\\_II.pdf](http://www.cdc.gov/biosafety/publications/bmbl5/BMML5_sect_II.pdf) for —Biological Risk Assessment help.

## **Research/Teaching requiring IBC approval**

1. Recombinant or Synthetic Nucleic Acid molecules activities as required by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
2. Infectious Microorganisms – Excluding those considered low risk to health humans that are contained at Biosafety Level 1

The following charts from CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) will assess the risk level and biosafety level of the agent(s) with which you are working

**Classification of Infectious Microorganisms By Risk Group (Risk Groups correlate with but do not equate to biosafety levels)**

RISK GROUP CLASSIFICATION	NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES 2013	WORLD HEALTH ORGANIZATION LABORATORY BIOSAFETY MANUAL 3RD EDITION 2004
Risk Group 1	Agents that are not associated with disease in healthy adult humans.	(No or low individual and community risk) A microorganism that is unlikely to cause human or animal disease.
Risk Group 2	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.	(Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).	(High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
Risk Group 4	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).	(High individual and community risk) A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available. <sup>3</sup>

**Summary of Recommended Biosafety Levels for Microorganisms (Note: BSL (Biological Safety Level) in BMBL is equivalent to BL (Biosafety Level) in the NIH recombinant DNA Guidelines)**

BSL	AGENTS	PRACTICES	PRIMARY BARRIERS AND SAFETY EQUIPMENT	FACILITIES SECONDARY BARRIERS
1	Not known to consistently cause diseases in healthy adults	Standard Microbiological Practices	None required	Open bench and sink required
2	<ul style="list-style-type: none"> <li>Agents associated with human disease</li> <li>Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure</li> </ul>	BSL-1 practice plus: <ul style="list-style-type: none"> <li>Limited access</li> <li>Biohazard warning signs</li> <li>"Sharps" precautions</li> <li>Biosafety manual defining any needed waste decontamination or medical surveillance policies</li> </ul>	Primary barriers: <ul style="list-style-type: none"> <li>Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials</li> <li>PPEs *:               <ul style="list-style-type: none"> <li>Laboratory coats; gloves; face protection as needed</li> </ul> </li> </ul>	BSL-1 plus: <ul style="list-style-type: none"> <li>Autoclave available</li> </ul>
3	<ul style="list-style-type: none"> <li>Indigenous or exotic agents with potential for aerosol transmission</li> <li>Disease may have serious or lethal consequences</li> </ul>	BSL-2 practice plus: <ul style="list-style-type: none"> <li>Controlled access</li> <li>Decontamination of all waste</li> <li>Decontamination of laboratory clothing before laundering</li> <li>Baseline serum</li> </ul>	Primary barriers: <ul style="list-style-type: none"> <li>Class I or II BSCs or other physical containment devices used for all open manipulation of agents</li> <li>PPEs:               <ul style="list-style-type: none"> <li>Protective laboratory clothing; gloves; respiratory protection as needed</li> </ul> </li> </ul>	BSL-2 plus: <ul style="list-style-type: none"> <li>Physical separation from access corridors</li> <li>Self-closing, double-door access</li> <li>Exhaust air not recirculated</li> <li>Negative airflow into laboratory</li> </ul>
4	<ul style="list-style-type: none"> <li>Dangerous/exotic agents which pose high risk of life-threatening disease</li> <li>Aerosol-transmitted laboratory infections have occurred; or related agents</li> </ul>	BSL-3 practices plus: <ul style="list-style-type: none"> <li>Clothing change before entering</li> <li>Shower on exit</li> <li>All material decontaminated on exit from facility</li> </ul>	Primary barriers: <ul style="list-style-type: none"> <li>All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit</li> </ul>	BSL-3 plus: <ul style="list-style-type: none"> <li>Separate building or isolated zone</li> <li>Dedicated supply and exhaust, vacuum, and decontamination systems</li> <li>Other requirements outlined in the</li> </ul>

BSL	AGENTS	PRACTICES	PRIMARY BARRIERS AND SAFETY EQUIPMENT	FACILITIES SECONDARY BARRIERS
	with unknown risk of transmission			text

**LABORATORY SAFETY STATEMENT**  
**COURSE NAME AND NUMBER – INSTRUCTOR NAME**

The following rules must be observed at all times to prevent accidental injury to and infection of yourself and others and to minimize contamination of the lab environment:

1. **Never place books, backpacks, purses, etc., on bench tops.** Always place these in the assigned cubicles. Keep manuals and pens on pull-out desks.
2. **Electronic devices should not be brought into the lab.** This includes, but is not limited to iPods, iPads, MP3 players, radios and cell phones.
3. **Clean your work area** with dilute bleach solution at the beginning **AND** end of each lab.
4. **Wash your hands** with soap and dry with paper towels when entering and leaving the lab.
5. Wear a **lab coat** at all times while working in the lab to prevent contamination or accidental staining of your clothing.
  - a. **Closed-toe shoes** (no sandals) are to be worn in the lab.
  - b. **Long hair must be tied back** to prevent exposure to flame and contamination of cultures.
  - c. **Gloves** should be worn when staining microbes and handling hazardous chemicals.
6. **Do not place anything in your mouth or eyes while in the lab.** This includes pencils, food, and fingers. Keep your hands away from your mouth and eyes.
  - a. Eating and drinking are **prohibited** in the lab at all times.
  - b. This includes gum, cough drops, and candy.
  - c. Do not apply cosmetics in the lab. This includes Chapstick and Blistex.
  - d. **Never pipet by mouth.** Use a mechanical pipetting device.
7. **Do not remove media, chemicals, equipment, or bacterial cultures from the laboratory.** This is absolutely prohibited and unnecessary.
8. Do not place contaminated instruments such as inoculating loops, needles, and pipettes on bench tops. Loops and needles should be sterilized by incineration, and pipettes should be disposed of in designated receptacles of bleach solution.
9. Carry cultures in a test tube rack when moving around the lab or when keeping cultures on bench tops for use. This prevents accidents and contamination of your person or belongings.
10. **Immediately cover spilled cultures or broken culture tubes with paper towels and then saturate them with disinfectant solution.** Notify your instructor that there has been a spill. After 15 minutes, dispose of the towels and broken items as indicated by your instructor.

11. **Report accidental cuts or burns to the instructor immediately.**
12. At the end of each lab session, place all materials in the proper disposal area.
13. If you are immune-compromised (including those who are pregnant or may become pregnant) and students living with or caring for an immune-compromised individual are advised to consult with your physician to determine the appropriate level of participation in the lab. Should your physician determine that you should not participate in this lab, please have him or her write a note stating the concerns. Alternative accommodations may be indicated.

**OSHA INFORMATION**

**Material Safety Data Sheets (MSDS)** are located \_\_\_\_\_

**The first aid kit** is located \_\_\_\_\_

**The eyewash station** is located \_\_\_\_\_

**The shower** is located \_\_\_\_\_

**The fire extinguisher** is located \_\_\_\_\_

**AGREEMENT ON LABORATORY SAFETY**

I have read the Laboratory Safety Statement and I understand its content. I agree to abide by all laboratory rules set forth by the instructor. I understand that my safety is entirely my own responsibility and that I may be putting myself and others in danger if I do not abide by all the rules set forth by the instructor.

**COURSE:**

**NAME OF FACULTY/STUDENT (PRINT):** \_\_\_\_\_

**SIGNATURE OF FACULTY/STUDENT:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

## **BSL-2 Biosafety Guidelines for Instructional & Laboratory Spaces**

[NOTE: This Document must be posted in all labs, readily visible, and distributed to all students, researchers, & Instructors]

### **I. Authority for Microbiology Lab and Prep Room Regulations**

Labs will follow the guidelines posted by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health. These guidelines describe acceptable biosafety practices in biomedical and microbiological laboratories and can be found at: <http://www.cdc.gov/biosafety/publications/bmbl5/index.htm> .

BSL1 precautions will be followed during routine media prep, autoclaving, and sub-culturing. Whenever a BSL2 agent is in use, biohazard signs will be posted on the doors and the entire room will follow BSL2 practices.

### **II. Regulations**

#### **A. Access, Training and Responsibilities**

1. Access is limited to individuals involved directly in media prep, clean up, lab prep, and research.
2. The lab and prep room doors will be closed when a BSL2 agent is in use.
3. All staff and students are required to read, understand, and follow these regulations before working in this facility.
4. All staff and students will receive training from the coordinating instructor or lab director concerning use of the equipment. Staff or students who have not received training from either a BU instructor or lab director must not operate any laboratory equipment.
5. The coordinating instructor or lab director will train staff and students on aseptic techniques appropriate for handling pathogenic agents. This will include the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures.
6. Personnel receive annual updates or additional training as necessary.
7. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.
8. Any staff or students found in violation of the regulations may have their access to this facility terminated.
9. The coordinating instructor or lab director is responsible for seeing that the consequences of student or staff actions are rectified, including correction of damages and violations and take-down of experiments.

#### **B. Apparel**

1. Personnel entering lab will be required to wear closed-toe shoes and have long hair tied back.
2. Personnel working in this facility at BSL2 must wear lab coats at all times. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., restroom, cafeteria, library, or administrative offices). All protective clothing is either autoclaved or laundered with bleach by the institution before being returned to personnel.



3. Gloves are worn when handling microorganisms or hazardous chemicals. Gloves are disposed of when contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Gloves are placed in a biohazard bag and autoclaved prior to disposal. Disposable gloves are not washed, reused, or used for touching “clean” surfaces (keyboards, telephones, etc.), and they should not be worn outside the lab. Hands are washed following removal of gloves.

4. In a BSL2 lab, safety goggles, safety glasses, or face shields are worn for normal lab procedures involving liquid cultures that do not generate a splash hazard (e.g., proper pipetting, spread plates, etc.). Safety goggles and face shields or safety goggles and masks are worn when performing procedures that may create a splash hazard.

5. When working in a biosafety cabinet, only lab coats and gloves are needed for personal protection.

### **C. Standard Microbiological Practices**

1. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the lab. Food for human consumption is never stored the lab.

2. An orange biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Information to be posted includes the agent(s) in use, biohazard symbol, biosafety level 2, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.

3. Persons wash their hands upon entering the lab, after they finish working in the lab, after removing gloves, and before leaving the laboratory.

4. Work surfaces are decontaminated prior to beginning any work in these rooms, on completion of work or at the end of the day with 10% bleach solution. Any spill or splash of viable material should be decontaminated with 25% bleach solution.

5. All procedures are performed carefully to minimize the creation of splashes or aerosols. Any procedure that would potentially create aerosols will be performed within the biosafety cabinet.

6. Mouth pipetting is prohibited; mechanical pipetting devices are used.

7. A limited number of needles and syringes are used for reconstituting reagents. After use, these materials are placed in a puncture-proof red sharps container. Do not recap needles.

8. All biohazardous cultures, swabs, and waste containers are decontaminated before disposal by autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container for transport from the laboratory.

### **D. Special Practices**

1. Access to the laboratory is limited or restricted by the laboratory director when work with infectious agents is in progress. Persons who are at increased risk of acquiring infection – e.g., those who are immunocompromised or

immunosuppressed – or for whom infection may have serious consequences, should consult with their physician to determine the appropriate level of participation in the lab.

#### **E. Transfer of materials**

1. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container that prevents leakage during collection, handling, processing, storage, and transport.

#### **F. Disposal of Materials and Decontamination**

1. Laboratory equipment and work surfaces should be decontaminated with 10% bleach on a routine basis and after work with infectious materials is finished. Overt spills, splashes, or other contamination by infectious materials should be decontaminated with 25% bleach.

2. Spills and accidents that result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

3. Broken glassware that does not contain live cultures should be swept up with the broom and dust pan and discarded in the glass disposal box.

4. Broken glassware that contains live cultures should be saturated with bleach solution. After 15 minutes, the debris should be “swept” up into an autoclave bin using a plastic beaker and/or paper towels. After being autoclaved, the glassware can go into the glass disposal box and the paper towels can go into the regular trash.

#### **G. Hygiene and Housekeeping**

1. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and bleach used to decontaminate the work surfaces.

2. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs used in laboratory work should be covered with a nonporous material that can be easily decontaminated.

3. **Material Safety Data Sheets (MSDS)** are located \_\_\_\_\_

4. **First aid kits** are located \_\_\_\_\_

5. **Eyewash stations** are located \_\_\_\_\_

6. **The shower** is located \_\_\_\_\_

7. **Fire extinguishers** are mounted on the wall \_\_\_\_\_

## Checklist for Biosafety Level 1 Laboratory Operations

Department \_\_\_\_\_ Building \_\_\_\_\_ Room # \_\_\_\_\_

Faculty \_\_\_\_\_ e-mail \_\_\_\_\_ Phone # \_\_\_\_\_

Contact (if different) \_\_\_\_\_ e-mail \_\_\_\_\_ Phone # \_\_\_\_\_

IBC Member(s) \_\_\_\_\_ Date Completed \_\_\_\_\_

The following statements are based primarily on the Biosafety Level 1 section of *Biosafety in Microbiological and Biomedical Laboratories*, 5th edition, 2007, ([http://www.cdc.gov/biosafety/publications/BMBL\\_5th\\_Edition.pdf](http://www.cdc.gov/biosafety/publications/BMBL_5th_Edition.pdf)). Check the appropriate box for each statement. Please provide comments or an explanation for “No” or “NA” (Not Applicable) responses. This checklist is to be used for individual laboratory assessment and as part of a review completed by the Institutional Biosafety Committee. Contact the Institutional Biosafety Committee ([dgolemboski@bellarmine.edu](mailto:dgolemboski@bellarmine.edu)) if you have any questions or require assistance.

### A. Standard Microbiological Practices

	Yes	No	N/A
1. Access to the laboratory is limited or restricted at the discretion of the Instructor or laboratory supervisor when experiments are in progress.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Personnel wash their hands after they handle viable materials and animals, after removing gloves, and before leaving the laboratory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Eating, drinking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear safety glasses, goggles or face shield. Food is stored outside the laboratory in cabinets or refrigerators designated for this purpose only.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Mouth pipetting is prohibited; mechanical pipetting devices are used.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. All procedures are performed carefully to minimize the creation of splashes or aerosols.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Work surfaces are decontaminated at least once a day and after any spill of viable material with a disinfectant effective against the agents of concern.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Cultures, stocks, contaminated plastic ware, and other non-sharps wastes are autoclaved prior to disposal. Consult specific University disposal requirements (e.g., clear autoclave bags, red biohazard bags).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. 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:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Non-disposable sharps must be placed in a hard walled sharps disposal container used for sharps disposal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- |   |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|
| d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Culture fluids and other contaminated liquid wastes are autoclaved or decontaminated with a suitable disinfectant before disposal down the sanitary drain.                                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and closed for transport from the laboratory.                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments/Explanations for Standard Microbiological Practices

**B. Special Practices**

- |  |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|
| 1. Hypodermic syringes and needles, when not in use, are secured (i.e., locking cabinet, drawer) against unauthorized access. A log of stock materials and their distribution is maintained. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|--|--------------------------|--------------------------|--------------------------|

Comments/Explanations for Special Practices

**C. Safety Equipment (Primary Barriers)**

- |  |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|
| 1. Special containment devices or equipment such as a biological safety cabinet is generally not required for manipulations of agents assigned to Biosafety Level 1.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. If used, biological safety cabinets are certified annually, when cabinets are moved, or when HEPA filters are changed.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Protective eyewear should be worn for conduct of procedures in which splashes of microorganisms or other hazardous materials is anticipated.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Laboratory coats, gowns, or uniforms are worn to prevent contamination or soiling of street clothes. This protective clothing is removed and left in the laboratory before leaving for or travel through non-laboratory areas (e.g., cafeteria, library, administrative offices, and public corridors). All protective clothing is disposed of in the laboratory, laundered by the institution, or autoclaved and laundered at home by personnel. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Gloves are disposed of when contaminated, removed when work is completed, and are not worn outside the laboratory. Disposable gloves are not washed or reused. Hands are washed after glove use.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments/Explanations for Safety Equipment

**D. Laboratory Facilities (Secondary Barriers)**

- |  |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|
| 1. Each laboratory contains a sink for hand washing.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. The laboratory is designed so that it can be easily cleaned and decontaminated. Carpets, rugs, and cloth furniture are not appropriate.                           | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Bench tops are impervious to water and resistant to moderate heat, acids, alkalis, organic solvents, and chemicals used to decontaminate the work surface.        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Laboratory furniture is sturdy and capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. If the laboratory has windows that open, they are fitted with fly screens.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. An autoclave for pre-treatment of laboratory wastes is available.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. An eyewash facility is readily available within the laboratory.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments/Explanations for Laboratory Facilities

## Checklist for Biosafety Level 2 Laboratory Operations

Department \_\_\_\_\_ Building \_\_\_\_\_ Room # \_\_\_\_\_  
 Faculty \_\_\_\_\_ e-mail \_\_\_\_\_ Phone # \_\_\_\_\_  
 Contact (if different) \_\_\_\_\_ e-mail \_\_\_\_\_ Phone # \_\_\_\_\_  
 IBC Member(s) \_\_\_\_\_ Date Completed \_\_\_\_\_

The following statements are based primarily on the Biosafety Level 2 section of *Biosafety in Microbiological and Biomedical Laboratories*, 5th edition, 2007, ([http://www.cdc.gov/biosafety/publications/BMBL\\_5th\\_Edition.pdf](http://www.cdc.gov/biosafety/publications/BMBL_5th_Edition.pdf)). Check the appropriate box for each statement. Please provide comments or an explanation for “No” or “NA” (Not Applicable) responses. This checklist is to be used for individual laboratory assessment and as part of a review completed by the Institutional Biosafety Committee. Contact the Institutional Biosafety Committee ([dgolemboski@bellarmine.edu](mailto:dgolemboski@bellarmine.edu)) if you have any questions or require assistance.

### A. Standard Microbiological Practices

	Yes	No	N/A
1. Access to the laboratory is limited or restricted at the discretion of the Instructor or laboratory supervisor when experiments are in progress.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Personnel wash their hands after they handle viable materials and animals, after removing gloves, and before leaving the laboratory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Eating, drinking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear safety glasses, goggles or face shield. Food is stored outside the laboratory in cabinets or refrigerators designated for this purpose only.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Mouth pipetting is prohibited; mechanical pipetting devices are used.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. All procedures are performed carefully to minimize the creation of splashes or aerosols.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Decontaminate work surfaces and laboratory equipment routinely after completion of work, and after any spill or splash of potentially infectious material with a disinfectant effective against the agents of concern. Contaminated equipment is decontaminated before removal from the facility, sent for repair or maintenance, or packaged for transport.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Cultures, stocks, contaminated plastic ware, and other regulated non-sharps wastes are discarded in red biohazard bags and treated as infectious medical wastes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. 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:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Reusable sharps, being disposed of, must be placed in a hard walled sharps disposal container used for sharps disposal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- |  |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|
| d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Culture fluids and other contaminated liquid wastes are autoclaved or decontaminated with a suitable disinfectant before disposal down the sanitary drain.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and closed for transport from the laboratory.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. An effective integrated pest management program is required.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. 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.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and exposure evaluation procedures (e.g., symptoms of a disease). Personnel must receive regular updates or additional training as necessary. Training is documented. Since personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions (e.g., chronic disease, medications) that may predispose them to infection. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments/Explanations for Standard Microbiological Practices

**B. Special Practices**

- |  |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|
| 1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. A laboratory-specific biosafety manual, standard operating procedures must be prepared and adopted as policy. The biosafety manual must be available and accessible.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with infectious agents.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. 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 and documented via the University reporting. Medical evaluation, surveillance, and treatment should be provided by Bellarmine Health Services or personal physician and appropriate records maintained. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- |   |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|
| 7. Projects that utilize biohazardous and/or recombinant DNA materials are registered with the Institutional Biosafety Committee.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Animals and plants not associated with the work being performed must not be permitted in the laboratory.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a biosafety cabinet (BSC) or other physical containment devices.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. On campus transport (between laboratories, buildings) of cultures, tissues, or specimens is conducted in closed, leak proof, break resistant containers, lined with absorbent material and labeled with the biohazard sign and contact information. Off campus transport must comply with domestic (US DOT) and/or international regulations (ICAO), including required training. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Stock cultures of infectious agents are secured against unauthorized access (e.g., locked freezers, secured laboratories).  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Hypodermic syringes and needles, when not in use, are secured (i.e., locking cabinet, drawer) against unauthorized access. A log of stock materials and their distribution is maintained.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments/Explanations for Special Practices

**C. Safety Equipment (Primary Barriers)**

- |   |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|
| 1. Properly maintained biological safety cabinets, preferably Class II, or other appropriate physical containment devices must be used whenever:  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads, centrifuge safety cups, or gasket-containing centrifuge tubes are used. These rotors, safety cups, or tubes are packaged and opened only in a biological safety cabinet.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Biological safety cabinets are certified annually, when cabinets are moved, or when HEPA filters are changed.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Face protection (goggles, mask, face shield or other platter guards) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face, when the microorganisms must be manipulated outside the biological safety cabinet.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. 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. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |



- |    |   |                          |                          |                          |
|----|---|--------------------------|--------------------------|--------------------------|
| 5. | 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:   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| a. | Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Wear two pairs of gloves when appropriate.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. | Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. | Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. | 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. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments/Explanations for Safety Equipment

**D. Laboratory Facilities (Secondary Barriers)**

- |    |  |                          |                          |                          |
|----|--|--------------------------|--------------------------|--------------------------|
| 1. | Each laboratory 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.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. | Laboratory doors should be self-closing and have locks in accordance with the institutional policies.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. | The laboratory is designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. | Laboratory furniture must be sturdy and capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| a. | Bench tops are impervious to water and resistant to moderate heat, acids, alkalis, organic solvents, and chemicals used to decontaminate the work surface.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. | Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. | 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, supply and exhaust vents, and other possible airflow disruptions. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. | Vacuum lines should be protected with High Efficiency Particulate Air (HEPA) or their equivalent. Liquid disinfectant traps may be required. Portable vacuum pumps may also be used (also properly protected with traps or filters).   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- |  |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|
| 7. 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. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Laboratory doors are kept closed whenever work with biohazardous materials is conducted.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. An autoclave for pre-treatment of laboratory wastes is available.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. An eyewash facility is readily available within the laboratory.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments/Explanations for Laboratory Facilities

## Appendix D: Guidelines for Disposal of Infectious Waste

### Infectious Waste Management Program

Regulations imposed by local, state, and federal agencies dictate that infectious waste must be segregated, packaged, and disposed of in a specific manner. The primary purpose of the regulations is to limit on-the-job exposure to blood and other potentially infectious materials.

All wastes listed in this section must be segregated from other wastes, packaged, and disposed of in accordance with University guidelines. The Bellarmine University recognizes three basic types of waste:

#### 1. Medical Waste

- a. Microbiological waste - Cultures and stocks of agents infectious to humans (including human, primate, and mammalian cell lines), associated biologicals (e.g., serums, vaccines, antigens, toxins), and culture dishes and devices used to transfer, inoculate or mix cultures (e.g., Petri dishes, vials, filtration devices, flasks, inoculation loops, disposable gloves).
- b. Human blood and blood products - i.e., all liquid blood, serum and plasma.
- c. Transgenic Plant Material - plant's genetic material that has been altered by the introduction of genes from another organism.

#### 2. Sharps - i.e., syringes, needles, razor blades, scalpels, broken glass pipets and vials; broken glass slides or cover slips that have been in contact with infectious material

#### 3. Pathological Waste

- a. Human pathological waste - including tissue, organs, and body parts, and specimens of body fluids and their containers.
- b. Animal wastes including carcasses, body parts, body fluids, blood, or bedding originating from animals known to be contaminated with (zoonotic organisms) or intentionally inoculated with infectious agents. Excludes preserved animals used for educational purposes.

All of the above items must follow packaging and disposal guidelines for infectious waste. It is the responsibility of every department, unit, or laboratory generating infectious waste to provide the appropriate packaging materials (i.e., sharps container and orange or red infectious waste bags). Biohazard waste bags must be orange or red and can be obtained currently from the current biohazard waste disposal contractor, otherwise these may be obtained from laboratory supply companies (i.e., Fisher Scientific, 1-800-766-7000).

### Infectious Waste Segregation

At the point of generation, Infectious waste is to be segregated by type and placed into separate containers for disposal. Laboratories and other infectious waste generating areas will separate each infectious waste stream into a 32-gallon red bin.

#### Medical Waste:

Medical waste will be placed in 32-gallon red bins lined with an approved biohazard bag. Place cultures and stocks of infectious agents, other biological including cell lines of human origin, cell lines of non-human origin which may be associated with zoonotic organisms, known or unknown organisms isolated from humans, tissues of human and non-

human origin; and non-sharps items (e.g., culture swabs used to obtain human cultures, gloves, pipet tips, test tubes) and any materials contaminated with biohazardous materials into red bags that have the biohazard symbol or the word "BIOHAZARD". Use double bags if necessary to prevent leakage. No tagging is necessary if the waste in these bins adheres to the "medical waste" definition.

### **Sharps:**

All sharps must be placed in an approved sharp containers that are prominently labeled with a universal biohazard sign and the word "BIOHAZARD". To prevent contamination and potential injury, dispose of needles and syringes directly into a sharps container without any further manipulation (e.g., NO clipping, bending, breaking, shearing, or recapping). Devices that clip off the needle are prohibited. When the sharp container is full, it must be placed into a 32-gallon red infectious waste bin.

### **Pathological:**

Pathological waste will be placed in 32-gallon red bins lined with an approved biohazard bag. These bins must be tagged "Pathological Waste." Pathological waste is defined as animal carcasses, body parts, body fluids, animal blood soaked materials, bedding, and associated containers can be infectious or noninfectious. Small animal carcasses contaminated with infectious agents (pathological waste) should be packaged in double red biohazard bags and refrigerated or frozen until they can be transported.

Note: Infectious waste must be segregated into the proper waste category, and into a properly labeled containment system at the point of generation. Biohazardous waste must be packaged, contained, and located in a way that protects and prevents its accidental release to the environment at any time. Waste minimization should be encouraged to reduce the amount of infectious waste that must be treated and disposed. Material that is not contaminated should be handled as outlined in the "**Standard Microbiological Work Practices**" section beginning on page 27.

It will be the responsibility of all Faculty or designated laboratory supervisors for ensuring that staff and students properly identify, segregate, package, store and dispose of Infectious Waste appropriately

## **Infectious Waste Definitions for Purposes of Waste Determination and Waste Segregation**

### **Medical Waste**

1. Microbiological waste-i.e. stocks, and or cultures of etiological or infectious agents, including culture plates, test tubes, swabs, etc. contaminated with these agents.
2. Human blood, blood products-i.e. all liquid blood, serum and plasma. Body fluids to which universal precautions apply. Containers/equipment and articles contaminated with blood/blood products.
3. Medical/laboratory glassware including slides, pipettes, blood tubes, blood vials, contaminated broken glass.
4. Transgenic Plant Material - plant's genetic material that has been altered by the introduction of genes from another organism.
5. Sharps-i.e. syringes, needles, and scalpel blades. All sharps need to be placed in a puncture-resistant, rigid container with the universal biohazard symbol on the container.

### **Pathological Waste**

1. Human organs, body parts and surgical specimens or body parts removed during surgery or invasive procedures i.e. obstetrical, autopsy and laboratory procedures.

2. Contaminated animal parts/tissues, and carcasses.
3. Chemotherapy waste.

Contact the Chemical Safety Officer for disposal of infectious waste. Infectious waste must be properly secured for collection by the Biohazard Waste contractor. "Properly secured" is defined as all biohazard (red or orange) bags tied, fastened or secured in the most efficient manner prior to removing the container from a work area.

All biohazard bags are to be kept in red Biohazard containers designated for infectious waste only. These containers are supplied by the University's infectious waste contractor.

#### Broken Glassware

Other wastes not covered in this guideline may require special handling or disposal as follows:

Pipettes, broken glassware, microscope slides, and cover slips not considered infectious under this guide should be regarded as injurious materials because they present a physical hazard to custodians when placed in the regular trash. Additionally, broken plastic vials, pipettes etc. are also defined as injurious and should be handled as such in the same manner indicated. These items should be boxed, sealed, and labeled "Broken glassware—disposal". Please ensure the box selected for transporting broken glass is suitable, sturdy and is taped completely closed. Boxes needed to ensure proper handling of broken glass and plastic can be ordered through Fisher Scientific (1-800-766-7000) or Lab Safety Supply (1-800-356-0783).

## Laboratory Waste Disposal Guide

Items	Contaminated with: (See definitions on the next page)				
	Biohazard <sup>A</sup>	Recombinant or Synthetic Nucleic Acid (r/sNA) <sup>B</sup>	Other Biological <sup>C</sup>	Chemical <sup>D</sup>	Chemotherapeutic <sup>E</sup>
(see all definitions from the above categories on the next page)					
<p><b>Regulated Sharps</b></p> <p>Syringes with needles (For your safety <b>do not</b> remove needles from syringes unnecessarily)                      Scalpel blades                      Needles                      Glass blood vials                      Glass Pasteur pipettes</p>	Sharps Disposal Container into Medical Waste (MW) Bin				Sharps Disposal Container into MW Bin
<p><b>Other Sharps:</b></p> <p>Broken serological pipettes, glass slides, cover slips, and glass vials                      Any broken glassware                      Broken plastic ware                      Razor blades</p>	Sharps Disposal Container into MW Bin	Sharps Disposal Container into MW Bin -----OR----- Puncture Resistant Container into Regular Trash	Puncture Resistant Container into Regular Trash		Sharps Disposal Container into MW Bin
<p><b>Disposable Non-Sharps:</b><sup>1</sup></p> <p>Serological pipettes                      Micropipette tips                      Swabs, sticks                      Glass slides, coverslips                      Syringes without needles                      Intact glassware &amp; plastic ware                      Plastic petri dishes with agar                      Gloves, disposable lab coats                      Bench paper and towels</p>	Red Biohazard Bag with Puncture Resistant Container <sup>1</sup> into MW Bin	Red Biohazard Bag into MW Bin -----OR----- Clear Bag into Regular Trash <u>Autoclave</u> into Regular Trash	Clear Bag into Regular Trash		Red Biohazard Bag into MW Bin
<p><b>Plant Materials:</b></p> <p>Plants                      Seeds                      Used potting media                      Plant cultures</p>	Red Biohazard Bag into MW Bin	Red Biohazard Bag into MW Bin -----OR----- Clear Bag into Regular Trash or Compost	Regular Trash or Compost	Consult hazardous waste manual or Contact Chemical Safety Officer	Red Biohazard Bag into MW Bin
<p><b>Carcasses and Tissues:</b></p> <p>Animal carcasses<sup>2</sup>                      Animal and human tissues                      Human cadaver waste</p>	Red Biohazard Bag into MW Bin or Designated Carcass Bin	Clear Bag into MW Or Designated Carcass Bin		Consult hazardous waste manual or Contact Chemical Safety Officer	Red Biohazard Bag into MW Bin
<p><b>Liquid Waste:</b></p> <p>Liquid media and cultures aspirated or decanted from flasks and dishes                      Body fluids</p> <p><i>Solutions of biological toxins must be inactivated<sup>3</sup></i></p>	Autoclave, then dispose of down the drain with a large volume of water			Consult hazardous waste manual or Contact Chemical Safety Officer	
<p><b>Mixed Wastes:</b></p> <p>Hazardous chemicals mixed with biohazard waste</p>	Consult appropriate waste manual or Contact Chemical Safety Officer <b>before</b> generating such waste				

## Laboratory Waste Disposal Guide Definitions and Footnotes

### Definitions of Contaminants:

**A.** Contains or potentially contaminated with human infectious agents, viral vectors used with human and animal cell culture, biologically-derived toxins, human blood and body fluids, all human and animal cell cultures, or fluids and tissues from infected animals.

**B.** Recombinant or synthetic nucleic acids or genetically modified microorganisms (e.g., bacteria, plants, insects, and animals). If also infectious, refer to Biohazard column.

**C.** Not infectious to humans or animals, and non-r/sNA. Contains or potentially contaminated with environmental microorganisms, plant and insect pathogens, or plant tissue cultures. If contaminated with chemical residue, refer to "Chemical" column.

**D.** Disposable items contaminated with residual amounts of non-acutely toxic chemicals only (e.g., phenol, chloroform, acrylamide, xylene). For acutely toxic waste items, including the original containers from manufacturer, consult the Hazardous Waste Manual or contact Chemical Safety Officer. Ethidium bromide-contaminated waste must be deactivated or collected as chemical waste by the Chemical Safety Officer.

**E.** Disposable items contaminated with residual amounts of substances used to imitate a biochemical response in tissue culture or in animals and includes: antineoplastic agents (e.g., cisplatin, doxorubicin, cyclophosphamide); hormones or hormone-like drugs (e.g., estrogens, tamoxifen); synthetic analogs and other carcinogens (e.g., BrdU).

### Footnotes

**1.** Non-glass biohazard items that can puncture bags (e.g., plastic pipettes, micropipette tips, swabs and sticks) may be placed in a puncture resistant container (e.g., cardboard box lined with biohazard plastic bag, biohazard labeled recycled plastic container) or manufactured "burn-up bin" and then finally packaged in a red biohazard bag for waste pick up. Serological pipettes can puncture bags when randomly mixed with other disposable items in plastic biohazard bags. Bundle the serological pipettes into a plastic sleeve conveniently placed inside the biohazard bag, which organizes them and prevents them from puncturing the outer red biohazard bag.

**2.** Separate carcasses and tissues from other disposable items (e.g., plastic and paper) whenever possible. Decant liquid away from carcasses, and dispose of the liquid appropriately (e.g., formalin and ethanol as chemical waste through the Chemical Safety Officer, buffer solutions as biohazard liquid waste).

**3.** Toxin Inactivation - below are commonly used inactivation procedures, though they may not be suitable for your particular toxin. Consult the product information sheet for your biological toxin for specific instructions on inactivation:

- Autoclave, if heat labile (steam at  $\geq 121^{\circ}\text{C}$  for 1 hour, up to 1 liter volume), or
- Treat with NaOCl (sodium hypochlorite) at 1 – 2.5% (w/v) for 30 minutes (commercially available bleach solutions typically contain 3 – 6% (w/v) NaOCl, or
- Treat with NaOH (sodium hydroxide) at 1N for 30 minutes, or
- Treat with a combination of 0.25% NaOCl and 0.25N NaOH for 30 minutes, or
- Treat with another recognized inactivating solution.

Dispose of the inactivated toxin solution down the drain with a large volume of water. You must neutralize solutions with a pH outside the range 5.5 to 9.5 before disposal. Lastly, you can dispose of active biological toxins as chemical waste through the Chemical Safety Officer. Any further questions, contact Institutional Biosafety.

## **Appendix E.**

### Biohazard Sign Templates



# BIOHAZARD

**ADMITTANCE TO AUTHORIZED PERSONNEL ONLY  
BSL-1**



<b>Biological Agent(s):</b>
<b>Special Procedures, PPE or Precautions:</b>

<b>Emergency Contact:</b>	
<b>Name</b>	<b>Phone</b>

# BIOHAZARD

**ADMITTANCE TO AUTHORIZED PERSONNEL ONLY  
BSL-2**



<b>Biological Agent(s):</b>
<b>Special Procedures, PPE or Precautions:</b>

<b>Emergency Contact:</b>	
<b>Name</b>	<b>Phone</b>