Purpose

The purpose of this document is to provide a standardized risk assessment procedure that helps to identify and minimize laboratory risks, develop mitigation measures, and ensure regular assessments.

Scope

This procedure applies to all individuals, including Principal Investigators (PIs), students, volunteers, laboratory technicians, visitors and anyone who handles infectious or potentially infectious materials.

Definitions

1. **Biosafety Level** - Designation which describes laboratory practices and techniques, safety equipment and laboratory facilities appropriate for the materials in use and the operations performed.

2. **Biosafety Level 1 (BSL-1)** - A laboratory level suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans. These agents present minimal potential hazard to laboratory personnel and the environment.

3. **Biosafety Level 2 (BSL-2)** - A laboratory level suitable for work involving agents of moderate potential hazard to personnel and the environment. It includes various bacteria and viruses that cause disease in humans for which there is often a vaccine or treatment available. Agents handled at BSL-2 often cause common childhood diseases, and are not usually spread via the airborne route in a lab setting, such as C. difficile, Staph aureus, Salmonella, etc. Other Potentially Infectious Materials (OPIM) are also handled at BSL-2. Materials handled at BSL-2 are generally safe to work with if using standard microbiological practices, such as hand washing, wearing gloves, preventing aerosols, etc.

4. **Biohazard** – A biological agent or substance that can cause disease in humans or animals. These include, but are not limited to, infectious organisms (viruses, bacteria, fungi) and parasitic agents, infected animals, infectious clinical specimens, and/or equipment contaminated with infectious agents. A biohazard may be handled at BSL-2, 3, or 4, depending on the severity of the disease it causes, how it is transmitted, the quantities being handled, and the types of operations to be performed.

5. **Biological Materials of Interest** – types of materials subject to oversight by CSUF IBC (Institutional Biosafety Committee). These materials include but are not limited to: recombinant/synthetic DNA; transgenic animals and plants; agents infectious for humans, plants, or animals; materials sourced from humans or non-human primates (e.g. tissue

culture cell lines, blood, serum, plasma, fixed cells, OPIM); animals exposed to infectious agents or infected with r/sDNA. For a complete list, please reference the CSUF IBC website.

6. **Bloodborne Pathogens** - Pathogenic microorganisms that may be present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

7. **BSL-2 Biohazard Signage** - Includes the international biohazard symbol, the word "Biohazard" and shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color, and include a list of the materials in use, contact information, and any special entry requirements or warnings.

8. **Engineering Controls** - Includes devices/equipment (e.g., biosafety cabinet (BSC), sharps containers) that contain or minimize the biological hazards in the workplace.

9. **Hazard** – potential for harm and is often associated with a condition or activity that, if left uncontrolled, can result in injury, illness, or loss. For example, hazards can include an object, chemical, infectious agent, or the way work is carried out.

10. **Human cell lines** – Immortalized cells propagated in vitro from primary explants of human tissue or body fluid. ATCC (American Type Culture Collection) and OSHA (Occupational Safety and Health Administration) recommend working with human cell lines as if potentially infectious (i.e., at BSL-2) because they cannot be tested for contamination with every potential pathogen and because they may become cross contaminated with potentially infectious materials when handling in the laboratory.

11. **Mitigation** – measures taken to reduce risk (likelihood and/or consequence) of a hazard.

12. **Non-hazardous material** - Generally includes animal specimens and animal cell culture lines (hamster, mouse, etc.) unless these are known to be infected with a pathogen or have been altered through the use of recombinant or synthetic DNA.

13. **Other Potentially Infectious Materials (OPIM)** - (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

14. **Pathogen** - For shipping purposes, microorganisms (including bacteria, viruses, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

15. **Reasonably Expected to Contain a Pathogen** - For shipping purposes, this refers to a material that has been tested and found to be or contain a pathogen, or that has been taken from a patient known to be infected with a pathogen.

16. **Risk** – the chance, high or low, that someone could be harmed by a hazard

17. **Risk Assessment (RA)** – an action or series of actions taken to recognize or identify hazards and measure the probability that something will happen because of that hazard and the severity of consequences. Risk assessment analyzes if enough precautions have been taken or if more are necessary. Several types of risk assessments include biological, job safety, and procedural.
    a. *Biological*: used to identify hazards for a specific infectious agent
    b. *Job Safety*: used to identify hazards for a specific task or activity
    c. *Procedural*: combines biological and job safety risks in a comprehensive manner

18. **Risk Control** - a method of managing the risk with the primary emphasis on controlling the hazards at its source. For a risk that is assessed as "high", steps should be taken immediately to minimize risk of injury. The method of ensuring that risks are controlled effectively is by using the "hierarchy of controls."

19. **Risk Management** – compasses the assessment, analysis, and management of risks. It is simply recognizing which events (i.e. hazards) may lead to harm in the future, and minimizing their likelihood (i.e. how often) and consequence (i.e. severity).

20. **Universal Precautions** - Refers to the basic biosafety practices for handling all blood, body fluids and cell lines from humans or non-human primates as potentially infectious.

21. **Work Practice Controls** – Methods to control risks (also known as mitigation). These include engineering controls (e.g., biosafety cabinets), administrative controls (e.g., written procedures), and personal protective equipment (e.g., lab coat, gloves).

Responsibilities

1. Principle Investigators (PIs), researchers, instructors, laboratory/clinical managers, students, volunteers, or other personnel proposing to work with or handle biological materials of interest are responsible for completing/performing a risk assessment(s).

2. Personnel in supervisory or management positions (e.g., PIs, Lab Managers or other managers) are responsible for ensuring that employees, students, volunteers and/or other personnel are adequately trained to perform this procedure.

3. The Biosafety Officer (BSO) and CSUF IBC is responsible for reviewing and approving risk assessments for biological materials of interest.

Procedure

1. Planning for the Risk Assessment

    a. Research the hazards of the biological material/agent. Consult industry-accepted references such as the BMBL (Biosafety in Microbiological and Biomedical Laboratories, 5th Edition), NIH Guidelines, PHAC PSDS (Public Health Agency of Canada Pathogen Safety Data Sheets), ABSA International Risk Database, CDC (Centers for Disease Control and Prevention) website on emerging pathogens, and/or scientific literature as appropriate.

    b. List, rank, and set priorities for process/procedures/hazardous activities. List activities with hazards that present unacceptable risks, based on those most likely to occur and with:
        i. Most severe consequences
        ii. Highest injury or illness rates
        iii. Potential to cause severe or disabling injuries or illness
        iv. Simple human error leading to severe accident or injury
        v. New or undergoing changes

    c. Gather information:
        i. Review the process/procedure/activity being assessed
        ii. Walk around the laboratory and workspaces and consider the activities, processes or substances used that could cause harm
        iii. Check the manufacturer's instructions for potential hazards
        iv. Look back at accident, illness or surveillance reports
        v. Review employee training records and competency assessments
        vi. Review Safety Data Sheets for biological/chemical hazards and suggest guidelines for safe handling (PPE, waste disposal, etc.)
        vii. Review the organism/agent's properties
        viii. Think about long-term hazards to health

    d. Understand the limitations of a Risk Assessment
        i. Subjective process that involves professional judgments based on knowledge and experience of past events
        ii. Potential hazards identified may be based on incomplete knowledge
        iii. Differing opinions on what constitutes a risk and what is an acceptable level of risk (i.e. risk tolerance)
        iv. There are many ways to conduct a risk assessment

v. It is not usually possible to eliminate risk to zero. Aim for what is reasonably practical.

e. Print and review the Procedural Risk Assessment Form (Appendix A)

2. Identify Activities or Specific Tasks

a. Consider from the time a material is received until it is stored or discarded.
   i. Go through the process/procedure step by step.
   ii. Receipt
   iii. Storage
   iv. Manipulation
   v. Disposal or Long-term Storage

b. List the steps/activity/specific tasks of the procedure in the first column of the Procedural Risk Assessment Form. This can be specific or more general. Refer to Appendix D.

3. Identify the hazards – what can go wrong:

a. List potential hazards in the appropriate column on the Risk Assessment Form. Each activity or task may have more than one hazard associated with it. Hazards are rarely a simple case of one singular cause resulting in one singular effect. Refer to Appendix D Potential Hazard Examples

4. Identify the current controls:

a. Risk control is a method of managing the risk with the primary emphasis on controlling the hazards at the source.

b. List the controls that are in place for each hazard. Refer to Appendix E for types and examples of Work Practice Controls. There may be several controls in place for each hazard.

5. Likelihood

a. Consider the Likelihood, with any listed current controls in place – Refer to Appendix F
   i. How often is the task done? Does this make the harm more or less likely?
   ii. How often are people near the hazard?
   iii. Has it ever happened before? How often?
   iv. What is the likelihood of the consequence identified happening?
      1. Rare: May happen only in exceptional circumstances

2. Unlikely: Might happen at some time
3. Possible: Could occur occasionally
4. Likely: Will probably occur in most circumstances
5. Almost Certain: Expected to occur in most circumstances

6. Consequences

   a. Review potential pathogens that could be isolated in the lab if working with human, animal or field samples. Refer to Appendix G and H
   b. Recommended step if pathogens are a possibility:
      i. Complete a CDC Biological Risk Assessment Worksheet for potential pathogens that may be encountered.
      ii. This will define standard environmental and administrative controls and PPE.
      iii. Review information on Risk Levels and the Canadian Biological Safety Data Sheets

   c. Consequence matrix:
      i. Minimal: Hazard or near miss requiring reporting and follow up action
      ii. Minor: Potential First Aid Injury
      iii. Moderate: Potential Medical Treatment Injury or Illness
      iv. Major: Potential Lost Time Injury, non-permanent disability
      v. Severe: Potential fatality or injury or illness with permanent disability

7. Estimate risk (How likely is it something will go wrong, and how bad is it likely to be?)
   a. There are many factors to consider when determining risk. (See Appendices F, G, H).
      i. Personnel factors
      ii. Laboratory environment
      iii. Possible outcomes
      iv. Routes of transmission and host entry portals
      v. Organism/Agent Considerations

   b. Estimate Risk: Risks are evaluated according to the likelihood of occurrence and severity of consequences – refer to Appendix I: Risk Matrix to determine overall risk.

8. Mitigate remaining hazards/ Actions based on Risk Matrix

   a. If the risk assessment identifies a number of unaddressed hazards, rank them in order of importance and address the most serious risks first.

b. Identify long-term solutions for the risks with the biggest consequences, as well as those risks most likely to cause accidents or ill health.
   i. Extreme Risk: Target resolution within 1 month
   ii. High Risk: Target resolution within 3 months
   iii. Medium Risk: Target resolution within 6 months

c. The control measures implemented will usually require changes to the way work is done due to new or modified equipment or processes, new or different chemicals, or new PPE. In these situations, it is usually necessary to support the new control measure with
   i. New procedures
   ii. Training, instruction, and information
   iii. Supervision

d. Total elimination of the hazard is not always possible.

e. Ensure the PI, Lab Management, Safety personnel, and the lab employees performing the activity are aware of associated risks and hazards.

9. Risk Control Plan Form (Appendix B)– specific control measures

   a. The Risk Control Plan describes practices, procedures, and resources needed to ensure the safety of an activity.

   b. List the controls required for the activity. Include Engineering and Administrative Controls and PPE.

10. Annual Review of the Risk Assessment (Risk Monitoring, Appendix C)

   a. Monitoring the control plan will help ensure the controls remain effective.

   b. Few procedures stay the same. New equipment, substances and procedures can lead to new hazards. A review is recommended:
      i. When the control measure is not effective in controlling risk
      ii. Injury or illness reports point to a new or unforeseen risk
      iii. A new hazard or risk is identified
      iv. When there is a change in the work process or flow
      v. When there is a change or addition to equipment or instruments
      vi. New employees are added
      vii. A move to a new work area
      viii. With the introduction of new chemicals or substances
      ix. When new information becomes available
      x. When indicated by a laboratory assessment

c. Outline the practices, what is monitored? And how often? (Appendix C)
    i. Competency and training records
    ii. Unusual occurrence Reports
    iii. Injury, illness reports
    iv. Instrument maintenance logs
    v. Direct observation of PPE
    vi. New or changes to the procedure
    vii. New or changes to the equipment
    viii. Annual procedure review

d. Revise policies and procedures to prevent recurrence of problems

e. Discuss RA with appropriate staff

f. Document all RA activities

References

1. Biosafety in Microbiological and Biomedical Laboratories, CDC-NIH, 6th edition: https://www.cdc.gov/labs/bmbl/index.html

2. Public Health Agency of Canada (PHAC) Canadian Pathogen Safety Data Sheets: https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html

3. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines): https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

4. ABSA International Risk Group Database: https://my.absa.org/tiki-index.php?page=Riskgroups

5. CSUF Biosafety Program

6. CSUF SOP: Working at Biosafety Level 2

7. CSUF Institutional Biosafety Committee Charter

Appendices

1. Appendix A: Risk Assessment Form
2. Appendix B: Risk Control Plan
3. Appendix C: Risk Monitoring
4. Appendix D: Examples of Activities or Specific Tasks and Potential Hazards
5. Appendix E: Hierarchy of Control
6. Appendix F: Likelihood Considerations
7. Appendix G: Consequence Considerations
8. Appendix H: Examples of Long-term Outcomes
9. Appendix I: Risk Matrix

Responsible Executive: Vice President for Administration and Finance
Responsible Office: Environmental Health and Safety
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Appendix A: Procedural Risk Assessment Form

Activity/Task Location:						**Approved by (signature/date):**	
Developed by:						**Date:**	
Identify Hazards		**Risk Controls/Work Practices**	**Risk Assessment**			**Control Plan**	
Activities/Specific Tasks	Hazards	Current Controls (Engineering/Admin/PPE)	L	C	Est. Risk	Additional Controls/Process (Improvements needed to reduce risk to lowest acceptable level)	Implementation Date
***Example**: Centrifugation of human blood samples*	*Leakage: Exposure to biohazardous material through inhalation of infectious aerosols*	*Centrifuge safety cups used for all biological samples. Centrifuge safety cups opened and unloaded in the BSC.* .	*rare*	*mod*	*low*	*Training on cleaning a spill in a centrifuge*	xxx

L= Likelihood; C= Consequence

Appendix B: Risk Control Plan

Risk Control Plan for: _____ Date: _____

Type of Control	Additional Controls Required; Describe practices/procedures needed to ensure safety of the activity
Engineering	
Administrative *Example: add centrifuge cleaning to BSL-2 SOP*	*Training on cleaning of a centrifuge spill, document reading of revised SOP.*
PPE	
Other: 1. **Elimination** 2. **Substitution** 3. **Isolation**	

Appendix C: Risk Monitoring

The following items are monitored to ensure the process/procedure/activity is compliant.

Monitor	**Frequency**
Example: Biosafety Cabinet Certification	*Annually*

Appendix D: Examples of Activities or Specific Tasks and Potential Hazards

Activities/Tasks:

- Centrifuging
- Cleaning up spills
- Contact with fomites or contaminated surfaces
- Handling biological waste
- Inoculating media and automated identification systems
- Leaky specimen containers
- Loose caps on containers
- Manipulating inoculation needles, loops, and pipettes
- Manipulating needles, syringes and sharps
- Manipulating specimens and cultures
- Mixing, blending, grinding, shaking, sonicating, vortexing specimens or cultures
- Pipetting
- Pouring, splitting, or decanting liquids
- Preparing smears, heat fixing or staining slides
- Reading culture plates
- Removing caps or swabs
- Spilling/dropping
- Splashing infectious material
- Streaking plates
- Subculturing
- Throwing contaminated items into biohazardous waste
- Transporting specimens/materials throughout the laboratory environment (inside and outside of the lab)
- Uncapping/opening vacutainers
- Use of animals
- Use of sharps
- Field work with animals or insects

Potential Hazards of Activities/Tasks:

- Exposure to biohazardous material through inhalation of infectious aerosols (list specific tasks)
- Exposure to biohazardous material via direct contact of specimens, specimen containers, or contaminated work surfaces with employee's skin
- Exposure to biohazardous materials through ingestion or mucous membranes
- Exposure to bloodborne pathogens
- Parenteral inoculations with syringe needles, razor blades, scalpels or other contaminated sharps
- Possible cuts from sharps used in specimen collection
- Spills and splashes onto skin
- Animal bites and scratches
- Animal zoonoses
- Insect bites while doing field work (Spotted fever, West Nile, Typhus

Appendix E: Hierarchy of Controls

Most Effective/Reliable

Order No.	Control	Definition	Examples
1	Eliminate	Remove the hazard *NOTE: Depending on the type of hazard, it may not be possible to completely remove it. In which case, eliminate as many risks associated with the hazard*	• Remove a hazardous piece of equipment from service • Consider safety when selecting new equipment • Eliminate use of glass in the laboratory
2	Substitute/Isolation	Substitute: replace hazardous process/material with a less hazardous one Isolation: separate the source of harm from people by distance or barriers; isolate the hazard from the person at risk	• Substitute a blunt tip needle for a hypodermic needle for syringe filtration. • Substitute *E. coli* K-12 for *E.coli* O157:H7 • Use a vaccine strain in place of a wild strain • Have robotic devices perform tasks (e.g., pipetting, decapping blood tubes)
3	Engineering	Physical control, including mechanical device or process, room change, etc. Use mechanical solutions to control the risk. Redesign a process, workflow, lab, or piece of equipment to make it less hazardous	• Use safety syringe for injections • Work in a biosafety cabinet • Add shielding to an instrument • Negative, inward airflow
4	Administrative/PPE	Administrative: Work methods or practices/procedures to minimize exposure to hazard PPE: Item worn to provide a barrier between the person and the hazard (e.g., gloves, lab coat). PPE limits exposure to harmful effects of hazard but only if used correctly, and if it does not fail (e.g., glove breaks)	• Working at an appropriate biosafety level • Not allowing mouth pipetting • Hand washing • Training requirements • Good housekeeping • Gloves, lab coat, safety glasses

Least Effective/Reliable

Appendix F: Likelihood Considerations

GENERAL	How often are people exposed to the hazard?	A hazard may exist all of the time or it may only exist occasionally. The more often a hazard is present, the greater the likelihood it will result in harm.
	How long is the exposure?	The longer someone is exposed to a hazard, the greater the likelihood that harm may result (e.g., animal allergens).
	How effective are current controls in reducing risk?	In most cases the risks being assessed will already be subject to some control measures. The likelihood of harm resulting from the risk will depend upon how adequate and effective the current measures are.
	Are hazards more likely to cause harm because of the working environment?	Did the environmental conditions change? Is there insufficient light and ventilation? Did the work level increase?
	Could the way people act and behave affect the likelihood of a hazard causing harm?	The possibility that people may make mistakes, misuse items, become distracted or panic in particular situations need to be considered. The effects of fatigue or stress may make it more likely that harm will occur.
	Do the differences between individuals in the workplace make it more likely for harm to occur?	Newer or young workers may be more likely to suffer harm because of inexperience. People who do not normally work at the workplace will have less knowledge than employees who normally work there, and may be more likely to suffer harm. These could include contractors, interns or students.
PERSONNEL	Age	
	Behavior	
	Duration/frequency of exposure	
	Education, experience, competence	
	Genetic predisposition	
	Immune status	E.g., Lupus, immune suppressive drugs, HIV+, spleen removal
	Overall health	
	Perception	E.g., attitude, follows safety precautions, takes shortcuts
	Pre-existing conditions	E.g., uncontrolled diabetes, asthma, blood conditions
	Pregnancy	Risk to mother vs. risk to fetus
	Stress, fatigue, mental status	
LAB	Equipment	Is it maintained? Operation in accordance with manufacturer's instructions?
	Facility	BSL-2, workspace, BSC, ventilation, lighting, is there enough room?, clutter?, clean?
	Procedures	What procedures are being performed?
	Field Collection	E.g., animal bites, insects, trips and falls, heat exhaustion

Appendix G: Consequence Considerations

GENERAL	What type of harm could occur? How severe is the harm? Could the hazard cause death, serious injuries, illness or only minor injuries requiring first aid?
	What factors could influence the severity of harm that occurs? For example, the distance someone might fall or the concentration of a particular substance will determine the level of harm that is possible. The harm may occur immediately or it may take time to become apparent.
	How many people are exposed to the hazard and how many could be harmed in and outside the workplace?
	Could one failure lead to other failures?
	Could a small event escalate to a much larger event with more serious consequences?
TASK	Mouth pipetting, splashing, eating/drinking, applying cosmetics in lab (entry: ingestion/oral, GI)
	Using needles/syringes, broken glass/sharps, using scalpels/razors, waste disposal (entry: non-intact skin/percutaneous)
	Splashing or spilling in eye/mouth/nose, working on contaminated work surfaces, improper use of loops/needles/swabs, handling contaminated equipment (entry: mucous membranes)
	Tissue culture, spill clean-up, manipulation of samples/cultures/specimens (entry: inhalation of aerosols, respiratory, non-intact skin)
	Working with animals, cleaning cages (entry: inhalation of aerosols, percutaneous)
AGENT	Ability to produce toxins or enzymes
	Concentration, volume
	Consequence (high risk pathogens)
	Ease and method of transmissibility
	Frequency of exposure
	Genetically modified, attenuated, or multiply resistant microorganisms
	Infectious dose, potential for infection
	Invasiveness
	Natural reservoir
	Potential for survival in the laboratory environment
	Prevalence in community
	Resistance to disinfectants or antibiotics
	Routes of Transmission

Appendix H: Long-Term Outcomes

- Colonization leading to carrier state
- Asymptomatic infection
- Infection – chronic or acute
- Illness and morbidity
- Disease and sequalae
- Toxicity, oncogenicity, allergenicity
- Death

APPENDIX I: RISK MATRIX

Choose the most appropriate Likelihood and the most appropriate Consequence to reach the risk rating.

Likelihood	Consequence				
	Minimal: Hazard or near miss requiring reporting and follow up action	**Minor**: Potential First Aid injury	**Moderate**: Potential Medical Treatment Injury or illness	**Major**: Potential Lost Time Injury, non-permanent disability	**Severe**: Potential Fatality or Injury or illness with permanent disability
Rare: May happen only in exceptional circumstances	**LOW**	**LOW**	**LOW**	**LOW**	**MEDIUM**
Unlikely: Could happen at some time	**LOW**	**LOW**	**MEDIUM**	**MEDIUM**	**HIGH**
Possible: Might occur occasionally	**LOW**	**MEDIUM**	**HIGH**	**HIGH**	**HIGH**
Likely: Will probably occur in most circumstances	**LOW**	**MEDIUM**	**HIGH**	**HIGH**	**EXTREME**
Almost Certain : Expected to occur in most circumstances	**MEDIUM**	**HIGH**	**HIGH**	**EXTREME**	**EXTREME**

LOW	Risk is tolerable; manage by well-established, routine process/procedures
MEDIUM	A Control Plan must be developed; existing controls need to be reviewed. Target resolution (ideally reduction to low level of risk) should be within 6 months.
HIGH	A "high" risk may also require immediate assessment and senior staff consideration; a Control Plan must be developed; regular monitoring and reported on to the relevant management/steering committee. Target resolution (ideally reduction to low level of risk) should be within 3 months.
EXTREME	An "extreme" risk requires immediate assessment and senior staff consideration is required; a detailed Control Plan must be developed, and consideration should be given to ceasing the activity unless the risk can be reduced to a level of high or less; regular monitoring and reported on to the relevant management/steering committee. Target resolution (ideally reduction to low level of risk) should be within 1 month.