Biosafety and Exposure Control Plan

For Laboratory Research

† Enter Name of Agents and/or Toxins
(Add all agents or toxins that apply.) Leave text formatting as-is in this area.

California State Polytechnic University, Pomona

Environmental Health and Safety
8/2/2012

http://www.cpp.edu/~ehs
Revised: 02/14
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Responsible Official: † Enter Name of RO
† Department
† Office Location
† Phone Number

Principal Investigator/Location: † Enter Name, Office of PI
Select Agents/Toxins: † Name of Agents or Toxins
Authorized Individuals:

University Police (Emergency): DIAL 911 from a Campus Phone

University Police (Non-Emergency): (909) 869-3070

Center for Disease Control (CDC)
Select Agents Program: (404) 718-2000

EVACUATION
Evacuation of the area were the regulated agents are used/stored will be via the established fire exits in the building. Evacuees will be directed to the evacuation staging area. Individuals that are contaminated will be held for proper decontamination.


An Incident Response Plan for Select Agents and University Emergency Plan for evacuation staging areas and staging areas shall be incorporated by reference.

The PI is responsible for creating a reasonable evacuation plan to have posted within the lab. The evacuation route must be approved by EH&S prior to use and must be included in adjoining plans (Security and Incident Response Plans) if applicable. The PI is responsible for creating all adjoining plans if they are required. Templates shall be made available to the PI upon request to facilitate this effort.

[TEMPLATE INSTRUCTIONS:

¥
PI:
Complete all areas in Red Times New Roman Size 12 and marked with this symbol. †
Once completed, reformat ONLY completed section text to Arial size 10, Black to match the document.
Items in Red and indicated with this symbol, ¥ are instructions only and shall be removed before publishing this document.
Program Description

The Biosafety program is a single segment under the Biosafety Sector of Environmental Health and Safety which was designed to maintain regulatory compliance in areas of research such as Recombinant DNA, Select Agents & Toxins, Infectious Agents and Aerosol and Transmissible Diseases. The Program Administrator shall be the Director of Environmental Health & Safety.

†

Click here to complete this section by providing a brief description of the program and the research if applicable.

Job Classifications*

Job Safety Classifications are determined by Environmental Health and Safety and are based on both the level of exposure as well as specific hazards the employee may be exposed to during the course of his or her job. While Job Classifications are assigned by Human Resources, occasionally similar job duties will share the same “Job Classification” and may be referenced. An example of this may be Police Officers or Medical Workers. In terms of Job Safety Classification assigned by EH&S, employees belonging to the following categories must comply with this document.

Laboratory Worker- Infectious
A laboratory infectious worker designation is given for those who work in a laboratory setting and have a higher than normal probability of exposure to infectious agents.

Medical Worker
Medical Worker designation is given to employees that operate in a medical or emergency assistance capacity. Those who are doctors, emergency responders, nurses and technicians may be assigned to this category. Since their duties may or may not include working in a laboratory, those working outside the lab shall utilize this document to meet compliance for exposure control while for the latter, this document shall be used to meet the requirements of a Biosafety Plan. The need for an exposure control plan is mandated under OSHA Requirements for Aerosol and Transmissible Diseases for workers who have a higher than normal probability of exposure to infectious agents transmissible by aerosol generation or inhalation and have person-person or direct patient contact.

The following classifications specify the level of exposure a worker is likely to be faced with. These classifications are further broken down into categories which specify individual workers. This process is optional and may be used to further define a job safety classification if needed.
**Exposure Classification Level A: Biosafety Level 2 work with Select Agents**

Category I: Authorized Workers with Direct Access
- Principal Investigator
- Graduate Students
- Research Students

Category II: Authorized Workers with Indirect Access
- RO
- ARO
- BSO

Category III: Unauthorized Individuals
- Custodial Staff
- Guests/ Visitors (escorted)

**Exposure Classification Level B: Biosafety Level 2 work NO Select Agents**

Category I: Authorized Workers with Direct Access
- Principal Investigator
- Graduate Students
- Research Students

Category II: Authorized Workers with Indirect Access
- RO
- ARO
- BSO

Category III: Unauthorized Individuals
- Custodial Staff
- Guests/ Visitors (escorted)

**Exposure Classification Level C: Biosafety Level 1/ Biosafety Level 1+**

No categories specified for BSL-1 unless requested by the IBC

*Please review the Standard Operating Procedures for Safe Work Practices to see specific tasks that have been identified as areas that present possible risks of exposure. Please complete the list above with any additional personnel that may be exposed to the agent or toxin and assign them to the categories listed.*
Respiratory Hazards

Respiratory hazards may exist with the generation of aerosols. Special precautions should be taken to reduce the risk of creating aerosols when working with regulated materials such as select agents or aerosol transmissible diseases. Please consult with Environmental Health and Safety to determine specific areas of concern and to establish protocols to reduce the risk of respiratory hazards in your workplace. Employees must be trained in BSL-2 handling, respiratory protection, Aerosol Transmissible Diseases, PPE and other areas as needed.

Scope

† Click here to complete this section by providing a description of the scope of this document. The scope should include any areas and individuals who will use this plan, a list of research projects involved and lab locations and ensure that all job classifications that may have exposure are identified in the section “Program Description” and are identified in their respective categories.

Definitions

‡ Add to this section only if necessary. All definitions and acronyms must be listed in alphabetical order.

ARO: Alternate Responsible Official
ATD: Aerosol and Transmissible Diseases
BMBL: Biosafety in Microbiology and Biomedical Laboratories
BSP: Biosafety Plan (ECP with respect to infectious agents and direct patient contact)
BSC: Biosafety Cabinet
ECP: Exposure Control Plan, expressed hereafter as BSP (Acts as a BSP under ATD Program)
LAI: Laboratory Associated Infection(s)
OPIM: Other Potentially Infectious Material
PI: Principal Investigator
PPE: Personal Protective Equipment
TAM: Threat Assessment Matrix
R/A: Risk Assessment
RO: Responsible Official
V/A: Vulnerability Assessment
Roles and Responsibilities

The campus President has the ultimate responsibility for establishing and maintaining effective policies regarding environmental and occupational health and safety within the institution. Policies that govern activities and responsibilities of the Environmental Health and Safety Department (EH&S) programs are thereby established under the final authority of the President. Department administrators will be responsible for the implementation of EH&S programs and shall provide continuing support.

It is recognized that certain responsibilities and expressed procedures in this program cannot be equally applied because of the wide diversity of operations within the university and the necessary differences in organizational structure within various departments. Therefore, some details which might be impractical for one department, to implement as directed, while another would have no difficulty in applying to everyone. Departments will have latitude in formulating and implementing alternative occupational Biosafety Plans as long as the objectives of this BSP are not compromised and a copy of individual department BSP’s are submitted to EH&S. Areas where direct contact with infectious agents through aerosol transmission and/or patient contact should reference the campus Aerosol and Transmissible Disease (ATD) program which contains an Exposure Control Plan which will operate in lieu of a functioning Biosafety plan.

**Institutional Biosafety Committee**

The Institutional Biosafety Committee shall be the only regulatory body that approves research protocols in the following areas:

1. Recombinant DNA
2. Select Agent Research
3. Infectious Agents

All research protocols must be in compliance with Cal Poly’s Institutional Biosafety Committee (IBC) Memorandum of Use document which is available through EH&S.

**Biosafety Officer**

The role of the Biosafety officer shall be to coordinate inspections of all areas that fall under the jurisdiction of the Biosafety Program and/or the Institutional Biosafety Committee. The Biosafety Officer shall act as a liaison with Environmental Health and Safety and other persons to ensure that correspondence is efficient and addresses any issues or concerns in question.

**Environmental Health and Safety (EH&S)**

It is the responsibility of EH&S to develop, monitor and maintain compliance of the University’s Health and Safety programs as they relate to Federal, State and Local Environmental/Occupational Health and Safety regulation standards. Further responsibilities are outlined below:

1. Provide consulting to administration personnel, Deans, Directors, Chairpersons and DSC regarding program compliance including the following:
   i. Consulting on issues of hazard identification and evaluation; procedures for correcting unsafe conditions;
ii. Advising on procedures for obtaining fiscal resources;
iii. Determining, and recommending appropriate control measures; and
iv. Administration of employee’s information and training programs and employee medical monitoring.

2. Provide centralized monitoring of the Biosafety Program and BSP activities on a consultative basis;
3. Maintain centralized copies of records and program documentation;
4. Maintain current information on legal requirements concerning regulated Health and Safety mandates;
5. Ensure appropriate audits are conducted. Review and evaluate the effectiveness of the BSP at least annually and update when necessary.

**Principle Investigator**

Principal Investigators shall be faculty or a non-faculty member who is specifically responsible for a particular laboratory and or research area. Additionally responsibilities for that person’s job description include providing Emergency First Aid. The Principal Investigators shall by virtue of education, experience and training, be familiar with all the operations, procedures and processes of a working environment where human blood or OPIM are present. Principal Investigators will have the following responsibilities:

1. Identify infectious body fluids and OPIM hazards;
2. Provide employee initial and annual training;
3. Identify materials considered particularly infectious; and
4. Conduct work area inspections as indicated in the Cal Poly injury and Illness Prevention Program;
5. Complete the Sharps Injury Log for all Sharps injuries;
6. Complete a working Biosafety Manual and train all employees to its contents;
7. Write all required Standard Operating Procedures (SOP’s) and keep them current and accurate.
8. Provide training documentation to the department.

**Departments and Colleges**

The departments and colleges will include correspondence between Department Safety Coordinators (DSC), Department Chair/Manager, and Dean. Department Safety Coordinators will communicate directly with the PI, Biosafety Officer and EH&S as necessary. Correspondence with higher levels of management includes channels for corrective action which can be found in the IBC Escalation Procedures located in the appendix of this document. At which time that correspondence with management levels (Chair, Dean, AVP, etc.) it is the responsibility of that official to communicate between the PI, Biosafety Officer, and EH&S as necessary to stimulate the required corrective action. Departments are responsible for submitting all records to EH&S on a timely basis as per record handling procedures.
Employees and Students

It is the responsibility of all parties whom operate under this plan to follow all safe work practices and procedures to the best of his/her abilities. Failure to have written documentation of all required training as dictated by the office of Environmental Health & Safety shall result in corrective action per the IBC Escalation Procedures located in the appendix of this document.
Risk Assessment

Responsibility for Biosafety exists at all levels and is shared throughout the University. The Environmental Health and Safety Department establishes policies for the safe use of biohazards and for compliance with all applicable regulations. Environmental Health and Safety department personnel must disseminate pertinent information; consult with faculty, staff, students and visitors; and monitor for non-compliance. Risk assessment is the process that enables the appropriate selection of safe work practices, safety equipment and facility safeguards that can prevent laboratory associated infections (LAI). Laboratory safety has continuous upgrades and revisions to ensure adequate protection to those who use the laboratory facilities and to maintain safe housing to protect the general public from infectious microorganisms contained within laboratories. The researchers, clinicians, and technicians who perform work with biohazards are keystone of the Biosafety program, as they must incorporate the Biosafety requirements and safety precautions into all facets of their work.

An integral part of maintaining regulatory compliance requires the process of conducting a risk assessment, a review of proposed work to identify potential hazards and vulnerabilities and then to adopt appropriate safety procedures before initiation of the experiments, thus known as risk management. Certain experiments require advanced registration and Institutional Biosafety Committee approval prior to initiation. The PI should refer to the IBC Memorandum and the Recombinant DNA Plan for an overview of IBC jurisdiction and experiments that fall under the jurisdiction of the NIH, respectively. Generally speaking, assessed risk can be mitigated or addressed through Primary and Secondary Barriers. A primary barrier is the first line of defense and is represented by safe work practices, standard operating procedures and engineering controls. Secondary barriers refer specifically to personal protective equipment (PPE) and if worn correctly and at the proper protection level, the combination with primary barriers will only further protect the employee or user.

**Note: Risks and Threats are determined by a Threat Assessment Matrix (TAM). Depending on the outcome of a TAM, your section will address Risks or Threats. Please see below for respective template sections based on the outcome of a TAM and disregard the other. A sample TAM is available in the appendix of this document and must be completed by the PI.**

**Risk Identification (Discard if using Threat Identification Section)**

a) **Risk #1**
   † Click here to enter risk text. Try to describe each risk as completely as possible.
   (a)(1) **Mitigation #1:**
   † Click here to enter mitigation text. Try to describe how each risk will be prevented through the use of engineering controls, procedures etc.

b) **Risk #2**
   † Click here to enter risk text. Try to describe each risk as completely as possible.
   (b)(1) **Mitigation #2:**
   † Click here to enter mitigation text. Try to describe how each risk will be prevented through the use of engineering controls, procedures etc.
Note: ¥ If a security plan is not required for your program, you should include a written contingency plan in the appendix of this document to describe how each of these risks will be addressed should mitigation steps not be adequate or fail. Alternately, each risk may have a contingency section (noted in text) with the specific contingencies written below each risk. This can be done in lieu of a written contingency plan amendment within the appendix. If an appendix is added, it must be referenced within the body of this plan respective to each risk.

**Threat Identification (Discard if using Risk Identification Section)**

a) **Insider**
Includes a single, non-violent person with authorized access inside the facility and or electronic systems. The insider is considered to be any person granted unescorted access to any portion of an Exclusion or Limited Access Area. The intent of a malevolent insider is to steal, destroy, or release a Moderate or High Risk agent, or to steal or destroy other high consequence assets from the laboratory without detection. The insider would be expected to abort any theft attempt to avoid detection or identification. Authorized access affords this person extensive knowledge of the facility and operating systems. The insider has the opportunity to choose the best time to commit a malevolent act.

(a)(1) **Mitigation:**
In an effort to address the risks of an insider with granted access, a multitude of steps have been implemented. These corrective measures include, but are not limited to the development and training of a written Security Plan to be included in the appendix of this document, the requirement of Security Risk Assessments of individuals prior to gaining unrestricted access, the development of an inventory tracking/verification system and the maintaining of three lockable barriers for all select agents and/or toxins.

b) **Outsider**
Threat of an individual without appropriate clearance with a desire to do harm (i.e. violent acts, anger, hatred, terrorist activity, civil disturbances, special interest groups, attack at gun point etc.

(b)(1) **Mitigation:**
In an effort to mitigate to risk of an outsider gaining access to Moderate or High Risk select agents, the select agents storage room has been keyed off the master system, accessible only by a separate key which is also keyed differently than the lesser restricted access lab. Any select agents that are in use outside the storage room are kept within freezers of refrigerators that maintain 3 lockable barriers. A written procedure must also be created within the Incident Response plan (Appendix) which outlines the protocols associated with any potential or possible security risk.

c) **Pest Management**
Includes the infestation or opportunistic access of any pest such as rodents, reptiles and insects which could potentially cause an unsafe situation. A pest could have access to Moderate of High Risk agents during lab working hours and particularly small insects and rodents are able to gain access to areas through very small openings. This presents the risk that a pest comes into contact with a Moderate or High Risk agent and evades the detection of the lab staff.
Mitigation:
A standing contract is in place on the campus to reduce the presence of rodents in its buildings which includes office space, classrooms, housing and laboratories. The preventative measures in place are currently employing the use of adhesive plates and mechanical traps inside high traffic areas such as offices, labs, etc. In areas such as around building perimeters, a series of bait modules are utilized to administer pesticides in gradually increasing doses. The traps and bait modules are serviced regularly through the off campus contractor. In the event that a contractor would require access to the lab area, they are escorted pursuant to the same protocols in place for maintenance and cleaning crews.

Threat Contingency Plan

† A contingency plan is required to address the presence of a risk that has now occurred. We first identified risk factors and stated measures in place to prevent them through mitigation techniques, but in the event that the mitigation steps are insufficient to prevent the risk from occurring, steps must be in place to contain the situation. A contingency plan can be addressed in a Security Access Plan if one is required or it can be satisfied by addressing the topic within the Incident Response Plan or within the body of the Biosafety plan.

Work Practices and Procedures

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Template work practices and procedures (SOP’s) have been created for topics such as PPE etc. All SOP’s relevant to this plan are located on the Biosafety Portal Website.

http://www.cpp.edu/~ehs/biosafety/procedures.shtml

The PI may opt to create his/her own SOP’s in which case, must be approved by EH&S prior to implementation. It is suggested that any change to the template SOP’s also be approved.

If template SOP’s are to be used, please download those that apply from the link above and complete the required areas. Once complete, they can be attached to the appendix of your completed Biosafety Plan and put on file in the lab.
Communication of Hazards

† In accordance with the Hazard Communication Plan, provided through Environmental Health and Safety, all employees, students and visitors have the right to be made aware of any hazards specific to any area to which they lawfully gain access or are allowed entry. To accommodate this right to know, special procedures are in place to address specific hazards which include but are not limited to:
- Signage
- Written Procedures
- Training
- MSDS’s (aka SDS’s) available etc.

Areas that are using specific agents under the scope of a Biosafety plan (Exposure Control Plan) are required to have all signage and warnings as a conventional lab. In addition to those conventional postings, additional signage or warnings may be required depending on the material being used.

Security Plan

† Pending the results of the threat assessment matrix, a written security plan may be required to be included within the appendices of this document.

**Any work with Select Agents is required to have a security plan and incident response plan. **

A sample security plan is included in the appendix.

Some areas that must be considered include the following:
- Entry/Exit Procedures
- Signage
- Employee access
- Visitor/Guest access
- Emergency Spill Procedures

Incident Response Plan

† It is a prudent practice to have an incident response plan for agents under the scope of this plan. A sample Incident Response Plan is provided in the appendices of this document and if implemented, must be approved by EH&S prior to use. The implementation of an Incident Response Plan will require additional training and coordination with Cal Poly Police Department.
Chemical Hygiene Plan

† The chemical hygiene plan is a standardized document that outlines safe work practices when working with chemicals. A large part of this document is represented in the Laboratory Safety Program which teaches safe work practices for laboratories and offers standard operating procedures for large groups of chemicals with varying hazards. A copy of the chemical hygiene plan should be made available within the lab area as part of Hazard Communication requirements. Contact EH&S with any questions.