
Section IV

Exposure Control Plan ***(Compliance Document for OSHA BBP Standard 29*** ***CFR 1910.1030)***

Exposure Control Plan [ECP]: LAB ROOM Numbers HERE

Employer: University of South Alabama

Laboratory Location:

Location Supervisor Name:

Location Manager Name:

Date Modified and Posted in Location Work Area:

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I. Introduction

The [OSHA Standard](#) has mandated that each work site develop an independent Exposure Control Plan (ECP) and implement the plan to ensure the safety and health of all personnel determined to have occupational exposure to human blood, body fluids, tissues and other potentially infectious materials in their job assignments.

The OSHA Standard requires that this Exposure Control Plan [ECP] be updated to identify the job classification and category assignment for this work site and all personnel at risk of infections with human bloodborne pathogens. The ECP must identify the duties, task and procedures associated with each job classification and category assignment where occupational exposure to bloodborne pathogens is most likely to occur. Employees performing these biohazardous tasks must comply with this work site ECP and the OSHA Standard.

The OSHA Standard requires that all personnel have access to a hard copy of the updated Exposure Control Plan for review before and after work assignments where the training will be addressed. It must be updated at least annually and whenever necessary to reflect new or modified tasks and procedures that affect occupational exposure to reflect new or revised employee positions with occupational exposure and to review the exposure incidents that occurred since the previous update.

II. Responsible Persons and Their Duties

Responsible Person(s)	Duties
Institutional Biosafety Committee	Develop and maintain ECP (except Appendix A)
Departments/Lab locations	Develop and maintain Appendix A (site specific plan)
Supervisors, Managers, Department Chairs, Directors	Ensure employees comply with this ECP and with the provisions of the OSHA BBP Standard

III. Exposure Determination

This plan covers all employees who may reasonably be anticipated to be at risk for exposure to human blood, or other potentially infectious materials (OPIM). Employees determined to be at risk for exposure must be offered the Hepatitis B vaccine at no charge to the employee and must receive annual Bloodborne Pathogens training. Principal Investigators must determine whether an employee has the potential for exposure without considering the use of personal protective equipment (PPE).

Check the job classifications in the lab with potential for exposure to human blood/OPIM:

- Laboratory/ Research Instructor
- Laboratory/ Research Technician – Edward Fiedler
- Laboratory Manager – Rosemary Roberts
- Post-Doctoral Fellow –
- Professor – Jonathan O. Rayner and Jin H. Kim
- Research Associate – Ryan Wood
- Other (specify): Undesignated rotating undergraduate and graduate students
- Student (specify): COM Research Honors Medical Student - Erin Schmale

Check the tasks and procedures performed by the employees listed above in which occupational exposure occurs:

- Handling and manipulating human blood or OPIM
- Other (specify): Handling viruses

1. Handling Tissue Culture cell lines: HEK-293T (human embryonic kidney), Vero (African green monkey kidney), BHK-21 (baby hamster kidney), MDCK (Mardin-Darby canine kidney), A549 (Adenocarcinomic human alveolar basal epithelial), and C6/36 (*Aedes albopictus*) cells.

2. Handling viruses: Venezuelan equine encephalitis virus (VEEV, vaccine strain TC-83); Chikungunya virus (CHKV, vaccine strain 181/25), Sindbis virus (SINV); Zika virus (ZIKV); Dengue virus (DENV, serotypes 1, 2, 3, and 4); Mayaro virus (MAYV); Influenza A virus (H1N1 and H3N2); Influenza B virus

IV. Methods of Compliance

Principal Investigators and all staff will comply with the OSHA Bloodborne Pathogens Standard 29 CFR 1910.1030 using the following methods:

A. Universal Precautions

All human blood and OPIM are considered contaminated with bloodborne and other pathogens. Employees must avoid direct contact with human blood, and OPIM to avoid exposure to bloodborne and other human pathogens.

B. Engineering and Work Practice Controls

Engineering controls and safe work practices will be used to minimize exposure to human blood, and OPIM by altering the physical manner in which specific tasks are performed (e.g., prohibiting recapping of needles, limiting the use of needles, eliminating glassware from lab operations and replacing it with plastic ware, requiring hand washing after working with biohazardous materials, etc.). Safe work practices are reviewed by the Institutional Biosafety Committee (IBC).

1. **Personal protective equipment.** If the potential for exposure remains in spite of work practice and engineering controls, personal protective equipment (PPE) must be used. Employers must provide, clean and dispose of PPE at no cost to the employee. PPE must be worn during procedures in which human blood or OPIM exposure to skin, eyes, nose or mouth is reasonably anticipated. PPE must be selected based on the type of exposure anticipated. PPE must cover all body parts and street clothes that may be exposed and must prevent soak through. Non-latex gloves should be available for employees with latex sensitivity or allergy. PPE and personal clothing must be removed if they become contaminated. Disposable PPE that is contaminated must be discarded as biomedical waste. Reusable PPE such as goggles and lab coats that have become contaminated must be placed in a specified container for decontamination and reprocessing.
 - a. **Lab coats and gowns.** Lab coats or gowns must be worn when working with human blood or OPIM when the potential for exposure exists. All PPE should be removed before leaving the laboratory for non-laboratory areas.
 - b. **Gloves.** Gloves must be worn when hands may come in contact with human blood, or OPIM, contaminated items or surfaces. Gloves must be worn when handling animals that have been inoculated with human cell lines, human tissue, or infected with HIV, HBV, HCV, or other human pathogens. Gloves must be replaced as soon as feasible if they are torn or contaminated. Disposable (single use) gloves must not be washed or decontaminated for reuse. Utility gloves may be decontaminated for reuse, but must be discarded if they are cracking, peeling or show other signs of deterioration.
 - c. **Protection for eyes, nose and mouth.** Work must be performed in a certified Biological Safety Cabinet or masks and eye protection (goggles or face shields) must be worn whenever splash or spray of human blood, or OPIM to the face is anticipated.
2. **Hand washing.** Hands must be washed with soap and water after contact with specimens, as soon as possible after removing PPE and whenever they become contaminated with human blood, or OPIM. Antiseptic hand cleaner may be used if soap and water are not available, but hands must be washed with soap and water as soon as feasible.

3. **Personal hygiene.** Eating, drinking, smoking, applying cosmetics or lip balm, or handling contact lenses in the lab is not permitted.
4. **Food.** Food and drink must not be stored in labs where human blood or OPIM are present.
5. **Pipetting.** Mouth pipetting is not permitted.
6. **Minimization of aerosols.** Splash, spray, spatter, or generation of droplets must be minimized during any procedure that involves human blood, or OPIM. If spattering or the generation of aerosols is reasonably anticipated, work should be performed in a certified Biological Safety Cabinet or eye protection plus a mask or face shield must be worn to prevent an exposure to the mucous membranes of the eyes, nose and mouth.
7. **Sharps handling.** Bending, recapping or removing needles is prohibited, except under specific infrequent circumstances. If recapping, bending or removing needles or other sharps is required by a specific procedure, and no alternative is feasible then a one handed scoop technique, mechanical device or forceps must be used. Written justification supported by reliable evidence must be included as an addendum to this Exposure Control Plan. This justification must state the basis for the Principal Investigator's determination that no alternative is feasible and must describe the specific procedure that requires the recapping, bending, or breaking of needles or other sharps. Disposable sharps must be placed in a plastic sharps container as soon after use as possible. Sharps containers must be easily accessible, with the opening visible, as close as possible to the area where sharps are used and maintained upright during use. Sharps containers must be promptly closed, removed, and replaced when they are $\frac{3}{4}$ full. Sharps containers must be placed on the sharps rack inside the biohazard containment area. When one $\frac{3}{4}$ full container is placed inside the containment area one empty container should be taken as a replacement. Reusable sharps, such as surgical instruments and large bore reusable needles pose the same exposure hazard as disposable sharps and must be handled in a manner similar to disposable sharps until they are reprocessed. The container used for temporary storage of contaminated reusable sharps must be puncture resistant, and labeled as Biohazard.
8. **Safe Medical Devices.** Safe medical devices are used to prevent percutaneous injuries (examples may include needleless devices, shielded needle devices or plastic capillary tubes). The Principal Investigator is responsible for involving employees in the selection of effective engineering controls and implementing the use of items that would eliminate or minimize exposures.
9. **Specimen Transport on Grounds.** For transport to sites within the grounds of USA, specimens of human blood and OPIM must be placed in a secondary leak proof carrier that can contain the contents if the primary container were to leak or break. Carriers must have the biohazard label affixed to the outer surface of the transport container.

10. **Servicing contaminated equipment.** Before servicing or shipping, contaminated equipment must be decontaminated if possible. If it is not possible to decontaminate equipment, it must be marked with a biohazard label describing what parts remain contaminated.
11. **Central reprocessing of contaminated reusable equipment.** Supplies and equipment returned to a central facility (e.g. department washroom or autoclave room) for decontamination and reprocessing must be put in a plastic bag or closeable container and marked with a biohazard label.
12. **Housekeeping.** The workplace must be maintained in a clean and sanitary condition. Human blood, or OPIM spills must be cleaned up immediately with a freshly made 1:10 bleach solution or other approved disinfectant using appropriate established spill clean up procedures.
13. **Equipment and Working Surfaces.** Contaminated work surfaces must be disinfected with 1:10 freshly made dilution of bleach or an alternative approved disinfectant. The decontamination of work surfaces must be done as soon as possible when contaminated with human blood, or OPIM, after completing procedures or at the end of the work shift if the surface may have become contaminated since the last cleaning. Temporary coverings (plastic backed paper, plastic wrap, etc.) over bench tops, equipment and other surfaces must be removed and replaced as soon as possible when contaminated or at the end of the work shift if the surface may have become contaminated since the last cleaning.
14. **Regulated Medical Waste.** Regulated Medical Waste is disposed of by USA in accordance with the Alabama Department of Environmental Management (ADEM) regulations. See biomedical waste policy located on the Biosafety website at:
<http://www.southalabama.edu/departments/research/compliance/biosafety/index.html>

V. **Communication of Hazards to Employees**

1. **Labels.** Biohazard warning labels must be affixed to refrigerators, freezers, incubators and other vessels used for storing human blood, or OPIM. Containers used for transporting human specimens beyond the immediate work area must have the biohazard label affixed to the outer surface of the transport container. Biohazard labels are required on areas and equipment reasonably anticipated to be contaminated with human blood, or OPIM.

VI. **Hepatitis B Vaccination Policy**

Employees identified as having potential for exposure to human blood or OPIM must be offered the Hepatitis B vaccine at no charge to the employee. The vaccination is a series of three injections given at approximately 0, 1 and 6 months. A routine booster dose is not recommended, but will be given at no charge if the U.S. Public Health Service (PHS) recommends it in the future.

- *The vaccine must be offered within 10 working days of initial assignment to a job category where exposure may occur.*
- *Employees who decline the Hepatitis B vaccine must sign a statement of declination. Principal Investigators must keep a copy of this declination statement on file.*
- *The University Physicians Group serves as the healthcare provider and scheduler of the vaccination series.*

VII. Procedures for Exposure Incidents

An exposure is defined as: blood or OPIM contact with broken skin, eyes, nose, mouth, other mucous membranes, a percutaneous injury with a contaminated sharp, or contact with blood or OPIM over a large area of apparently intact skin.

In the event of exposure:

1. Wash the area with soap and water or flush eyes, nose or mouth with large amounts of water for 15 minutes.
2. All exposures must be reported to the immediate supervisor. In the event of an exposure, employees, students, and/or visitors should document the incident using the electronic form located on the [USA Biosafety website](#), to include incident reporting instructions. All reported incidents are documented in the annual Institutional Biosafety Committee (IBC) inspection report. If there are any noted trends in reported incidents, these may be used as topics for educational sessions.

A. Evaluation and Treatment of Exposures

The evaluation and treatment of an exposure is confidential and will be given by or under the supervision of a licensed physician and will follow an established protocol in compliance with OSHA standard 29 CFR 1910.1030, U.S. Public Health Service and CDC guidelines. Evaluation and treatment of exposures are managed by the USA Physicians Group.

If the infectivity status of the source individual is unknown and blood is available, it will be tested for HIV, hepatitis B and C in accordance with state law. The exposed employee will be told what the test results are and what they mean.

If the employee consents, his or her blood will be tested as soon as possible after exposure to provide baseline hepatitis B, C and HIV status. If the employee does not consent to HIV testing, the sample will be stored for 90 days and tested if the employee consents in that time period.

Post-exposure prophylaxis will be offered to exposed employees when medically indicated and as recommended by the US Public Health Service. Counseling and medical evaluation will be offered for any reported illnesses the employee develops as a result of the exposure.

B. Documentation of Circumstances

Documentation of the circumstances surrounding the exposure incident is required and allows for the identification and correction of occupational hazards.

VIII. Employee Training

All employees who may have the potential for occupational exposure to human blood, or OPIM must attend a Bloodborne Pathogens training session at the time of their initial assignment to tasks where occupational exposure may take place and annually thereafter. Annual retraining is completed via the following website address www.citiprogram.org under "Biosafety/Biosecurity"

IX. Recordkeeping Procedures

Medical records required by the OSHA BBP Standard include the name, job title, and classification for work with potentially infectious materials, social security number and Hepatitis B vaccination status for all employees at risk for occupational exposure to human blood or other potentially infectious materials. When an exposure incident occurs, the results of all post-exposure testing, information that is provided to University Physicians Group and the post exposure opinion letter confirming that all requirements of the OSHA Standard for exposed patients has been done must be documented and filed. All of these records must be retained for 30 years following the conclusion of employment. The Office of Research Compliance and Assurance will track all employees who complete Biosafety training. Training records will be maintained for at least 3 years.

X. Exposure Control Plan Record of Training

Research personnel must date and sign the record of training document to indicate review of lab specific ECP with the P.I./supervisor and the potential biological hazards associated with research activities.

APPENDIX A

Site Specific Information

Laboratory of Infectious Diseases: Rooms 138 and 147

Venezuelan equine encephalitis virus (VEEV, vaccine strain TC-83); Chikungunya virus (CHKV, vaccine strain 181/25), Sindbis virus (SINV); Zika virus (ZIKV); Dengue virus (DENV, serotypes 1, 2, 3, and 4); Mayaro virus (MAYV); Influenza A virus (H1N1, H3N2); Influenza B virus; *Escherichia coli*. VEEV, CHKV, and SINV will be reconstituted from infectious clones and propagated in human, monkey, rodent, or arthropod cell lines. ZIKV, DENV, Influenza A and B, and MAYV will be acquired commercially (ex. ATCC) or from collaborators and propagated in human, monkey, rodent, canine, or arthropod cell lines.

Potentially biohazardous techniques to be used include tissue culturing, electroporation, centrifugation, pipetting. All work will be conducted as directed by Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition, 2007 or more recent.

All work with infectious agents and infectious cultures will be carried out in a Class II Type A2 biological safety cabinet (BSC) with appropriate PPE including gloves, eye protection and a laboratory coat at a minimum.

The BSC will be decontaminated before and after use, and between uses of different viruses with an appropriate contact time specific to the decontaminant to prevent cross contamination. Any equipment used in the BSC will also be decontaminated with an appropriate disinfectant (i.e. 10% bleach – 0.5% hypochlorite, 70% ethanol, 5% Microchem Plus) prior to removal or between uses with different pathogens.

All waste generated in the conduct of the work will be decontaminated or bagged in the hood and collected in biological waste receptacles and autoclaved prior to disposal.

Vaccination against seasonal flu is recommended and anti-influenza virus therapies are available; however, there are no commercially licensed vaccines or therapeutics currently available for the remaining viruses in use. Supportive care is provided to alleviate symptoms which might include fever and body aches, etc.

Recent isolates of Zika virus have been implicated in fetal development abnormalities; thus, pregnancy should be reviewed with all personnel prior to work with this agent.

Procedures to be used in the event of a spill are as directed in the Biological Spill Response BSL-2 on the USA Biosafety website.

In brief:

- Contaminated clothes will be removed and the body part washed at the sink or using the safety shower.
- If there is exposure to eyes, they will be flushed at the eyewash stations.
- In the event of a large spill – the area will be marked to warn others of the danger.
- Using the spill kit: don appropriate PPE, cover the spill with absorbent material, pour disinfectant on the area and allow to stand for 30 min.
- Contact the PI to assess the magnitude and need for further action.
- Safely pick up broken glass or sharps with tongs into a dust pan and dispose in sharps container.
- Place spill material in autoclave bag.
- Clean and disinfect area thoroughly.
- Soak contaminated clothes and shoes with an approved disinfectant.
- Report the spill to the Office of Research Compliance and Assurance.

