

SOP: Working with Human and Non- human primate (NHP) materials

*Includes established human cell lines*

*All labs working with human and non-human primate materials must have a bloodborne pathogens exposure control plan (BBP-ECP) as required by California/OSHA bloodborne pathogens standard 8CCR Sec. 5193* [***http://www.dir.ca.gov/title8/5193.html***](http://www.dir.ca.gov/title8/5193.html)*. All personnel handling such materials must take the Bloodborne Pathogens training course, provided via UCLC, annually.*

## Lab Contacts

Principal Investigator:

Phone:

Email:

Alternate:

Phone:

Email:

IBC Protocol #

IACUC Protocol # (if applicable)

Lab location:

Containment level: (*BSL2, BSL2+)*

No one is allowed to work with human and NHP materials without having prior training by the Principal Investigator (PI) who supervises their work, or their designated technical expert. The worker should demonstrate good microbiological and tissue culture technique and an understanding of this Standard Operating Procedures (SOP) prior to being permitted to work with human and NHP materials. This SOP must be available and at an accessible location in the laboratory at all times. All staff involved with the handling of human and NHP materials must receive lab core safety training, bloodborne pathogen, and medical waste management training provided by UCI EH&S via <http://www.uclc.uci.edu/>, and lab-specific training provided by the PI or the lab supervisor. Additional training may be required depending on the type of work associated with the use of these materials.

*Please refer to the lab BBP-ECP for spill procedure, medical emergency contact information, reporting and documentation of injury and post exposure evaluation and follow-up.*

Background

Human source materials covered by this SOP include blood, as well as its components and derivatives, and other potentially infectious materials (OPIM) comprising bodily fluids, tissues, organs, and primary cells, including cell lines. These materials are potential sources of bloodborne pathogens (BBP), including but not limited to human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). NHP materials, specifically those derived from macaques, may harbor Herpes B virus (*Macacine herpesvirus 1*), which, in the laboratory setting, is most commonly transmitted to humans through mucosal exposure or percutaneous injuries. Although cases of infection in humans are rare, severe infections may be fatal.

To mitigate the risk of exposure to BBPs, personnel will observe the concept of Universal Precautions which is an approach to infection control whereby all human and NHP source materials are treated as if known to be infectious for BBPs.

Type of human or NHP materials used in the lab. For each item, indicate if human or NHP source:

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| --- | --- |
| **Material (if cell line, provide name)** | **Source****(human or NHP?)** |
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Modes of Transmission

The most probable routes of exposure for this work are percutaneous via sharps injury (needle-sticks, cuts); mucosal via contact with the eyes, nose, and mouth (splash); or by contact with nonintact skin (scratches, chaps, abrasions, dermatitis).

Biosafety requirements and procedures

1. Physical Containment. All work with human and NHP materials must be performed in a BSL2 laboratory or BSL2+ laboratory. This includes but is not limited to a room suitable for tissue culture and equipped with a certified Class II Biosafety Cabinet (BSC). Access to the laboratory must be limited when the agent is in use. Vacuum lines to be used for aspiration must be equipped with an in-line HEPA filter and a vacuum flask. Doors must always be kept closed to maintain the BSL2/2+ containment. Please refer to Section IV of the CDC BMBL guidelines for BSL2 and BSL3 (for BSL2+) requirements.
2. Personal Protective Equipment (PPE). The following PPE must be worn when working with human and NHP materials: gloves (double gloves for BSL2+) and lab coat (dedicated lab coat for BSL2+). A surgical mask and eye protection (goggles) or face shield is optional, but recommended any time there is a risk of aerosol/splash/spray of the human/NHP materials to the face outside the BSC. In some case a N95 respirator (annual fit testing required) might be required.
3. Spill Kit. The lab must have a spill kit, or the components of such readily accessible in the event of a spill. This comprises: an easy-to-read outline of the spill response SOP; gloves, masks, goggles, clean lab gown or lab coat, paper towels to absorb contaminated liquids, disinfectant, tongs or forceps to pick up broken glass and a red biohazard bag.
4. General Procedures for working with human and NHP materials: Standard BSL2 practices should be employed, including a prohibition of eating, drinking, food storage, handling of contact lenses, applying lipstick or lip balm, mouth pipeting, and a requirement of appropriate PPE. Additional practices include the following recommendations:

* 1. Biosafety Cabinet: If the blower on the BSC is not left on continuously, it should be turned on and run for 3 minutes to allow complete exchanges of air before work can begin. At the beginning of the work session, plastic-backed absorbent toweling can be placed on the work surface (optional), but not obstructing air flow. Alternatively, the stainless steel work surface can be wiped down with 70% Ethanol. At the end of the work session, all items to be removed from the BSC must be decontaminated. The surface of the BSC must be wiped down with an effective disinfectant including 10% fresh bleach followed by 70% Ethanol.
	2. Sharps should be avoided whenever possible. Plastic aspirating pipets (<http://www.thomassci.com/Supplies/Pipets/_/Plasteur-Plastic-Pasteur-Pipets/> ) should be substituted for glass Pasteur pipets. If needles are required, they must never be re-capped, and must be disposed of in a sharps waste container immediately after use. While working with sharps inside the BSC, the sharps container must be kept inside the BSC.
	3. Solid Waste: Everything that comes in contact with human/NHP material must be decontaminated before exiting the biosafety cabinet. Solid waste including pipet tips and tubes can be collected in a biohazard bag inside the Biosafety Cabinet. The biohazard bag must be inside a leak-proof, rigid container with a tight fitting lid and labeled biohazard. Another option is to fill a plastic container with some bleach and put the solids inside this container while carrying out the procedure. At the end of the work session, the biohazard bag will be closed, outside will be sprayed with 70% Ethanol and deposited into a biohazardous waste container. In case of the plastic container with bleach, pretreatment vessel, the bleach can be dumped down the sink with copious amount of water and the solid waste can be dumped in the biohazardous waste container.

* 1. Liquid Waste is aspirated into a vacuum flask containing 1/10 volume concentrated bleach. The vacuum flask must have a final concentration of at least 10% bleach, for a minimum time of 30 minutes prior to drain disposal. Liquid waste may also be collected in the hood in a simple 500 ml bottle (like a bottle used to store cell culture medium) that contains 50 ml concentrated bleach (10% final v/v). Allow a minimum of 30 minute incubation before pouring down the drain.
	2. Centrifugation. Centrifuge tubes should be prepared and sealed/loaded and unloaded in the rotor/buckets in the biosafety cabinet. This includes methods to ensure tubes are properly balanced (unless the balance tube contains no infectious material). At the end of the procedure, rotors and/or buckets must be decontaminated.
	3. Vortexing must be done in the BSC.
	4. If any human/NHP materials are to be transported (from one location to another) a secondary container is required. The secondary container must be leak proof, rigid container, with a tight fitting lid and labeled biohazardous. A simple food storage container with a latchable lid and labeled with a biohazard sticker would suffice as a secondary transport container.
	5. Storage of human/NHP materials must be in leak-proof secondary containers (i.e. freezer boxes) clearly labeled to indicate the type and source of materials.

1. Please refer to the BBP-ECP for spill procedures, medical emergency contact information, reporting and documentation of injury and post exposure evaluation and follow-up

Procedures

Insert lab-specific procedures here.

References

*Biological Safety Principles and Practices*, 3rd edition, 2000. ASM Press. Edited

by Diane O. Fleming, Ph.D, and Debra Hunt, Dr.P.H.

*Biosafety in Microbiology and Biomedical Laboratories*, 4th edition, May 1999.

Centers for Disease Control. <https://www.cdc.gov/labs/BMBL.html>

California/OSHA bloodborne pathogens standard 8CCR Sec. 5193

<https://www.dir.ca.gov/title8/5193.html>

*Guidelines for Research Involving Recombinant DNA Molecules,* April 2019.

National Institutes of Health. <https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html>

UCI Biosafety manual

<https://www.ehs.uci.edu/programs/biosafety/BiosafetyManual.pdf>

Acknowledgement

**As the Principal Investigator, it is your responsibility to ensure that all individuals listed in the IBC application are taught correct procedures for the safe handling of hazardous materials involved in this study. It is also your responsibility to assure that your personnel attend all the required training. Both PI and all persons associated with the protocol must sign the following acknowledgement: *I have read, asked questions, and understand the hazards of and safe working procedures for the activity/materials described herein.***

PI Signature DATE

Other Personnel (add more rows as needed):

Name/ Signature DATE

Name/Signature DATE

Name/Signature DATE

Name/Signature DATE