****

**ECP Attestation for Laboratory Work with Human Cells, Tissues, and Fluids**

**Potential Hazards:**

The potential laboratory hazards associated with human cells, tissues, and fluids include the bloodborne pathogens HBV and HIV, as well as agents such as Mycobacterium tuberculosis that may be present in human lung tissues. Potential hazards to laboratory workers are presented by cells transformed with viral agents, such as SV-40, EBV, or HBV, as well as cells carrying viral genomic material. Tumorigenic human cells also are potential hazards as a result of self-inoculation.

**Regulations and Guidelines:**

Unfixed human cells, tissues, and fluids must be handled using BIOSAFETY LEVEL 2 practices, using Universal Precautions. Universal Precautions assume that all human source material is infectious with bloodborne pathogens. This is recommended by the CDC (BMBL 6th edition, <https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf>) and ATCC (<https://www.atcc.org/support/technical-support/faqs/biosafety-level-for-atcc-cultures>) and REQUIRED by the University of Utah. Additionally, all human samples and cells that have the potential to be infected with bloodborne pathogens are covered by the Occupational Safety & Health Administration (OSHA) Bloodborne Pathogen Standard, 29 CFR 1910.1030.

The University of Utah Institutional Biosafety Committee (IBC) has oversight over research with human samples and cells, and all laboratories (PI’s) must register work with these samples and cells with the IBC (<https://ibc.utah.edu/ibc-registration.php>). **This is inclusive of commercial human cell lines (such as those purchased from ATCC).**

All employees and students working with human cells and tissues must complete annual [Bloodborne Pathogens (BBP) training](https://ibc.utah.edu/training.php), and must work under the policies and guidelines of the [University of Utah Exposure Control Plan (ECP](https://ibc.utah.edu/biosafety-policies.php)). Attestation of adhering to the ECP must be made in **Appendix 1**. Hepatitis B vaccination is recommended and provided by the institution via Occupational Medicine. Information on enrollment into the Occ Med’s Hepatitis B vaccination program will be provided during the BBP training.

**Minimum Personal Protective Equipment:**

* 1. Protective laboratory coats or gowns, designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; it should never be taken home by personnel.
	2. Gloves (latex or nitrile) are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. 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.
	3. Face protection (safety glasses or goggles, along with a surgical type mask, a face shield or other splatter guard, such as a Perspex screen or a fume hood) is used to protect from splashes or sprays of potentially infectious or other hazardous materials to the face when working outside of a biosafety cabinet (BSC). Work with samples likely to harbor pathogenic agents or with human and non-human primate cells must be conducted within a BSC, to provide operator protection from aerosols and sample protection from contamination.

**Laboratory Procedures:**

Detailed laboratory practices for work at BSL-2 are described in the [University of Utah Biosafety Manual](https://ibc.utah.edu/biosafety-policies.php), and all workers should be familiar with those practices. A summary of the most pertinent procedures is provided below.

1. All work with samples that are likely to harbor pathogenic agents must be performed in a biosafety cabinet.
	1. Work with routine human samples may be conducted on a bench as long as splash (face) protection is employed, as described above.
2. All potentially infectious material must be decontaminated by autoclaving or disinfection with an appropriate disinfectant (typically a freshly prepared 1:10 dilution of bleach) before discarding.
3. Eating, drinking, smoking, applying cosmetics and contact lenses, or storage of foods is not permitted in the laboratory.
4. Personnel must wear at least the minimum PPE described in this document in conjunction with long pants and solid, closed shoes. PPE must be removed when leaving the laboratory.
5. Personnel must wash their hands and wrists with soap and water after handling potentially infectious material, removal of gloves, and before leaving the laboratory.
6. The laboratory must have controlled access when work with human materials is being performed.
	1. Keep laboratory doors and windows closed while work is in progress.
	2. Post a caution sign when human material is present. Caution signs, with the Biohazard symbol, can be obtained from [EHS](https://oehs.utah.edu/resource-center/forms/hazard-warning-signage-questionnaire).
		1. Work with samples likely to harbor a pathogen will require a Warning sign; contact the Biosafety Office (Biosafety@EHS.Utah.edu)
	3. Limit access to the laboratory during procedures involving human materials.

**Spills and Exposures (These procedures must be posted in the BSL-2 laboratory).**

\*Bleach (diluted 1:10 with cold water, creating a 0.5% sodium hypochlorite solution) is an appropriate disinfectant for decontaminating human cells and samples. Alternatively, [another EPA-approved disinfectant](https://www.epa.gov/pesticide-registration/epas-registered-antimicrobial-products-effective-against-bloodborne) can be used.

1. Spills inside of a Biosafety Cabinet
	1. Stop work.
	2. If you are splashed by the material, change PPE. Always change gloves.
	3. Keep the biosafety cabinet running.
	4. Contain the spill by covering with paper towels (to avoid splashes or aerosols).
	5. Saturate spill with freshly prepared 1:10 dilution of bleach\**.* Let sit for 20-minute exposure time.
		1. For large spills (greater than 10ml) use undiluted bleach\* or disinfectant.
		2. In the event of a spill into the drip pan/catch basin, add an equal volume of disinfectant and wait for 20 minutes to clean up the disinfected material.
	6. Wipe up spill, disposing of towels in biohazard bag.
		1. If the biohazard bag is to be autoclaved, liquid bleach should be neutralized with sodium thiosulfate after it is used for disinfection. A good rule of thumb is if your absorbent towels are dripping wet, the bleach should be neutralized prior to autoclaving.
	7. Spray spill area with freshly prepared 1:10 dilution of bleach\**.* Allow to air dry.
	8. Disinfect all other materials used in the biosafety cabinet by disinfecting the surface with freshly prepared 1:10 dilution of bleach\*with a 20-minute contact time. Do not attempt to disinfect contaminated cardboard or other paper items that absorb liquid: contaminated items should be disposed of.
	9. Wipe spill area and disinfected equipment with alcohol or water.
	10. Place all towels or absorbent materials into a designated container for biohazardous waste.
	11. Remove PPE, discard disposable PPE as biohazardous waste and wash hands.
	12. Run the biosafety cabinet for 10 minutes to purge the air before re-starting work.
2. Spills outside of a Biosafety Cabinet
	1. Stop work.
	2. If you are splashed by the material, dispose of PPE and wash hands.
	3. Ensure that any other people in the vicinity are notified that a spill has occurred and that the room should be evacuated. Post a “Do Not Enter” notice on the door. Notify the PI or lab supervisor.
	4. If you need assistance with the spill clean-up, call EHS (1-6590).
	5. Wait 60 minutes before re-entering the room to allow aerosols to settle.
	6. Assemble Spill cleanup materials and don PPE, including lab coat, eye protection and face shield or mask, 2 pair of gloves, shoe covers. If the lab coat does not have cuffed sleeves, disposable sleeve covers should be worn.
	7. Contain the spill by covering with paper towels (to avoid splashes or aerosols)
	8. Saturate spill with freshly prepared 1:10 dilution of bleach\**.* Let sit for 20-minute exposure time.
		1. For large spills (greater than 10ml) use undiluted bleach\* or disinfectant.
		2. Wipe areas around the spill that may have splatter and any reusable equipment with freshly prepared 1:10 dilution of bleach\**.*
	9. Wipe up spill, disposing of towels in biohazard bag: if sharps may be present use tongs or a brush and pan and dispose in biohazard sharps container.
		1. Work concentrically to clean up the absorbent material. Always work from the outer edge of the spill toward the center.
		2. If the biohazard bag is to be autoclaved, liquid bleach should be neutralized with sodium thiosulfate after it is used for disinfection. A good rule of thumb is if your absorbent towels are dripping wet, the bleach should be neutralized prior to autoclaving.
	10. Spray spill area with freshly prepared 1:10 dilution of bleach\**.* Allow to air dry.
	11. Wipe spill area and disinfected equipment with alcohol or water.
	12. Remove PPE, discard disposable PPE as biohazardous waste and wash hands.
	13. Remove the “Do Not Enter” sign and inform others that it is safe to re-enter the room.
	14. Once the spill has been contained, complete an [EHS Incident Report.](https://oehs.utah.edu/incidentnear-miss-report)
3. Spills Inside of a Centrifuge Contained Within a Closed Cup, Bucket, or Rotor
	1. Put on lab coat, gloves, and proper eye protection prior to opening centrifuge. Open carefully to assess the damage.
	2. Prepare the disinfectant*: consult the instructions of the centrifuge rotor to identify suitable disinfectants*.
	3. If the spill is contained within a closed cup, bucket, or rotor, spray the exterior with disinfectant and allow at least 20 minutes of contact time. Remove the carrier to the nearest biosafety cabinet (BSC).
		1. *Note, if possible, avoid using bleach on centrifuge rotors and buckets to avoid damaging the equipment. If bleach is used, ensure all surfaces are wiped down with soap and water after disinfection. Alternatively, use an EPA-registered disinfectant, such as Cidex or Cavicide.*
	4. Gather supplies needed, such as a sharps container for broken glass and bins filled with disinfectant and place into the BSC.
	5. Open the centrifuge rotor or bucket inside of the BSC. Use a mechanical device (forceps, tongs, etc.) to remove broken glass and place directly into sharps container. Carefully remove any unbroken tubes and place into a bin filled freshly prepared 1:10 dilution of bleach\* for at least 20 minutes. Wipe carrier/bucket with disinfectant.
	6. After disinfection, carrier, bucket, or rotor must be washed with a mild soap and water.
	7. Spray the interior of the centrifuge chamber with disinfectant, let sit for at least 20 minutes and then wipe down with soap and water.
	8. Dispose of all clean-up materials (except sharps) in an appropriate biohazardous waste container. Dispose of sharps in a biohazard sharps container.
	9. Remove PPE, discard disposable PPE as biohazardous waste and wash hands.

If you are concerned that the spill is not contained within the rotor or bucket:

* + 1. Ensure that any other people in the vicinity are notified that a spill has occurred and the room should be evacuated. Post a “Do Not Enter” notice on the door. Notify the PI or lab supervisor.
		2. If you need assistance with the spill clean-up, call EHS (801-581-6590)
		3. Wait 60 minutes before re-entering the room to allow aerosols to settle.
		4. Proceed with clean up as described above.

**Note**: Many centrifuge rotors can be disinfected by autoclaving. Check the manufacturer’s instructions.

1. Exposure to skin, eyes or clothing
	1. Stop work.
	2. Remove exposed PPE, taking care to avoid contact of unexposed areas to infectious agents on the PPE.
	3. Inform others in the immediate area about any biohazardous materials out of containment to prevent further exposure.
	4. Immediately wash affected areas with soap and water, or if exposure to eyes or mucous membranes occurred, immediately flush affected area with water for 10-15 minutes.
	5. For serious/life threatening exposures or chemical burns, call 911.
	6. After washing, notify lab supervisor or Principal Investigator of the exposure if they are immediately available. If not, seek medical attention first and then report the exposure to them later.
	7. During normal working hours proceed directly to RedMed Clinic or the Redwood Health Center Occupational Medicine Clinic. For those who find it more convenient, Occupational Medicine (~7:30a-12:30p) and an Emergency Department (24 hours) are available at South Jordan Health Center. After 8:30 pm seek medical attention the next morning unless:
		* You are exposed to any of the following seek medical attention immediately. After 8:30 pm go to the University of Utah Hospital Emergency Room. Post exposure prophylaxis must be initiated as soon as possible after exposure:
			+ Human samples from a patient (or animal) with a known infectious disease, such as HBV, HIV, Rabies, Invasive Group A Streptococcus, Invasive Meningococcus, Tuberculosis.
			+ Samples from macaque or other old-world primates

**RedMed Employee Health Clinic**

**(ground floor of the A. Ray Olpin Student Union Building)**

200 Central Campus Dr.

Salt Lake City, UT 84112

Phone: (801) 213-3303\*\*

Hours: M-TH: 8:00AM – 5:00PM, Friday: 9:00AM – 3:30PM

Closed from 1:30 to 2:00PM

\*\*calling first is recommended, as this is a smaller clinic, and for some exposures/injuries, they may recommend Redwood Health Center.

**Redwood Health Center Occupational Medicine Clinic**

1525 West 2100 South

Salt Lake City, UT 84119

Phone: (801) 213-9777

Hours: M-F 8:00AM - 5:00PM

**After Hours**

**Redwood Health Center Urgent Care**

1525 West 2100 South

Salt Lake City, UT 84119

M-F 5:00PM – 8:30PM

Sat.-Sun.: 9:00AM – 8:30PM

 (801) 213-9700

**After 8:30 PM**

Emergency Department at University Hospital

(main floor, northeast side of the hospital)

50 N. Medical Drive

Salt Lake City, UT 84132

(801) 581-2292

**An alternative Occ Med and ER location:**

**South Jordan Health Center**

5126 W. Daybreak Parkway

South Jordan, UT 84009

(801) 213-4500

* 1. Ensure that the physician is aware of all materials that were being used at the time of exposure (e.g., virus, bacteria, human tissue, animal tissue, other potentially infected material).
	2. Inform the Healthcare Provider of any medical conditions, such as pregnancy or immunosuppression, or drug treatment that you currently have or take. The Healthcare Provider must have this information to evaluate and develop a proper post treatment evaluation. Notify your care provider that the University of Utah worker’s compensation carrier is Worker's Compensation Fund (WCF) and give your provider the information you gave your employer regarding the accident.
* Write your name and social security number on all medical forms the same way it appears on all of the University's payroll information.
* Ask your physician to immediately send all relevant information to Workers Compensation Fund.
1. Upon returning to work, fill out the Employers First Report of Injury E1 Form. This form can be downloaded from the human resources website under “Forms” (<https://benefits.utah.edu/work-related-injury-or-illness>).
2. After medical care, ensure that the incident is immediately reported to the EHS and the Biosafety Officer (801-581-6590) or using this [link](https://oehs.utah.edu/incidentnear-miss-report).

**Appendix 1. Attestation to follow the procedures in the University of Utah Exposure Control Plan when working with Human Samples and Cells.**

The University of Utah campus-wide Exposure Control Plan (ECP) describes the complete guidelines for working with blood and other potentially infectious material (OPIM) at the University of Utah. This includes the federal regulations, roles of University officers, risks, work and engineering controls, PPE requirements, waste disposal requirements, and spill and exposure responses. The institute’s ECP is updated annually by the Biosafety Officer and posted on the IBC website.

Here, members of the *Name* Laboratory attest to familiarity with the guidelines in the U of U ECP and agree to work according to the guidelines.

Signing this document each year indicates an annual review of this ECP Attestation and the U of U’s ECP and completion of annual BBP training, all of which are required to work with human samples at the University of Utah.

**Signature and Acknowledgement of Risk**

We, the undersigned, understand that the agents used in this laboratory and described in this plan are potentially hazardous.  We have read and understand this plan and agree to follow the stated policies and procedures.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Signature** | **Date Reviewed Manual** | **Date completed BBP training** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |