**University of California, Davis**

 Aerosol Transmitted Diseases (ATD’s) Biosafety Plan

To comply with Cal-OSHA Title 8, Section 5199

<https://www.dir.ca.gov/Title8/5199.html>

To the Principal Investigator:

This Biosafety Plan describes the procedures and measures to establish, implement and maintain an effective program to minimize research laboratory employee exposure to Aerosol Transmitted Pathogens – Laboratory (ATPs-L) as mandated by California Occupational Safety and Health Standards board Title 8, section 5199. Consult Appendix D of the standard to determine the specific pathogens covered under the standard, but note that many human pathogens, including pathogens not normally considered likely to infect humans by aerosolization, could be covered under the standard depending on the potential worker exposure to the pathogen. Some of the agents used in UC Davis laboratories that are covered under the ATD standard include all retroviruses, all arboviruses, *Salmonella* sp., *Chlamydia trachomatis*, influenza viruses, Risk Group 2 *Mycobacterium* sp., and all microbial agents normally handled at BSL3. Other agents are also covered if used in a manner or quantity that could result in aerosolization of the agent. Replication defective viral vectors from ***other than commercial sources*** may also be subject to this standard if aerosol exposure to laboratory or animal care staff could occur.

The Standard requires that each laboratory that works with any of the agents specified in Appendix D of the Standard must develop a biosafety plan which must be reviewed and approved by the person identified in (1a or 1b), below. The ATP-L Biosafety Plan must include the required information in sufficient detail to provide a useful training document for laboratory employees and students. The information included in Item 4 below should be considered a minimum requirement to be expanded to reflect actual risks and practices for your work site.

**Completion and adoption of this document does not substitute for obtaining a Biological Use Authorization (BUA) from the Institutional Biosafety Committee (IBC) that authorizes the possession, storage, transfer, and use of the biohazardous materials noted in this biosafety plan.** **Further,** ***completion and annual update of this biosafety plan is a prerequisite for securing and maintaining IBC approval of your BUA.*** Where practicable, the information included in this biosafety plan may duplicate information presented in your Biological Use Authorization, but you are responsible for training your staff and students in both documents.

Please include the completed ATP-L Biosafety Plan with your new or renewal Biological Use Authorization Application. If you have completed the ATP-L Biosafety Plan separately, please e-mail the completed plan to biosafety@ucdavis.edu.

**Definitions:**

ATD: Aerosol Transmissible Diseases

ATP-L Aerosol Transmissible Pathogens-Laboratory

BMBL: “Biosafety in Microbiological and Biomedical Laboratories,” Centers for Disease Control and Prevention, US Department of Health and Human Services

BUA: Biological Use Authorization

IBC: Institutional Biosafety Committee

**Site-Specific Responsibility**

**for Aerosol Transmissible Diseases Biosafety Plan**

**University of California, Davis**

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| Department:  |       |

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| Department Chair or Director: |       |  | Phone: |       |
| E-mail: |       |  |  |  |

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| --- | --- | --- | --- | --- |
| Principal Investigator (PI): |       |  | Phone: |       |
| E-mail: |       |  |  |  |

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| --- | --- | --- |
| PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: |       |

**Locations of work sites:**

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| Building name | Room # |
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| Implementation Date: |       |

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| Annual Review Date: |       |

 (Keep a cumulative account of annual review dates)

1. **Biosafety Officer**:
	1. **Laboratory Biosafety Officer** with sufficient knowledge to conduct required laboratory-specific risk assessments, to develop risk minimization measures specific to the laboratory, and to implement, review, and update this Biosafety Plan:

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| Name: |       | Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date: |       |  |

* 1. **Campus Biosafety Officers** with the responsibility to review the laboratory risk assessments, to approve the Biosafety Plan, and to review plans to modify the facility that would affect control measures:

Philip Barruel

Biosafety Officer (EH&S)

530 752 1777

Adrienne Zweifel

Associate Biosafety Officer (EH&S)

530 752 8674

Vivian Xian

Associate Biosafety Officer (EH&S)

530 752 8608

James Baugh

Associate Biosafety Officer (EH&S)

530 752 8230

1. **Employees, tasks and procedures:**
	1. Job Classification(s) – on the supplied page please provide a list of names associated with the job classification(s) provided below, including training date(s):
		1. Faculty
		2. Staff
		3. Students
		4. Volunteers
		5. Visitors
	2. Job Task(s) and Procedure(s) – please check off the procedures being performed in the laboratory with ATPs-L:

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| [ ]  | Animal handling |
| [ ]  | Centrifuging |
| [ ]  | Homogenizing |
| [ ]  | Injecting |
| [ ]  | Mixing |
| [ ]  | Necropsy |
| [ ]  | Pipetting |
| [ ]  | Plating |
| [ ]  | Pouring |
| [ ]  | Sample collection |
| [ ]  | Shaking |
| [ ]  | Sonicating |
| [ ]  | Vortexing |
| [ ]  | Other:       |
| [ ]  | Other:       |
| [ ]  | Other:       |

1. **ATPs-L known or reasonably expected to be present in the laboratory.**

Please refer to appendix D of the Cal-OSHA Title 8 Standard 5199 (<https://www.dir.ca.gov/Title8/5199.html>) and list the ATPs in use in the laboratory:

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| Name | Form (culture, infected tissue, environmental sample, etc) |
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Use additional pages if necessary

1. **Safe handling practices:**
	1. Practices for handling samples and specimens will follow the standards described in the BMBL. These are **Standard Practices** to be used by all laboratories that work with ATP’s-L, to be supplemented by other practices as appropriate.
		1. Access to the laboratory is controlled by written institutional and investigator policy.
		2. Persons must wash their hands after working with potentially hazardous materials, after removing gloves, and before leaving the laboratory.
		3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing food for human consumption is not permitted in the laboratory. Food must be stored in areas outside of the laboratory designed for this purpose.
		4. Mechanical pipetting devices are to be used at all times (no mouth pipetting allowed).
		5. Sharps including razor blades, scalpels, and hypodermic needles and other sharp instruments are limited to use only when there is no alternative.
			1. Disposable sharps must be placed in hard-walled sharps waste containers designed and approved specifically for that purpose.
			2. Non-disposable sharps must be transported to the autoclave in a hard-walled container for decontamination before further processing.
			3. Plasticware should be substituted for glassware wherever possible.
			4. Broken glass must be picked up with broom or brush and dustpan, tongs, or forceps and disposed to a container approved for that use.
		6. Perform all procedures in a manner that minimizes splashes or aerosols.
		7. Perform all aerosol-generating procedures in a containment device such as a biological safety cabinet or a centrifuge with sealed rotors.
		8. Work surfaces will be decontaminated at least once per day and after any spill or splash of infectious material with an approved disinfectant. Check chemical disinfectants available in the laboratory:

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| [ ]  | Household bleach |
| [ ]  | Iodophor |
| [ ]  | Quaternary ammonia |
| [ ]  | Other:       |

* + 1. All cultures, stocks, and other regulated liquid waste, will be decontaminated before disposal by addition of bleach to a 10% final bleach concentration in the contaminated liquid and 30 minutes minimum contact time. The decontaminated material may be disposed in the sink, followed by a water rinse sufficient to flush all of the decontaminated material down the drain.
		2. Dry waste must be discarded in approved medical waste bags and disposed in the medical waste stream.
		3. The laboratory door and all equipment and storage sites where infectious materials may be present must be posted with signs incorporating the universal biohazard symbol. The entryway sign must include the following information:
			1. Biosafety level of the laboratory.
			2. Supervisor or other responsible individual’s name and **complete** contact information.
			3. Name of the biohazardous agent(s) in use in the laboratory (except select agents)
			4. Required procedures for entering and exiting the laboratory (e.g., access limited to authorized personnel only, escorted access only, PPE requirements for entering the laboratory, PPE doffing order for exiting the laboratory, other laboratory-specific requirements)
		4. All individuals who work with the agents in use in the laboratory must be enrolled in a health surveillance program specific to the hazards of the agents in use and the experiments being conducted in the laboratory. Persons with special health concerns such as pregnant women or immunocompromised individuals are encouraged to self-identify to the Occupational Health physician and will receive special counseling on work with the agents in use in the laboratory.
		5. Specific training depends on each person’s activity within the facility. This includes personnel such as supervisors, staff employees, students, and visitors. All such training must be documented.
		6. Other safe work practices specific to the laboratory:

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* 1. Additional practices at BSL-3:
		1. Access to the laboratory is limited to specially trained, authorized persons only.
		2. The BSL-3 laboratory must be secured from unauthorized entry at all times.
		3. Each person must demonstrate knowledge and proficiency in the following areas before being granted access to the BSL-3 laboratory.
			1. Standard microbiological practices
			2. Project-specific SOPs
			3. Specific hazards of the agents in use
			4. Symptoms of infection
			5. Security procedures
	2. Additional prohibited practices in all laboratories:
		1. Do not break, shear, or recap hypodermic needles, or remove hypodermic needles from disposable syringes.
		2. Do not place your head into a Biological Safety Cabinet.
		3. Do not sniff cultures and other samples.
		4. Other prohibited (unsafe) work practices specific to the laboratory:

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1. **Engineering controls:**

BSL-2 laboratories:

* 1. All procedures involving the potential aerosolization of infectious materials are conducted within a ***certified Biological Safety Cabinet*** or other physical containment device.
		1. Specify other available physical containment devices at your laboratory locations:

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* 1. An eyewash station is available inside the laboratory.
	2. Laboratory doors are self-closing.
	3. The laboratory floors and walls can be easily cleaned and decontaminated.
	4. Carpets and rugs are not permitted. Seams, floors, walls, and ceiling surfaces are sealed.
	5. Furniture can be easily cleaned and decontaminated. Chairs are covered with non-porous material than can be easily cleaned and decontaminated with appropriate disinfectant.
	6. Spaces between benches, cabinets, and equipment are accessible for cleaning.
	7. A sink for hand washing is available in the laboratory.
	8. An autoclave capable of inactivating infectious waste is available in the building.[[1]](#footnote-2)

BSL-3 laboratories:

All engineering controls listed for BSL-2 laboratories plus:

1. The laboratory is separate from parts of the building that have unrestricted foot traffic.
2. The laboratory is secured against all unauthorized entry.
3. Access to the laboratory is restricted by a series of two self-closing doors.
4. Air flows directionally into the laboratory and exhausts to the outdoors without recirculation.
5. A *hands-free sink* is available for hand washing within the laboratory.
6. An autoclave capable of inactivating infectious waste is available within the laboratory.
7. Walls, floors, and ceilings are smooth and impervious to standard disinfectants and chemical cleaners at normal working concentrations.
8. Walls, floors, and ceilings are specially sealed to prevent leakage of decontaminant gases and vapors.
9. All open work with infectious agents and materials is conducted in a properly certified Biological Safety Cabinet.
10. **Personal protective equipment (PPE):**
	1. Check PPE to be used when working with and near potential ATPs

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| [ ]  | Lab coat |
| [ ]  | Closed front gown/coverall |
| [ ]  | Disposable sleeves |
| [ ]  | **Double** gloves |
| [ ]  | Goggles |
| [ ]  | Respirator[[2]](#footnote-3) |
| [ ]  | Shoe covers |
| [ ]  | Other:       |

* 1. List procedures that require use of PPE

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* 1. List operations or conditions that require use of respirators2

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1. **Decontamination and disinfection procedures for laboratory surfaces and equipment:**
	1. List surface and equipment decontamination procedures

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| **Equipment** | **Decontamination Procedures** |
| Biological Safety Cabinet |       |
| Centrifuges |       |
| Incubators |       |
| Walls, floors |       |
| Benches |       |
| Other:       |       |
| Other:       |       |
| Other:       |       |
| Other:       |       |

1. **All incoming packages containing ATPs-L will be treated as containing the virulent or wild-type pathogen until verified at the laboratory that a pathogen has been inactivated or is an attenuated strain.**
	1. Unopened package surface inspected for integrity, wiped down or sprayed with 0.5% sodium hypochlorite (10% bleach).
	2. The package must always be opened inside a Biological Safety Cabinet to ensure worker protection.
2. **Annual laboratory inspection and biosafety audit:**

The Environmental Health and Safety Biological Safety Office will conduct an annual inspection of the laboratory. The inspection will cover the following areas:

* 1. Training compliance documentation
		1. Biological Use Authorization
		2. ATP-L Biosafety Plan (this document)
		3. Bloodborne Pathogen Exposure Control Plan (if applicable)
		4. Medical Waste Management Plan
		5. Respirator clearances
		6. Health surveillance participation
	2. Safe handling practices
	3. PPE availability
	4. Biological Safety Cabinet certification up to date
	5. Security (if applicable)
1. **Emergency procedures for uncontrolled releases of biohazardous materials**[[3]](#footnote-4)**:**
	1. **Spills** within the laboratory facility:
		1. Emergency response including evacuation:

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* + 1. Cleanup inside a containment device such as a biological safety cabinet:

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* + 1. Cleanup outside of a containment device:

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* + 1. Personal decontamination:

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* 1. Loss of negative pressure in biological safety cabinet (including power failure):
		1. Emergency response including evacuation:

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* + 1. Spill cleanup inside the biological safety cabinet:

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* + 1. Personal decontamination:

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* 1. Loss of negative pressure in a BSL3 laboratory (including power failure):
		1. Emergency response including evacuation:

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* + 1. Follow-up from outside of the laboratory:

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* + 1. Cleanup inside the laboratory after negative air flow is restored:

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* + 1. Personal decontamination, if applicable:

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* 1. Earthquake, severe weather events, fire, bomb threat, gas leak, security breach, intruder:
		1. Emergency response including evacuation:

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* + 1. Follow-up from outside of the laboratory:

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* + 1. Cleanup inside the laboratory after the emergency is resolved:

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* + 1. Personal decontamination, if applicable:

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1. **Medical treatment and services:**
	1. Recommended vaccinations for work with ATP’s-L used in this laboratory:

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* 1. Medical follow-up for employees who experience exposure to ATP-Ls used in this laboratory[[4]](#footnote-5):

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* 1. Annual TB test requirement for employees potentially exposed to TB as a work hazard (specify N/A if not applicable):

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1. **Procedures for initial training and annual refresher employee training:**

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* 1. Training records shall include the following information[[5]](#footnote-6):
		1. The date of the training session.
		2. The contents or a summary of the training session.
		3. The names and qualifications of persons conducting the training or who are designated to respond to interactive questions.
		4. The names and job titles of all persons attending the training session.
1. **Procedures to involve employees in the evaluation of the effectiveness of this Biosafety Plan in the work areas**[[6]](#footnote-7)**:**

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**Vaccination Declination Statement (Mandatory)**

The employer shall ensure that employees who decline to accept a recommended vaccination offered by the employer sign and date the following statement as required by subsection (h)(5)(E):

I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring infection with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of disease or pathogen). I have been given the opportunity to be vaccinated against this disease or pathogen at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ , a serious disease. If in the future I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.

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Employee Signature Date

1. Only those autoclaves that are registered with the California Department of Public Health: Medical Waste Program may be used to terminally inactivate solid medical waste. Otherwise, accumulate solid medical waste in red-medical waste bags and transport to a designated medical waste accumulation site within seven days of starting the bag accumulation. [↑](#footnote-ref-2)
2. All individuals using a respirator must participate in the campus respiratory protection program, including medical clearance and fit-testing by Occupational Health Services. [↑](#footnote-ref-3)
3. Uncontrolled releases within the laboratory facility and untreated releases outside the laboratory facility shall be reported to the local health officer. §5199 f.4.J. [↑](#footnote-ref-4)
4. All individuals potentially exposed to ATPs-L in the course of their work MUST report to Occupational Health Services or the nearest hospital emergency room. [↑](#footnote-ref-5)
5. §5199 j.2.A. Training records shall be maintained for three years from the date on which the training occurred. [↑](#footnote-ref-6)
6. Evaluation of this document should be performed annually and documented in writing. §5199 j.3.A. [↑](#footnote-ref-7)