**Biological Hygiene Plan**

**PI Last Name** **Lab**

* *This form is both a review tool to assess/develop the safety practices of the lab, as well as a biological hygiene plan outlining some of the safety standards and procedures associated with the lab for lab staff review.*
* *Please upload a copy into the biological registration documents section at the bottom of your Biological Registration submission.*

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| **Section 1: Administration** | | | | | | | | |
| Principle Investigator: |  | | | | PI Phone: | |  | |
| PI Email: |  | | | | | | | |
| Lab/Safety Manager: |  | | | | Manager Phone: | |  | |
| Manager Email: |  | | | | | | | |
| Biosafety Cabinets in Use | |  | BSC Type: | N/A | | Certification Date | |  |
| BSC Room Location(s) | |  | | | | Expiration Date | |  |

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| **Section 2: Training Requirements for Lab** | | |
| Check each box that is applicable | | Required Training for Lab |
|  | 1. Infectious or otherwise risk group 2 agents | Biosafety |
|  | 2. Human source materials | Bloodborne Pathogens |
|  | 3. Genetically modified organisms or synthetic nucleic acid molecules | Recombinant DNA |
|  | 4. Biological materials/specimens shipped to another facility.   * Specify designated shipper(s): | Shipping of Dangerous Goods  Shipping of Biological Materials |

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| **Section 3: Hazard Communication** | |
| Type of Material Used/Stored by Lab | Specify Genus Species or Disease within Specimen |
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| Provide an overview of the lab and how these biological materials function to serve the aims of the research. | |
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| **Section 4: Risk Assessment** |
| What are the possible transmission/exposure routes of the materials used in the lab? (ie. Inhalation, bloodborne, etc.) |
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| List the signs and symptoms of exposure to these materials: |
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| Assess the exposure risks associated with the procedures employed in this lab. How are these risks mitigated? |
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| How would exposures to these hazards be handled/treated? |
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| What disinfectants are used for agent inactivation? If applicable, what disinfectants are used in the BSC? |
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| If applicable, specify how materials are being transported between facilities and/or shipped to other facilities: |
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| List the PPE requirements for researchers in this lab: |
| Gloves  Safety Glasses  Lab Coat  Face Shield  Disposable Gown  N95 Respirator  Other(s): List... |

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| **Section 5: Hygiene Plan** | |
| Please review the standard operating procedures below and check/modify as appropriate for adoption by your lab. | |
|  | **Part A: Engineering Controls** |
|  | Access to this laboratory is always restricted, requiring a key or card access to gain entry. |
|  | When manipulating specimens, traffic into the room will be limited to only that which is unavoidable. |
|  | No other research may be allowed in the room while active work on this project is ongoing. |
|  | All manipulations of potentially pathogenic materials will always be performed in the biosafety cabinet(s) listed. |
|  | All procedures are performed carefully to minimize the creation of aerosols, and that which is unavoidable must be performed in the biosafety cabinet, as is all work involved in the manipulation of the biohazardous material. |
|  | Biosafety cabinets will be certified annually, or visually labeled so as to prevent work in them. |
|  | No open-bench work with infected samples or materials carrying viable pathogens is allowed under any circumstances, all such work must be carried out in the biosafety cabinet. |
|  | The surface of the biological safety cabinet is cleaned with disinfectant before and after use. |
|  | **Part B: Work Practice Controls** |
|  | Employees will wash their hands with soap immediately after contact with potentially infectious materials, following the removal of protective gloves, and before exiting the lab. |
|  | The following activities are prohibited: eating; drinking; smoking; application of cosmetics; handling of contact lenses; storage or preparation of food or drink. |
|  | All supplies that come into contact with potentially infectious materials (*e.g.*, pipettes, filter units, culture dishes) are disposed of in biohazardous waste for decontamination off-site. |
|  | Liquid waste will be decontaminated with a 1:10 dilution of bleach and poured down the drain. |
|  | Work surfaces are decontaminated at least once per day, and after any spill of viable material. |
|  | Containers for potentially infectious laboratory waste will be labeled, leak-proof, and closeable. |
|  | Long hair must be pulled back and contained. |
|  | Employees will place used needles, scalpels, and other sharps directly into a labeled, puncture-proof sharps container immediately following use, without any effort made to recap by hand, destroy or remove needles from the syringes. |
|  | Employees with increased risk (broken skin, immunocompromised) should avoid working with potentially infectious materials. |
|  | During transport, samples will be triple packed, meaning a leak-proof, sealed, inner container, a leak-proof, sealed secondary container such as a Ziploc bag, and a sturdy outer container such as a cooler. The container shall be delivered directly from the point of pick-up to its delivery location, the site of manipulation, in the PI’s lab. It will not be handed off to another individual for co-delivery, it will not be left in any location except at the lab and handed to the PI’s lab directly. |
|  | Any human specimen samples remaining unused, or materials that have a chance of having been exposed to and carrying viable pathogens, must be placed in a sealable container and the outside surface decontaminated with 70% ethanol inside of the biosafety cabinet before the container can be removed and disposed of in a biological waste container. Any sharps bins containing any such hazards must have any openings covered and/or sealed prior to removal from the biosafety cabinet, prior to their disposal in a biohazardous bin. |
|  | **Part C: Personal Protective Equipment** |
|  | When there is a potential for occupational exposure to infectious agents, protective clothing and devices must be used. |
|  | When there is ongoing work in the lab, all individuals present in the lab must wear protective clothing and devices, such as safety glasses. |
|  | In general, gloves will be worn when employees have the potential for direct or indirect contact with blood or other potentially infectious materials. This includes during handling of closed vessels containing tissue, blood, or culture medium that is contaminated with tissue or blood. Gloves will also be worn during all cleaning and decontamination procedures, and during handling of biomedical waste. |
|  | Lab coats must be decontaminated before laundering or professionally cleaned. |
|  | **Part D: Human Materials and Bloodborne Pathogens** |
|  | We will apply the criteria recommended for biosafety level 2 (BSL-2) in terms of practices, safety equipment, and facilities, and we will adopt the concept of "universal precautions", which assumes that all blood, body fluids, tissues, secretions, and excretions from all persons are potentially infectious. |
|  | Standard practices for occupational exposure to blood or other potentially infectious materials have been defined by the University of Miami in accordance with Federal Regulations (Blood-Borne Disease Standard, 29 Code of Federal Regulations 1910.1030). |
|  | Bloodborne pathogens are pathogenic microorganisms that are present in human blood, or blood components, which can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). HBV constitutes the primary occupational infection hazard to healthcare workers, wherein approximately 18,000 cases occur annually. The risk of occupational infection with HIV is very low, although the consequences are much more severe. Other bloodborne diseases that pose sporadic but infrequent occupational infection risks include: hepatitis C, syphilis, malaria, babesiosis, brucellosis, relapsing fever, human T-lymphotropic viruses, viral hemorrhagic fever agents, and arboviruses. |
|  | Specimens will come from *otherwise* healthy patients, not known to be infected with HBV, HCV, HIV, herpes, or any other highly contagious pathogen. |
|  | **Part E: Exposure, Spill, and Emergency** |
|  | In the event of an exposure, research staff will use sink/eyewash/safety shower located in room       for 15 minutes. |
|  | Spills and accidents that result in exposure are immediately reported to the Employee Health Office, the Biosafety Office, the IBC (if material is used on a recombinant DNA project), and the PI, who will arrange for the appropriate medical evaluation and follow-up. *Failure to report incidents will result in suspension of protocols.*   * EHS Office: 305-243-3267; after business hours: 305-299-4684 |
|  | Employees who experience exposures to potentially infectious materials or agents must prepare an Injury/Exposure Intake Form and submit it to Employee Health. |
|  | All spills shall be immediately contained and cleaned up by appropriately trained individuals. The EHS Biosafety Office and IBC (when applicable) will be notified of the spill immediately to determine whether it can be cleaned by lab staff or if professional services are needed.   * EHS Biosafety Office: 305-243-3400 |
|  | In the event of a spill in the biosafety cabinet, the BSC will be left on to mitigate aerosol creation. |
|  | **Part F: Special Use Standard Operating Procedures** |
|  | Recapping of needles is sometimes needed for procedures in this lab: Explain why and when it's needed and the techniques and/or engineering controls used to mitigate recapping needle-stick risks. |
|  | Use of N95 respirators are required for this lab: Explain why an N95 is necessary, when and where they're required, and the need for annual respiratory protection program enrollment. |
|  | Additional special procedures: Detail... |

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| **Section 6: Select Agents Assessment** | | |
| * + The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. Here is a list of [excluded agents and toxins](https://www.selectagents.gov/SelectAgentsandToxinsExclusions.html). | | |
| 2.1 | **Agent or Toxin Actively Used By Or Stored In Lab (check all that apply)** | |
| **HHS SELECT AGENTS AND TOXINS**  Abrin  Bacillus cereus Biovar anthracis  Botulinum neurotoxins  Botulinum neurotoxin producing species of  Clostridium  Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)  Coxiella burnetii  Crimean-Congo haemorrhagic fever virus  Diacetoxyscirpenol  Eastern Equine Encephalitis virus  Ebola virus  Francisella tularensis  Lassa fever virus  Lujo virus  Marburg virus  Monkeypox virus  Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)  Ricin  Rickettsia prowazekii  SARS-associated coronavirus (SARS-CoV)  Saxitoxin  South American Haemorrhagic Fever viruses:  Chapare  Guanarito  Junin  Machupo  Sabia  Staphylococcal enterotoxins (subtypes A,B,C,D,E)  T-2 toxin  Tetrodotoxin  Tick-borne encephalitis complex (flavi) viruses:  Far Eastern subtype  Siberian subtype  Kyasanur Forest disease virus  Omsk hemorrhagic fever virus  Variola major virus (Smallpox virus)  Variola minor virus (Alastrim)  Yersinia pestis | **OVERLAP SELECT AGENTS AND TOXINS**  Bacillus anthracis  Bacillus anthracis Pasteur strain  Brucella abortus  Brucella melitensis  Brucella suis  Burkholderia mallei  Burkholderia pseudomallei  Hendra virus  Nipah virus  Rift Valley fever virus  Venezuelan equine encephalitis virus  **USDA SELECT AGENTS AND TOXINS**  African horse sickness virus  African swine fever virus  Avian influenza virus  Classical swine fever virus  Foot-and-mouth disease virus  Goat pox virus  Lumpy skin disease virus  Mycoplasma capricolum  Mycoplasma mycoides  Newcastle disease virus  Peste des petits ruminants virus  Rinderpest virus  Sheep pox virus  Swine vesicular disease virus  **USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS**  Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines)  Peronosclerospora philippinensis  (Peronosclerospora sacchari)  Ralstonia solanacearum  Rathayibacter toxicus  Sclerophthora rayssiae  Synchytrium endobioticum  Xanthomonas oryzae  **NONE** |

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| **Section 7: Dual Use Research of Concern (DURC) Assessment** | | |
| * + Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called Dual Use Research (DUR).   + Dual Use Research of Concern (DURC) is a subset of DUR and is defined as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”   + On March 29, 2012, the US Government released the [US Government Policy for Oversight of Life Sciences Dual Use Research of Concern](http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf) to establish the requirements for the oversight of DURC by the US Government. On September 24, 2014, the [US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) was released to establish the requirements for institutional (i.e., non-US Government) oversight of DURC. The US Government considers these two policies to be complementary.   + These definitions could potentially encompass a number of life sciences research projects at the University of Miami, however, the current scope of the policy has been limited to the following agents and toxins and categories of experiments. Research must involve both a listed agent/toxin and category of experiment to be deemed potential DURC. | | |
| 1.1 | **Agent or Toxin Actively Used By Or Stored In Lab (check all that apply)**  *Verify if this project directly involves non-attenuated forms of 1 or more of the 15 listed agents.* | |
| Avian Influenza (highly pathogenic  Bacillus anthracis  Botulinum neurotoxin (any quantity)  Burkholderia mallei  Burkholderia pseudomallei  Ebola virus  Foot-and-mouth disease virus  Francisella tularensis | Marburg virus  Reconstructed 1918 influenza virus  Rinderpest virus  Toxin producing strains of *Clostridium botulinum*  Variola major virus  Variola minor virus  *Yersinia pestis*  **NONE** |
| 2.2 | **Experimental Effects (check all that apply)**  *Indicate whether the research project indicated above produces, aims or can be reasonably anticipated to produce any of the following experimental effects.*  Enhances the harmful consequences of the agent or toxin.  Disrupts the immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.  Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against the agent or toxin or facilitates its ability to evade detection methodologies.  Alters properties of the agent or toxin in a manner that would enhance its ability to be disseminated.  Alters the host range or tropism of the agent or toxin.  Enhances the susceptibility of a host population to the agent or toxin.  Generates or reconstitutes an eradicated or extinct agent or toxin listed in Question 6.2 of this form.  **NONE**  ***If you checked any of the above experimental effects, please explain:*** | |

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| **Section 8: Acknowledgement and E-Signature** |
| I have read and am familiar with the standard and special microbiological practices, containment equipment, personal protective equipment, and laboratory facilities recommended for the biosafety level applicable to this project. I will ensure that all faculty, staff, and students working on this project will review this document and will follow these recommendations as a condition of approval of this project.  Type Your Full Name Date Completed |