**Biological Ancillary Review Assessment Form**

* *This form is part of a required review from the Biosafety Office for any IRB protocol involving the introduction of biological materials or the collection of human specimens. It may also be required by labs falling outside of the purview of the IBC but still requiring biosafety review.*
* *This form is both a review tool to assess/develop the safety practices of the lab, as well as a hygiene plan aimed at researchers outlining some of the safety standards and procedures associated with this protocol.*
* *All labs must complete the first page, sections 1-4, as well as the digital signature at the end. If your project involves risk group 2 organisms or higher, or upon request, the entire form must be completed.*
* *Please submit to the Biosafety Office at* [*biosafety@umiami.edu*](mailto:biosafety@umiami.edu) *for review when complete.*

|  |  |  |
| --- | --- | --- |
| **Section 1: General Protocol Information** | | |
| PI Name: |  | |
| Protocol Title: |  | |
| Lab Building: | Room(s): | Biosafety Level: N/A |
| BSC type: N/A | BSC Lab Room Location: | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 2: Lab Members** | | | |
| List the researchers in the lab who will be involved with any part of this portion of the project, including the PI, and their corresponding training dates. | | | |
| Name | Biosafety | Bloodborne Pathogens | Lab Safety |
| PI name / add researchers | Date Completed | Date Completed | Date Completed |

|  |  |  |
| --- | --- | --- |
| **Section 3: Pre-Screening Questions** | | |
|  | 1. This project involves the introduction of foreign biological materials. | |
|  |  | 1a. The materials used are infectious, toxic, or otherwise risk group 2 or higher. |
|  | 2. Human specimens, such as blood, or other biological materials are being collected. | |
|  |  | 2a. The lab will be manipulating or processing these samples to any extent. |
|  |  | 2b. Specimens will be collected, but shipped to and processed by another lab. |
|  |  | 2c. Specimens are coming from patients known to be or suspected of carrying a disease.   * Specify: |
|  | 3. Materials in this lab are genetically modified, transgenic, or otherwise synthetic. | |
|  | 4. Biological materials/specimens will be shipped to another facility.   * Specify designated shipper:       Shipping training completion: Date Completed | |

|  |  |
| --- | --- |
| **Section 4: Protocol / Pathogen Overview** | |
| Type of Material | Specify Genus Species or Disease within Specimen |
|  |  |
| In lay terms, please provide an overview of the protocol. Be sure to list the purpose of and how each material listed above is being used, highlighting the aims of the research, and briefly describing how this will be accomplished: | |
|  | |

*If any of the materials listed above are Risk Group 2 or higher, please proceed with the rest of the application. If not, you may scroll to Section 7, sign, and submit this application as complete. If your protocol requires an IBC application, you may sign the form at Section 7 and submit.*

|  |
| --- |
| **Section 5: Biohazard Risk Assessment** |
| Briefly describe the procedures of this lab, from the moment materials are introduced/collected, to the point of disposal: |
|  |
| What are the highest risk procedures in this experiment? How are those risks being addressed by the lab? |
|  |
| List every material noted in Section 4: what are the signs and symptoms of exposure and the potential routes of exposure to these hazards? |
|  |
| What is the research team’s previous experience working with these agents or similar materials? |
|  |
| How and where will these items be stored? |
|  |
| How would an exposure to this organism be addressed and treated? |
|  |
| If applicable, specify how materials are being transported between facilities and/or shipped to other facilities: |
|  |
| List the PPE requirements for researchers in this lab: |
| Gloves  Safety Glasses  Lab Coat  Face Shield  Disposable Gown  N95 Respirator  Other(s): |
| List the training requirements for researchers in this lab: |
| Biosafety  Bloodborne Pathogens  Lab Safety  Shipping |

|  |  |
| --- | --- |
| **Section 6: Hygiene Plan Adoption** | |
| 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 will be cleaned with 70% isopropanol 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 exposures to infectious material are immediately reported to the PI, who will arrange for the appropriate medical evaluation and follow-up, Employee Health, and the EHS Biosafety Office. |
|  | 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 will be notified of the spill immediately to determine whether it can be cleaned up by lab staff or if professional services are needed. |
|  | In the event of a spill in the biosafety cabinet, the BSC will be left on to mitigate aerosol creation. |

|  |
| --- |
| **Section 7: 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 follow these recommendations as a condition of approval of this project.  Type Your Full Name Date Completed |