**Biological Ancillary Review Assessment (BARA) Form**

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

* *Completing this form is required for IRB submissions requiring EHS (Environmental Health & Safety) review.*
* *Please upload a copy under EHS on the “Reviews” tab on the IRB submission page.*
* *Note that EHS is NOT notified of further edits on already submitted studies, please email us for re-reviews.*
* *For questions or if assistance is needed to complete this form, please contact us at* [*BSO\_Review@miami.edu*](mailto:BSO_Review@miami.edu)*.*

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| **Section 1: Administration** | | | | | |
| Full Protocol Title: |  | | | | |
| Principal Investigator: |  | | IRB Number: |  | |
| PI Email: |  | PI Emergency Phone #: | | |  |

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| **Section 2: Study Personnel & Training Verification** | | | | | |
| List the PI & personnel on the study who will be involved with either collecting, handling, or processing specimens or investigational products. This must include the PI and corresponding training dates, as appropriate. | | | | | |
| Name | Biosafety  (every 3 yrs) | Bloodborne Pathogens  (annually) | Lab Safety  (every 5 yrs) | Shipping of Dang Goods  (every 2 yrs) | Shipping of  Bio Materials  (every 2 yrs) |
| PI name / add researchers | mm/dd/yyyy | mm/dd/yyyy | mm/dd/yyyy | mm/dd/yyyy | mm/dd/yyyy |

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| **Section 3: Risk Screening Questions** | | |
|  | 1. This project involves biological investigational product(s). | |
|  |  | 1a. The investigational product is infectious to humans. |
|  | 2. This project involves recombinant or synthetic nucleic acid molecule based investigational product(s). | |
|  |  | 2a. The investigational product is a viral vector. |
|  |  | 2b. The investigational product is a product created by a viral vector. |
|  | 3. Human specimens, such as blood, or other biological materials are being collected. | |
|  |  | 3a. Our lab will be manipulating or processing collected samples. |
|  |  | 3b. Our lab will collect specimens, but they are processed/manipulated by another lab. |
|  |  | 3c. Specimens are coming from patients known to be or suspected of carrying a disease.   * Specify: |
|  | 4. We will be responsible for shipping materials to another facility. | |

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| **Section 4: Specimen Processing and Manipulation** | | | |
|  | Collected specimens will be processed, manipulated, or shipped by another lab or core facility at the University.   * Note that this lab is required to complete the [Biological Hygiene Plan](https://ehs.miami.edu/_assets/pdf/biosafety/biological_hygiene_plan_1.docx) and be inspected annually by EHS. | | |
| PI Name/Core Lab Facility: | | |  |
| Contact Email for Lab: | | |  |
| Contact Phone # for Lab: | | |  |
|  | Collected specimens will be processed/manipulated by a non-University entity. | | |
| Name of Entity: | |  | |
| Location of Entity: | |  | |

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| **Section 5: Hazard Communication** |
| Describe investigational products/drugs and specimens collected by lab, their nature, and their associated hazards. |
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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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| How are the specimens being handled or collected by your lab? |
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| What are the possible transmission/exposure routes of the materials used in the lab? (ie. Inhalation, bloodborne, etc.) |
|  |
| List the signs and symptoms of exposure to these materials: |
|  |
| Assess the exposure risks associated with the procedures employed in this lab. How are these risks mitigated? |
|  |
| How would exposures to these hazards be handled/treated? |
|  |
| What disinfectants are used for agent inactivation? |
|  |
| 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 6: 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 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.  Professional Investigator Full Name Date Completed |

*If your lab is processing/manipulating specimens or investigational products, please complete Section 7: Hygiene Plan. If specimens or investigational products are being processed/manipulated by another lab, you may stop and submit.*

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| **Section 7: 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... |