**Registration Form for Infectious Agents, Human and Animal Biological Materials, OPIM**

**Purpose:** This form is to document all known microorganisms, biological materials, or OPIM that will be housed or analyzed at the university to establish a definitive inventory. This will not necessarily match the risk assessments provided in an IBC protocol. Please review additional information provided in the Appendix for further clarification.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Principle Investigator:** | | Click or tap here to enter text. | | |
| **Department:** | Click or tap here to enter text. | | | |
| **Office Location:** Office Location. | | | | **Phone:** Office Phone. |
| **Lab Location:** Lab Location. | | | | **Storage Location:** Storage Location. |
| **Alternate Contact Person:** | | | Click or tap here to enter text. | |

**Agent or Material Information**:

Indicate the appropriate category for registration (descriptions available in Appendix I):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Non-pathogenic microorganism(s)** |  | **Pathogenic microorganism(s)** | | |
|  | **Human blood, cell lines, and/or tissues** |  | **Animal blood, cell lines, and/or tissues** | | |
|  | **Other Potentially Infectious Materials (OPIM)** | | |  | **Toxin** |

Is this a potential human, animal, or plant infectious agent, or toxin?

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Human** |  | **Animal** |  | **Plant** |  | **N/A** |

If a toxin, is the LD50greater than 100 nanograms per kilogram of body weight?

**Yes**  **No  N/A**

**Microorganism:**

|  |
| --- |
| **Scientific name of the organism:** Click or tap here to enter text. |
| **Strain description (if applicable):** Click or tap here to enter text. |
| **Source of organism:** Click or tap here to enter text. |
| **Is the organism attenuated?**   **Yes**   **No** |
| **Does the organism produce a toxin?**   **Yes**   **No** |
| **Is there work done with the produced toxin?**   **Yes**  **No  N/A** |
| **Is drug resistance expressed?**   **Yes**   **No** |
| **Where is the organism stored when not in use?**  Room/Location. |
| **Where will the organism be in use?** Room/Location. |
| **Does the work involve quantities greater than 1 liter?**   **Yes**   **No** |
| **What is the largest volume anticipated?** Click or tap here to enter text. |
| **If applicable, are biohazard warning labels in use?**  **Yes**  **No** |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Is the organism inactivated prior to use? | | | | | | | | |  | | **Yes** | | | |  | **No** | | | | |
| **Inactivation method(s) used:** | | | | | | | | | | | | | | | | | | | | |
|  | | **Heat** |  | **Chemical** | |  | **Radiation** | | | |  | | **Other:** | | | | | | | |
| Will the agent be concentrated? | | | | | | | | |  | | **Yes** | | | |  | **No** | | | | |
| **Concentration method(s):** | | | | | | | | | | | | | | | | | | | | |
|  | **Centrifuge** | | |  | **Filtration** | |  | **Precipitation** | | | | | |  | **Other:** Specify Other. | | | | | |
| Are cultures, stocks, and contaminated items decontaminated prior to disposal? | | | | | | | | | | | | | | | | |  | **Yes** |  | **No** |
| **Decontamination method(s):** | | | | | | | | | | | | | | | | | | | | |
|  | **Autoclave** | | |  | **Chemical disinfectant** | | | | |  | | **Other:** Specify Other. | | | | | | | | |

**Human blood, cell lines, and/or tissues**

**\***Includes ATCC established cell lines of human/primate origin or OPIM

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| --- |
| **List materials:**  Click or tap here to enter text. |
| **Are the materials known to contain an infectious agent?**  **Yes**   **No** |

**Animal blood, cell lines, and/or tissues**

|  |
| --- |
| **List materials:** Click or tap here to enter text. |
| **List the species of animal(s) they originated from:** Click or tap here to enter text. |
| **Are the materials known to contain an infectious agent?**  **Yes**   **No** |

**Other Potentially Infectious Materials (OPIM)**

|  |
| --- |
| **List materials:** Click or tap here to enter text. |
| **Are the materials known to contain an infectious agent?**  **Yes**  **No** |

**Toxin**

|  |
| --- |
| **Name of toxin:** Click or tap here to enter text. |
| **Quantity used/stored:** Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| **Indicate if the toxin falls into any of the following categories** | **Yes** | **No** |
| On the CDC/USDA Select Agent and Toxins list? |  |  |
| On the CDC/USDA Select Agent and Toxins Exemptions list? |  |  |
| Be used in an experiment that is not regulated under the Federal Select Agent Program due to permissible toxin amounts? |  |  |
| Not regulated under the Federal Select Agent Program? |  |  |

**Recombinant and Animal Use Information:**

**\*** *If your work involves r/sNA molecules, you must submit a protocol registration with the IBC.*

Are any of the above microorganisms recombinant?  **Yes**   **No**

Will any cells/tissues/microorganisms, modified or unmodified, be introduced into animals?

**Yes**   **No**

If yes, list the animal species and housing location: Click or tap here to enter text.

**Safety Measures:**

*\*If your work involves BSL-2 microorganisms, you must submit a protocol registration with the IBC.*

The organism and/or materials will be handled at which Biosafety Level?  **BSL-1**  **BSL-2**

What PPE is necessary to handle the organism and/or materials?

**Lab coat**  **Gloves**  **Safety Goggles**   **Other:** Specify Other.

What disinfectant(s) should be used for routine cleaning and spills?

**10% bleach**  **70% ethanol**   **Other:** Specify Other.

**Personnel:**

List out all personnel in the laboratory that will handle or be exposed to any microorganism, biological material, toxin, or OPIM. If students, then indicate the course name and semester.

|  |  |
| --- | --- |
| **Name** | **Title** |
| Click or tap here to enter text. | Click or tap here to enter text. |
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**Principal Investigator AFFIRMATION:**

I accept responsibility for ensuring all personnel receive appropriate training on the hazards and proper protocols required to safely work with the identified microorganisms/biological materials/toxins/ and/or OPIM. I agree that all procedures are available to lab personnel in a laboratory manual that is easily accessible. I will inform the IBC Chair if the microorganisms/biological materials/toxins/ and/or OPIM are no longer in use and properly disposed of or if there is a change in use, storage, or associated locations.

|  |  |
| --- | --- |
| **Signature:** |  |
| **Date:** | Click or tap to enter a date. |

**Appendix I:**

**Non-pathogenic microorganisms:** not known to consistently cause disease in healthy adults. Potential hazard and risk are minimal to laboratory personnel and the environment. These can be handled and maintained in a BSL-1 laboratory using standard microbiological practices on an open lab bench or table wearing PPE as needed.

Note: Due to potential for housing organisms that are recombinant potentials, it is important to know all microorganisms that are housed and accessible to researchers.

**Pathogenic microorganisms:** Agents capable of causing disease in immune competent, healthy adults. Associated with diseases of varying severity. These must be maintained at BSL-2 level with restricted access and appropriate PPE worn. All procedures that can result in the generation of aerosols or splashes should be performed inside of a BSC.

**The following applies to Human and animal biological materials as well as OPIM:**

Human biological materials should be treated as potentially infectious and handled within a BSL-2 laboratory, including cells lines obtained from commercial sources. Training in Bloodborne pathogens should be completed by all individuals that handle human cell lines and/or tissues. Bloodborne pathogens present in human blood and in other potentially infectious material (OPIM) may include hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) as well as other pathogenic microorganisms such as *Mycobacterium tuberculosis*. All human and animal blood, body fluids, cell lines, and tissues must be handled under BSL-2 conditions as if they were primary cells or tissues.

**Biological toxin:** can be a peptide, small molecule, or macromolecular protein. They are produced by biological organisms and cause disease by interfering with biological processes (e.g. neurotoxins, snake venom toxin, etc.). Safe practices and engineering controls must be utilized as well as appropriate PPE. Dilute toxins may be handled within BSL-2 laboratories if proper protocols and additional precautions, such as the use of a BSC, are taken.

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition.

**Appendix II: Use and purpose**

Use this form for known microorganisms and human or animal derived materials, to be stored at the university and to disclose the use and storage of OPIMs for research. Do not use this form to indicate all the potentially infectious microorganisms associated with the various biological materials used in the research. Those potentials should be indicated in the IBC protocol registration to provide the necessary information for risk assessments and exposure risks. The microbe registration form is used to keep accurate and definitive inventories of biological agents, biological materials, and potentially infectious materials (“the knowns”). The IBC protocol is used to determine the overall risk associated with the research and to ensure all necessary information is provided for exposure mitigation, medical surveillance, and post-exposure information (“the knowns” and “the unknowns”).

*Example:* Mammalian tissue is taken and stored at the university to determine if a targeted pathogen is present. The PI stores this pathogen at the university to use as a positive control in PCR analysis. There are other pathogens that are known to infect this species of mammal and colonize within the same tissue. The IBC protocol registration form lists the positive control, targeted pathogen, and the other pathogens that may be present within the tissues. The risk assessment will then determine the appropriate biosafety level and procedures for all pathogens listed, known and unknown, while providing the necessary medical information. The microbe registration form will be used to register the positive control and the tissue as those are the only confirmed biological materials and/or agents that can be inventoried and documented. If an unknown pathogen is later identified within the tissue and/or isolated from the tissue, a new registration form must be filled out to indicate the storage of this pathogen in the tissue and/or as an isolate.