|  |  |
| --- | --- |
| Description: Arizona State University Arizona State University Institutional Biosafety Committee |  **RECOMBINANT/SYNTHETIC DNA & SELECT AGENT DISCLOSURE** **FORM EHS 112C** |
| **NOTE: Forms need to be completed and submitted to the IBC at least two weeks in advance of the meeting date. Meeting dates are posted on the IBC website at** [**https://researchintegrity.asu.edu/biosafety/disclosure-submission**](https://researchintegrity.asu.edu/biosafety/disclosure-submission)**. Submit disclosure forms to** **IBC@asu.edu****. Late submissions will be reviewed the following month.** |

**For IBC Use Only:**

**IBC#\_\_\_\_\_\_\_ BSL\_\_\_\_\_\_\_**

**[ ]  New Disclosure** [ ]  **Renewal: Prior disclosure #**

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator #1: |       | ASURITE: |       |
| Department: |       | Phone: |       |
| Building, Room, Mail Code |       | Email: |       |
| Principal Investigator #2: |       | ASURITE: |       |
| Department: |       | Phone: |       |
| Building, Room, Mail Code |       | Email: |       |
| Project Title: |       |
| Funding Agency: |       | ASU Proposal or Award #:       |
| Funding Agency: |       | ASU Proposal or Award #:       |

1. Please provide a brief (300 words or less) synopsis in LAY TERMS of proposed research.

1. What select agent(s) and toxin(s) will be used in this project? Please refer to the CDC list of select agents and toxins located at <https://www.selectagents.gov/SelectAgentsandToxinsList.html>

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of Agent(s) or Toxin(s) (Genus/species and strain)** | **Genetically Modified (Y/N)** | **Antibiotic Resistant (Y/N)** | **Source (e.g. ATCC)** | **Host Range (e.g. animal, plant, human)** | **Normal Routes of Transmission** | **Unique Diagnostic Characteristics** | **Maximum Volume Used or Stored** |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |

1. Do you use, store, or generate genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed as select agents or their toxic subunits?

[ ]  No [ ]  Yes

Please list:

1. What biosafety level (BSL/ABSL) will be used while performing these experiments?

1. Where will the select agent(s) or toxin(s) be stored? Please list all locations; list campus, building and room:

1. Where will the experiments be conducted? Please list all locations; list campus, building and room:

1. Do you plan on receiving, shipping, or transporting the select agent(s) or toxin?

[ ]  No [ ]  Yes If yes, please provide permit information prior to transport.

1. Are laboratory personnel involved with the experiments enrolled in an appropriate medical surveillance program?

[ ]  No [ ]  Yes

1. Have laboratory personnel been informed of immune suppressive conditions and other conditions that may predispose them to infection:

[ ]  No [ ]  Yes

1. Is there a vaccine available and recommended for persons handling the select agent(s) and toxin(s)?

[ ]  No [ ]  Yes

Please list vaccine information and include process for offering vaccinations (or declination option):

1. Is medical treatment available and recommended for persons handling this select agent and toxin?

[ ]  No [ ]  Yes

Please list information on therapeutics and include process for informing and providing to participants.

1. Does the research involve human blood, human tissue, bodily fluids, or bloodborne pathogens?

[ ]  No [ ]  Yes

If yes, describe:

Does this study involve the use of human gene therapy?

[ ]  No [ ]  Yes

Is a human subjects IRB protocol in place?

[ ]  No [ ]  Yes IRB Protocol #:

Please describe process for offering Hepatitis B vaccinations (or option for declination):

1. Does the experiment involve research animals?

[ ]  No [ ]  Yes Species:

Are the animals being infected with anything that could be released into the environment (e.g. through shedding or excretion)?

[ ]  No [ ]  Yes

Does this study involve transgenic animals?

[ ]  No [ ]  Yes

If yes, are you breeding and/or creating a transgenic animal?

[ ]  No [ ]  Yes

Do you have IACUC approval for all animal activities?

[ ]  No [ ]  Yes IACUC Protocol #:

1. Does the experiment involve plants?

[ ]  No [ ]  Yes Species:

If yes, are they genetically-modified plants?

[ ]  No [ ]  Yes

1. What is the maximum total volume of culture or solution of infectious agents being used at any one time?
2. **Synthetic or Recombinant Nucleic Acids**
3. Experiments involve the use of (check all that apply):

[ ]  Bacteria:

[ ]  Fungi:

[ ]  Insects:

[ ]  Parasites:

[ ]  Viruses:

[ ]  Human or NHP blood, bloodborne pathogens, blood products, tissue, or cells (including cell cultures), list:

1. List genetic material to be transferred. Please explain abbreviations.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Gene, Plasmid, Nucleic Acid, etc.** | **Source (Species of Origin)** | **Propagation Host (genus/species)** | **Target Recipient (genus/species)** | **Method of Transfer**  |
| *Sample: GFP* | *Jellyfish* | *E. Coli K-12* | *HeLa cells* | *Lentiviral host vector system* |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

1. Synthetic or Recombinant Nucleic Acids or Gene Transfer will involve (check if applicable):
2. [ ]  Physical methods (e.g. pronuclear injection, electroporation, “gene gun”, etc.)

Describe:

1. [ ]  Host-Vector System

Describe:

Are human, animal, insect, or plant pathogens used as host-vector systems?

[ ]  No [ ]  Yes

1. [ ]  Other (e.g. conjugation, etc.)

Describe:

 For virus work:

* + 1. Do experiments involve formation of synthetic or recombinant nucleic acids containing >2/3 of the genome of any eukaryotic virus?

[ ]  No [ ]  Yes

* + 1. Do experiments involve the use of infectious nucleic acid viruses; or defective animal or plant viruses in the presence of helper virus?

[ ]  No [ ]  Yes If yes, please **attach** your procedures to determine the relative proportions of helper virus and defective virus in potentially mixed virus stock.

**Attach a detailed map of all vectors and inserts to be used**. Please indicate any regions that increase the safety of this construct. Provide copies of key references that describe the construction of the vector(s) to be used.

1. **Safety Information:**
	1. List potential exposure hazards during sample preparation and experimental manipulations
	(e.g. aerosol generation when transferring, pipetting, mixing, blending, sonicating, or centrifuging, use of sharps, excretion by animals, large scale cultures):

* 1. Describe safety procedures that will be employed to minimize risk and prevent release of the select agent and toxin (e.g. personal protective equipment or clothing, use of biological safety cabinet, sharps disposal procedures, waste disposal procedures):

* 1. Describe procedures for accidental spills and exposures:

* 1. Describe the methods that will be used to inactivate or disinfect select agents or toxins as well as procedures that will be used to decontaminate work surfaces and equipment. List the types of disinfectants to be used.

* 1. Describe detailed waste disposal procedures.

* 1. Describe the training that laboratory personnel will receive regarding their duties, the necessary precautions to prevent exposure and exposure evaluation procedures:

* 1. Has an effective integrated pest management program been implemented in the facility?

[ ]  No [ ]  Yes

* 1. Will there be a need to remove select agent or toxins from the facility?

[ ]  No [ ]  Yes If yes, please describe the procedure used for transporting the materials:

**The laboratory specific biosafety manual and all laboratory specific standard operating procedures (SOP’s) for the use of select agents and toxins must be provided to the Biosafety Officer.**

1. **PI Training/Experience**

Please indicate the Principal Investigator’s degree, training, experience and proficiency working with the organisms listed in this disclosure. PI must have current biosafety training for BSL2 or BSL3 disclosures. Biosafety training is **NOT** the same as Laboratory Safety training.

|  |  |
| --- | --- |
|  | **For IBC Use Only**Biosafety Training Verification |
|  |

1. **Personnel**

Identify all personnel conducting the experiments (including students and staff). Specify degree, project responsibilities, applicable training and experience including duration (e.g. 2 years). Current biosafety training is required for BSL2 and BSL3 disclosures. Biosafety training is **NOT** the same as Laboratory Safety training.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Participant Name** | **ASURITE Name** | **Degree** | **Project Responsibilities** | **Prior Experience or Training Related to these Responsibilities** | **For IBC Use Only**Biosafety Training Verification |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**If changes in the information provided above occur, a revised form must be submitted for approval.**

By signing below you warrant **1)** that you have read and understood this Select Agent Registration Form and the summary, **2)** that you are aware of the hazards present in the work area and **3)** that you are aware of and in compliance with the requirements of the Department of Health and Human Services Standard, “[Possession, Use, and Transfer of Select Agents and Toxins; Final Rule](https://www.federalregister.gov/documents/2017/01/19/2017-00726/possession-use-and-transfer-of-select-agents-and-toxins-biennial-review-of-the-list-of-select-agents)” (42 CFR § 73). *Note: If application is approved, all personnel are subject to Department of Justice/FBI Clearance.*

In addition, by signing this you ensure that all work on this project will be conducted using biosafety practices described in the CDC/NIH Publication entitled *Biosafety in Medical and Biomedical Laboratories (BMBL).* Additional stipulations required by the Institutional Biosafety Committee on behalf of Arizona State University will also be followed.

Principal Investigator’s Signature: Date:

|  |
| --- |
| **IBC USE ONLY** |
| **Approved by IBC** | **IBC Chair or Designee** | **Date** |
| [ ]  | **IBC only** | **IBC only** |