****

|  |  |
| --- | --- |
| Institutional Biosafety Committee (IBC) MAIN Protocol Form | IBC protocol #:      Date Submitted: Click or tap to enter a date. |
| Biosafety Office Use Only:Date Approved: Click or tap to enter a date. |

**Section I - BASIC INFORMATION**

|  |  |
| --- | --- |
| **Title of Protocol:** Information |       |

**Section I: Study Personnel**

**Section I. A: Principal Investigator**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |       |    | Title: |       |  |
| Department: |       |    | Mail Code: |       |  |
| Office Phone: |       |    | Cell phone: |       |  |
| Lab Phone: |       |    | E-Mail Address: |       |  |

**Section I. B: Secondary Contact** 

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |       |    | Title: |       |  |
| Department: |       |    | Mail Code: |       |  |
| Office Phone: |       |    | Cell phone: |       |  |
| Lab Phone: |       |    | E-Mail Address: |       |  |

**Section I. C: Other Authorized Personnel**

|  |  |  |  |
| --- | --- | --- | --- |
| **Last Name/ First Name** | **Job Title** | **Email** | **Phone Number** |
|  1.       |       |       |       |
|  2.       |       |       |       |
|  3.       |       |       |       |
|  4.       |       |       |       |
|  5.       |       |       |       |
|  6.       |       |       |       |
|  7.       |       |       |       |
|  8.       |       |       |       |
|  9.       |       |       |       |
| 10.       |       |       |       |
| 11.       |       |       |       |
| 12.       |       |       |       |
| 13.       |       |       |       |

 *Contact the IBC, if you need to add more rows to this table.*

**Section I. D: Experiment Location(s)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Building Name** / **Room Number** | **Type/Function of Location**   *(e.g., main lab, open lab bench, tissue culture room, freezer room, microscope room, cold room*) | **BSC** Information**present?** | **Shared Space?** |
|  |  | YES | NO | YES | NO |
|       |       |[ ] [ ] [ ] [ ]
|       |       |[ ] [ ] [ ] [ ]
|       |       |[ ] [ ] [ ] [ ]
|       |       |[ ] [ ] [ ] [ ]
|       |       |[ ] [ ] [ ] [ ]
|       |       |[ ] [ ] [ ] [ ]
|       |       |[ ] [ ] [ ] [ ]
|       |       |[ ] [ ] [ ] [ ]
|       |       |[ ] [ ] [ ] [ ]

 *Contact the IBC, if you need to add more rows to this table.*

Non-UC Facilities are used in this protocol?

|  |  |
| --- | --- |
| [ ]  YES [ ]  NO | *If* ***YES****, specify facility (institution/location) used and its function:*       |

**Section II: RESEARCH ELEMENTS**

**Section II. A: Research Items** 

*Check ALL applicable boxes and complete related forms*

|  |  |
| --- | --- |
|[ ]  Recombinant or Synthetic Nucleic Acids, including Viral Vectors (Ref: [NIH Guidelines Section III - A to E](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines)) | [Form A](https://researchhow2.uc.edu/docs/default-source/default-document-library/form-a.docx) |
|[ ]  Infectious Agents (e.g., Bacteria, Viruses, Fungi, Protozoa, Transducing Proteins Information NO Viral Vectors  | [Form B](https://researchhow2.uc.edu/docs/default-source/default-document-library/form-b.docx) |
|[ ]  Human/Non-Human Primate Derived Materials (including established cell lines) | [Form C](https://researchhow2.uc.edu/docs/default-source/default-document-library/form-c.docx) |
|[ ]  Biohazardous Materials used in Live Animals | [Form D](https://researchhow2.uc.edu/docs/default-source/default-document-library/form-d.docx) |
|[ ]  Use of Ionizing Radiation, Biohazardous Materials used with Radioactive Materials (RAM) | [Form E](https://researchhow2.uc.edu/docs/default-source/default-document-library/form-e.docx) |
|[ ]  Biological Toxins Within the Select Agents Exempt Amounts (Ref: [Select Agent Program – toxins](https://www.selectagents.gov/sat/permissible.htm)) Information | [Form F](https://researchhow2.uc.edu/docs/default-source/default-document-library/form-f.docx) |
|[ ]  Biological Toxins Above the Select Agents Exempt Amounts (Ref: [Select Agent Program – toxins](https://www.selectagents.gov/sat/permissible.htm)) Information |

|  |
| --- |
| **Section II. B: Research Description – Abstract** Information*Provide a brief summary of the purpose of your research project(s) describing how the materials indicated above will be used. Do not include details about the research experimenst and safety precautions; these will be asked in further sections.*      |

**Section II. C: Biosafety Level** 

*Indicate the highest biosafety level adopted in your lab.*

 [ ]  BSL 1 [ ]  BSL 2 [ ]  BSL 2 plus  [ ]  BSL 3

**Section II. D: Dual Use Research Potential & Major Actions Under the NIH Guidelines**

|  |  |  |
| --- | --- | --- |
| YES | NO | *Indicate whether your research will involve any of the following:* |
|[ ] [ ]  Renders a useful vaccine ineffective |
|[ ] [ ]  Enhances pathogen virulence and/or increases pathogen transmissibility |
|[ ] [ ]  Widens the pathogen’s host range |
|[ ] [ ]  Environmental stabilization of pathogens |
|[ ] [ ]  Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (Ref: NIH Guidelines [Section III- A-1](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457033) ) |
|[ ] [ ]  Cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight (Ref: NIH Guidelines [Section III – B](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457034) and [Univ. Florida LD50 table](http://www.ehs.ufl.edu/programs/bio/toxins/toxin-table/)) |
|[ ] [ ]  Regulated biological toxins (exceeding the exempt amounts) (Ref: [Select Agents Program – toxins](https://www.selectagents.gov/sat/permissible.htm)) |

**Section II. E: Large Scale Production**

Do the planned experiments involve the generation or use of **more than 10 liters** of culture in a **single vessel**?

|  |  |
| --- | --- |
| [ ]  YES [ ]  NO | *If* ***YES****, explain the culture procedures, including location, types of equipment used, special precautions to handle large volumes:*      |

**Section III: SAFETY**

**Section III. A – Aerosol Producing Lab Equipment**

|  |  |
| --- | --- |
| **Equipment** | **Aerosol Exposure and Prevention Plan**Information*(go* [***HERE***](http://researchhow2.uc.edu/search?indexCatalogue=researchhow2%2Ddev&searchQuery=This+eManual+provides+information+on+how+to+minimize+the+risk+of+exposure+with+aerosolized+particles+generated+in+a+lab+setting&wordsMode=0) *for the eManual on Aerosol Exposure Control)* |
| Blender |[ ]        |
| Tissue Grinder |[ ]        |
| Cell Sorter |[ ]        |
| Centrifuge |[ ]        |
| Ultracentrifuge |[ ]        |
| Vortex |[ ]        |
| Sonicator |[ ]        |
| Homogenizer |[ ]        |
| Pipet |[ ]        |
| **Other**:       |[ ]        |
| [ ]  Not Applicable |

**Section III. B -Engineering Controls**  **/ Safety Equipment**

 Comments:

|  |  |
| --- | --- |
| [ ]  Biosafety Cabinet Information |       |
| [ ]  Fume Hood (to handle biohazards) |       |
| [ ]  Safety Cups (centrifuge) |       |
| [ ]  Sealed Rotors (centrifuge) |       |
| [ ]  Safety Blender |       |
| [ ]  Vacuum System Trap *see* [***HERE***](http://researchhow2.uc.edu/docs/default-source/default-document-library/vaccumm-trap.pdf) |       |
| [ ]  Sharps Containers |       |
| [ ]  Needle Safety Device(s) |       |
| [ ]  Scalpel Safety Device(s) |       |
| [ ]  **Other**:       |  |

**Section III. C: Personal Protective Equipment (PPE)** *Check all that apply. Do not include PPE used at the LAMS facilities*

 *(PPE information can be found* [***HERE***](http://researchhow2.uc.edu/search?indexCatalogue=researchhow2%2Ddev&searchQuery=This+eManual+explains+how+to+protect+your+employees+from+biological+hazards+by+using+personal+protective+equipment&wordsMode=0) *)*

 Comments:

|  |  |
| --- | --- |
| [ ]  Single Gloves  |       |
| [ ]  Double Gloves |       |
| [ ]  Lab Coat/Gown |       |
| [ ]  Fluid resistant Lab Coat/Gown |       |
| [ ]  Fluid resistant Body Suit |       |
| [ ]  Safety Goggles |       |
| [ ]  Face (surgical) Mask  |       |
| [ ]  Face Shield |  |
| [ ]  Respirator*Individuals using respirators* *must comply with the* [*UC Respiratory Protection Program*](https://ehs.uc.edu/Advisories/Advisory_11_0.pdf) | [ ]  N95[ ]  N99 [ ]  N100[ ]  PAPR  |  |
| [ ]  Closed Toe Shoes |       |
| [ ]  Shoe Covers |       |
| [ ]  **Other**:       |       |

**Section IV: Transportation Method**

Primary container(s) with infectious or potentially infectious materials is transferred between labs inside a specially designated leak-proof secondary container labeled with the universal biohazard symbol. Secondary container also should have enough absorbent material to totally contain a spill should the primary container fail. If materials are transported in public streets, a tertiary container (e.g. cardboard box) is used. When materials are shipped out-of-UC Campus, the Biosafety Office is contacted for information about shipping requirements.

|  |
| --- |
| [ ]  I will follow the above method. |
| [ ]  I have a different method. | Describe:      |

**Section V: Surface Decontamination**

*For proper disinfection, disinfectants must remain in contact with the material or surface to ensure proper disinfection. Contact time will vary depending on the product and organism targeted; read the label of the brand you choose.* Comments:

|  |  |
| --- | --- |
| [ ]  70% Ethanol or Isopropanol Information |       |
| [ ]  10% Household bleach [*How to prepare*](https://researchhow2.uc.edu/docs/default-source/default-document-library/bleach-disinfectant.jpg) Information |       |
| [ ]  Clorox wipesTM Information |       |
| [ ]  DispatchTM (stabilized Sodium Hypochlorite) Information |       |
| [ ]  Super Sanicloth TM (purple top) |       |
| [ ]  SporklenzTM |       |
| [ ]  Others: Name/EPA #       |  |

**Section VI: Waste Disposal**

Biohazardous waste is managed by the Environmental Health and Safety (EH&S) office. The procedures for disposal of biohazardous materials are outlined in their [Advisory 10.2](https://ehs.uc.edu/Advisories/Advisory_10_2.PDF).

|  |
| --- |
| [ ]  I will follow the EH&S procedures (Advisory 10.2). Comments:      **Section VII: Spill Management** It is important that all authorized personnel be prepared to respond to a spill involving infectious or potentially infectious materials[ ]  I will follow the Biosafety Office procedures for [spills](http://researchhow2.uc.edu/search?indexCatalogue=researchhow2%2Ddev&searchQuery=response+spill+biosafety&wordsMode=0) involving biohazardous materials. Comments:       |

**Section VIII: Biohazardous Materials Storage ONLY**

List all biohazardous materials which **are not actively being used** and which will only be maintained in storage for potential future use (Note: IBC approval will be needed to actively use these materials in the future).

|  |  |  |
| --- | --- | --- |
| **Biohazardous Material** | **Storage Location** | **Storage Description** (e.g. freezer, liquid nitrogen) |
| 1.       |       |       |
| 2.       |       |       |
| 3.       |       |       |
| 4.       |       |       |
| 5.       |       |       |
| 6.       |       |       |
| 7.       |       |       |
| 8.       |       |       |
| 9.       |       |       |
| 10.      |       |       |
| 11.      |       |       |
| 12.      |       |       |
| 13.      |       |       |
| 14.      |       |       |
| 15.      |       |       |

 *Contact the IBC, if you need to add more rows to this table.*

**Section IX: Investigator Assurance**

By signing my name below, I attest that:

[ ]  The information provided in this protocol form is accurate and complete.

[ ]  No work that requires IBC approval will be initiated or modified until approval is granted.

[ ]  I acknowledge my responsibility for the conduct of this research in accordance with University Policy,

[Section IV-B-7](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457063) of the current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ([NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm)) and recommendations of the CDC/NIH published in the [Biosafety in Microbiological and Biomedical Laboratories (BMBL).](https://www.cdc.gov/labs/BMBL.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fbiosafety%2Fpublications%2Fbmbl5%2Findex.htm)

[ ]  I will comply with the [OSHA Bloodborne Pathogens (BBP) Standard 29 CFR 1910.1030](https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030), if I plan to work with human-derived materials such as cells, tissues, blood. This includes [annual training](https://ehs.uc.edu/itc/compliance.aspx) of authorized personnel, including myself.

[ ]  I will ensure that all authorized personnel, and myself, complete any other applicable training (e.g. Viral Vector, Biosafety Cabinets).

[ ]  I will follow all BSL3 Facility SOPs, if doing BSL3 work.

[ ]  I have familiarized myself, and will ensure that authorized personnel familiarize themselves, with the UC procedures for [laboratory accidents involving the biohazardous materials](https://research.uc.edu/support/offices/biosafety/lab-accidents) and will immediately report any accident to the Biosafety and Environmental Health and Safety Offices.

 **Date** Click or tap to enter a date.

|  |  |
| --- | --- |
|  |  |
| **PI Signature** (paste the picture of your signature above) |  |  |