

**Institutional Biosafety Committee**

**Biological Use Authorization Form (BUA)**

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| --- | --- | --- | --- | --- |
| **New Submission  Renewal: Previous IBC # Click to enter text** | | | | |
| **Tab or place cursor in field to fill in document** | | | | |
| **PRINCIPAL INVESTIGATOR:** |  |  | **Click to enter text** |
| Department: | **Click to enter text** | Phone #: | **Click to enter text** |
| Building, Office Room # | **Click to enter text** | Email: | **Click to enter text** |
|  | | | | |
| **CO-INVESTIGATOR:** | **Click to enter text** |  | **Click to enter text** |
| Department: | **Click to enter text** | Phone #: | **Click to enter text** |
| Building, Office Room # | **Click to enter text** | Email: | **Click to enter text** |

The University’s Institutional Biosafety Committee (IBC) is comprised of both active researchers and lay persons. Each member has one vote, and it is therefore particularly important that the language used in each section of the application be understood by all. Present the goals and justifications of the proposed research in the clearest possible terms. Upon approval, this disclosure may become a public record, so do not disclose proprietary information.

1. **SYNOPSIS**

In the box below, provide a brief synopsis of the proposed project(s)/course(s) in lay terms including, if appropriate, a graphical abstract, as well as information regarding the experiments to be performed:

|  |
| --- |
| **Click to enter text** |

1. **CONTAINMENT**

Select the required biosafety containment level (BSL 1, 2, 3; Use Biological Risk Assessment Worksheet determination): **Select biosafety level**

1. **RESEARCH MATERIALS**

Select and list all materials used in experiments:

1. Human/NHP Products – blood and blood products, tissues, bodily fluids, archaeological samples:

**Click to enter text**

1. Primary Cells or Cell Lines (include species of origin):

**Click to enter text**

1. Microorganisms – bacteria, viruses, yeasts, parasites, algae, etc.:

**Click to enter text**

1. Are any microorganisms transgenic?

No Yes: **Click to enter text**

1. Recombinant and/or Synthetic Nucleic Acids (fill out Appendix A)
2. Arthropods:

**Click to enter text**

1. Are any arthropods transgenic?

No Yes: **Click to enter text**

1. Whole Plants or Fungi:

**Click to enter text**

1. Are any plants or fungi transgenic?

No Yes: **Click to enter text**

1. Environmental Samples:

**Click to enter text**

1. Toxins of Biological Origin:

**Click to enter text**

1. Human Subjects IRB Protocol #: **Click to enter text**
2. Animals: IACUC Protocol #: **Click to enter text**

**Click to list animals**

1. Are any animals transgenic?

No Yes: **Click to enter text**

1. Are any materials listed above (A. through I.) used with animals?

No Yes: **Click to enter text**

1. **METHODS**
2. Select all methods used and include additional information as needed:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Pipetting | Vortex/Mixing | Blending | Sonication | Grinding |
| Glassware | Scalpels, Scissors, Razors | | Injecting Animals | Excretion by Animals |
| Needles, type: **Click to enter text** Intended procedures for needles: **Click to enter text** | | | | |
| Centrifuging using:  Sealed Rotors Safety Cup | | | | |
| Other: **Click to enter text** | | | | |

1. List all procedures that are performed in a biosafety cabinet (if applicable):

**Click to enter text**

1. Will there be any transfer or transport of biohazardous material?

No Yes (if yes, explain transfer/transport procedures): **Click to enter text**

1. **SPECIAL CONSIDERATIONS**

Does the proposed research (include explanations for those marked “Yes”):

1. Involve any material volumes of 10 liters or larger?

No Yes: **Click to enter text**

1. Involve an intentional release into the environment?

No Yes: **Click to enter text**

1. Enhance the harmful consequences of a biological agent/toxin (e.g. increase pathogenicity/symptom severity)?

No Yes: **Click to enter text**

1. Disrupt immunity or the effectiveness of immunization without clinical and/or agricultural justification?

No Yes: **Click to enter text**

1. Confer to a biological agent/toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent/toxin or facilitate their ability to evade detection methodologies?

No Yes: **Click to enter text**

1. Increase the stability, transmissibility, or the ability to disseminate a biological agent/toxin?

No Yes: **Click to enter text**

1. Alter the host range or tropism of a biological agent or toxin?

No Yes: **Click to enter text**

1. Enhance the susceptibility of a host population?

No Yes: **Click to enter text**

1. Generate a novel pathogenic agent/toxin, or reconstitute an eradicated or extinct biological agent?

No Yes: **Click to enter text**

1. Are you using any biological select agents (click [here](http://www.selectagents.gov/SelectAgentsandToxinsList.html) for a list)?

No Yes (if yes, complete and submit this ): **Click to enter text**

1. Select any of the following agents, including nucleic acids from the agents, or toxins that you use:

|  |  |  |
| --- | --- | --- |
| Avian influenza virus (highly pathogenic) | *Bacillus anthracis* | *Botulinum* neurotoxin |
| *Burkholderia mallei* | *Burkholderia pseudomallei* | Ebola virus |
| Foot-and-mouth disease virus | *Francisella tularensis* | Marburg virus |
| Reconstructed 1918 Influenza virus | Rinderpest virus | Toxin-producing strains of *Clostridium botulinum* |
| Variola major virus | Variola minor virus | *Yersinia pestis* |

1. **SAFETY**
2. Attach and submit a copy of the following documents as separate files (use this check-list to verify):
3. Accidental Spill and Exposure Procedures (see Cal Poly Biosafety Program)
4. Biohazardous Disposal Procedures (refer to Cal Poly Biosafety Program)
5. Standard Operating Procedures (SOPs) related to this project
6. Select all personal protective equipment (PPE) or safety equipment used:

|  |  |  |
| --- | --- | --- |
| Lab Coat | Gloves | Cover Gown/Booties |
| Safety Glasses | Goggles | Surgical Mask |
| Face Shield | Respirator, type: **Click to enter text** | | |
| Biological Safety Cabinet (BSC)  Non-ducted or  Hard-ducted | | | |
| Other: **Click to enter text** | | | |

1. If working with animals, will the animals, caging, bedding material, or other animal equipment be contaminated with hazardous materials that will pose a risk to personnel handling these animals?

No Yes: **Click to enter text**

1. Do any of the proposed materials pose a health risk to humans?

No Yes (If yes, attach and submit a copy of the material’s Hazard Information Sheet)

1. Medical surveillance requirements; exposure and medical intervention:
2. Are personnel at risk of infection or disease from the use of the biohazard(s) or hazardous drug(s) (e.g. pregnant, immune-compromised, allergic, etc.)?

No Yes: **Click to enter text**

1. Are any special immunizations or vaccinations needed or provided for personnel involved in the research (e.g. Hepatitis B, Tetanus/Tdap, etc.)?

No Yes: **Click to enter text**

1. Is there a need to monitor the health of personnel involved (e.g. serum banking, continued testing)?

No Yes: **Click to enter text**

1. Are any agents being used resistant to any therapeutics used for treatment? This information will be forwarded to health services in the case of an emergency.

No Yes: **Click to enter text**

1. **LOCATIONS**

List all locations associated with this project:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Campus** | **Building** | **Room** | **Room Function** | **Cold Storage Type** | **IBC Use Only**  **Inspection** |
| **Example:**  **Cal Poly** | **52** | **A12** | **Lab  Storage  Live Animals** | **4 °C  -20 °C  -80 °C  LN2** | **1/10/17** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Lab  Storage  Live Animals** | **4 °C  -20 °C  -80 °C  LN2** | **IBC only** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Lab  Storage  Live Animals** | **4 °C  -20 °C  -80 °C  LN2** | **IBC only** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Lab  Storage  Live Animals** | **4 °C  -20 °C  -80 °C  LN2** | **IBC only** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Lab  Storage  Live Animals** | **4 °C  -20 °C  -80 °C  LN2** | **IBC only** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Lab  Storage  Live Animals** | **4 °C  -20 °C  -80 °C  LN2** | **IBC only** |

1. **PERSONNEL**

All personnel must have biosafety training prior to working in the laboratory. Biosafety Officer/IBC to assign and verify the training based on biosafety level and materials used.

1. Indicate the Principal Investigator’s degree, training, experience and proficiency working with the materials on this disclosure.

|  |  |
| --- | --- |
| **Click to enter text** | **Biosafety Training Verification** |
| **IBC only** |

1. Identify all personnel conducting the experiment(s). Specify degree, project responsibilities, and applicable training and experience (including experience duration):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Participant Name** | **Cal Poly ID** | **Degree** | **Project Responsibilities** | **Prior Experience or Training Related to Responsibilities** | **Biosafety Training Verification** |
| **Example: John Smith** | **Jsmith1** | **B.Sc.** | **miRNA extraction from whole blood, urine, and saliva qPCR** | **1 yr. BSL2 bench experience during undergraduate studies performing PCR; 3 week training by lab manager** | **12/21/16** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Click to enter text** | **Click to enter text** | **IBC only** |
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1. **FUNDING**

List all external funding associated with the project(s) covered by this disclosure:

|  |  |  |  |
| --- | --- | --- | --- |
| **Sponsor** | **Cal Poly Proposal or Award Number** | **Title** | **Status** |
|
| **Example: NIH** | **GDO-#01-1** | **Concussions and minor traumatic brain injuries in athletes** | **Pending** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Choose an item** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Choose an item** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Choose an item** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Choose an item** |

By signing below, you are agreeing 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 Cal Poly State University will also be followed.

**Principal Investigator’s Signature: Click to enter text** **Date:** **Click to enter date**

Send the completed form to:

IBC, Office of Research and Development

By Email: research-compliance@calpoly.edu

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

**APPENDIX A – RECOMBINANT/SYNTHETIC NUCLEIC ACIDS**

1. Briefly describe, in lay terms, the work to be performed with recombinant or synthetic nucleic acid molecules.

|  |
| --- |
| **Click to enter text** |

1. List the vectors included in this project:

|  |  |  |
| --- | --- | --- |
| **Vector Type**  (plasmid, viral, phage, etc.) | **Technical Name**  (include vendor if applicable) | **Gene Transfer Method** (transformation, transfection, electroporation, etc.) |
| **Click to enter text** | **Click to enter text** | **Click to enter text** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** |
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| **Click to enter text** | **Click to enter text** | **Click to enter text** |

1. List the genes/nucleic acids included in this project:

|  |  |  |  |
| --- | --- | --- | --- |
| **Gene/Nucleic Acid**  (specific name of gene, promoter, regulatory sequence, etc.) | **Source Organism**  (genus and species or common name) | **Nature of Insert or Protein Expressed**  (reporter gene, virulence factor, DNA repair, etc.) | **Use/Purpose**  (cloning for sequencing, PCR, expression, etc.) |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Click to enter text** |
| **Click to enter text** | **Click to enter text** | **Click to enter text** | **Click to enter text** |
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1. Attach and submit a detailed map of a representative sample of the vectors and inserts to be used. Indicate any regions that increase the safety of this construct. Provide copies of key references that describe the construction of the vector(s) used.
2. List any proteins that are produced:

**Click to enter text**

1. Will the nucleic acids contain genes for the biosynthesis of toxic molecules lethal to vertebrates?

No Yes (If yes, list the toxin’s LD50): **Click to enter text**

1. Will the nucleic acids contain genetic material from [select agents or toxins](https://www.selectagents.gov/SelectAgentsandToxinsList.html)?

No Yes: **Click to enter text**

1. What is the maximum volume of culture per container used at any one time?

**Click to enter text**

1. Is secondary containment used?

No Yes (If yes, describe the containment): **Click to enter text**

1. If using a virus vector:
   1. Describe how nucleic acids will be used to create the virus:

**Click to enter text**

* 1. What will host the virus vector?

**Click to enter text**

* 1. Are nucleic acid molecules containing ≥ 2/3 of the genome of any eukaryotic virus created?

No Yes: **Click to enter text**

* 1. Do experiments involve the use of infectious human, animal, or plant viruses?

No Yes: **Click to enter text**

* 1. Do experiments involve the use of defective animal or plant viruses in the presence of a helper virus?

No Yes (if yes, attach your procedures to determine the relative proportions of helper virus and defective virus): **Click to enter text**

* 1. Are the nucleic acids likely to make the virus more pathogenic?

No Yes: **Click to enter text**

1. Are oncogenic genes being used?

No Yes (If yes, identify which are oncogenic): **Click to enter text**

1. Does your research involve a gene editing technology?

No Yes (If yes, select the technology/technologies being proposed):

|  |  |  |  |
| --- | --- | --- | --- |
| CRISPR/Cas9 | ZFN | TALENS | Meganucleases |
| Other: **Click to enter text** | | | |

1. Will the genome editing technology be used in prokaryotes, eukaryotes, or mammalian cells?

No Yes (If yes, specify which): **Click to enter text**

1. How is the gene editing technology being delivered (e.g., nanoparticles, plasmid, lentivirus, adeno-associated virus, etc.)?

**Click to enter text**

1. Will the gene editing technology target embryos or germ line cells?

No Yes: **Click to enter text**

1. Will the gene editing technology be used for human gene transfer research?

No Yes: **Click to enter text**

1. For CRISPR/Cas9 systems, are the guide RNA (gRNA) and nuclease on the same plasmid, vector, or delivery vehicle?

No Yes (If yes, explain if this plasmid, vector, or delivery vehicle can transfect or infect a human cell and explain if the gRNA or CRISPR nuclease can be expressed in human cells): **Click to enter text**

1. For CRISPR/Cas9 systems, are you inserting the gene for Cas9 (or a similar nuclease) and a guide RNA into the chromosome of a sexually reproducing organism?

No Yes: **Click to enter text**

1. For CRISPR/Cas9 research involving viral vectors, a Genome Target Scan (GT-Scan) for off target effects by your gRNA must be completed. This is necessary to determine if there is homology to human DNA and for assessing the risk of potential exposure in the event of an unanticipated incident (Bae et al., 2014; O’Brien and Bailey, 2014). An off-target database is available [here](http://www.rgenome.net/cas-offinder/).
2. Will the inserted nucleic acid sequences contain a guide RNA that can target the insertional locus of the unmodified chromosome?

No Yes I don’t know

1. Can the inserted nucleic acids act as a gene drive (i.e., can the inserted sequences in any way alter Mendelian inheritance at this locus)?

No Yes I don’t know

**NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES**

The *NIH Guidelines* can be found at: <http://osp.od.nih.gov/office-biotechnology-activities/biosafety>

On the following pages, select all *NIH Guidelines* categories that apply to your research:

|  |  |  |
| --- | --- | --- |
| **SECTION III-F includes recombinant or synthetic nucleic acid molecules that are exempt from the *NIH Guidelines*, but still require registration with the Institutional Biosafety Committee:** | | |
|  | **III-F-1:** | Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell, and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. |
|  | **III-F-2:** | Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes. |
|  | **III-F-3:** | Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. |
|  | **III-F-4:** | Those that consist entirely of nucleic acids from a non-pathogenic prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another non-pathogenic host by well-established physiological means. |
|  | **III-F-5:** | Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species). |
|  | **III-F-6:** | Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. |
|  | **III-F-7:** | Those genomic DNA molecules that have acquired a transposable element provided the transposable element does not contain any recombinant and/or synthetic DNA. |
|  | **III-F-8:** | Those that do not present a significant risk to health or the environment as determined by the NIH Director. Check the appropriate appendices below. |
| **SECTION III-F-8 Appendices** | | |
|  | **C-I:** | Recombinant or synthetic nucleic acid molecules containing less than one-half of any eukaryotic viral genome that are propagated and maintained in cells in tissue culture. |
|  | **C-II:** | Experiments that use *Escherichia coli* K-12 host-vector systems. |
|  | **C-III:** | Experiments involving *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host-vector systems. |
|  | **C-IV:** | Experiments involving *Kluyveromyces lactis* host-vector systems. |
|  | **C-V:** | Experiments involving *Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems. |
|  | **C-VI:** | Extrachromosomal Elements of Gram Positive Organisms. |
|  | **C-VII:** | The purchase or transfer of transgenic rodents, BSL1 only. |
|  | **C-VIII:** | Generation of BSL1 transgenic rodents via breeding. |

|  |  |  |
| --- | --- | --- |
| **SECTION III-E covers experiments not found in sections A, B, C, D, and F, and are not exempt from the *NIH Guidelines*, but still require Institutional Biosafety Committee notice simultaneous with initiation of work:** | | |
|  | **III-E:** | Experiments not included in Sections III-A, III-B, III-C, III-D, III-F; and experiments in which all components are derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes and may be conducted at BSL1. |
|  | **III-E-1:** | Recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus may be propagated and maintained in cells in tissue culture (BSL1). For such experiments, it must be demonstrated that the cells lack helper virus for the specific families of defective viruses being used. |
|  | **III-E-2:** | Experiments involving nucleic acid molecule-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants. |
|  | **III-E-3:** | Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). BSL1 containment only. Experiments BSL2 or higher are covered under Section III-D-4. |

|  |  |  |
| --- | --- | --- |
| **SECTION III-D covers experiments that require Institutional Biosafety Committee notice prior to initiation of work:** | | |
|  | **III-D-1:** | Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as host-vector systems. |
| **Select Risk Group:  RG2  RG3  RG4** | | |
|  | **III-D-2:** | Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems. |
| **Select Risk Group:  RG2  RG3  RG4** | | |
|  | **III-D-3:** | Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems. |
| **Select Risk Group:  RG2  RG3  RG4** | | |
|  | **III-D-4:** | Recombinant or synthetic nucleic acid experiments involving whole animals (e.g., non-human vertebrate or invertebrate organism, including arthropods). |
| **Select Risk Group:  RG1  RG2 or RG3** | | |
|  | **III-D-5:** | Experiments involving whole plants or insects. Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules (BSL2 or higher). |
|  | **III-D-6:** | Experiments involving more than 10 liters of culture in a single culture vessel. |
|  | **III-D-7:** | Experiments involving influenza viruses. |
| **Risk Group Definitions** | | |
| **Risk Group 1 (RG1):** Agents that are not associated with disease in healthy adult humans.  **Risk Group 2 (RG2):** Agents are associated with human disease which is rarely serous and for which preventative or therapeutic interventions are often available.  **Risk Group 3 (RG3):** Agents that are associated with serious or lethal human disease for which preventative or therapeutic interventions may not be available.  **Risk Group 4 (RG4):** Agents are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are not usually available. | | |

|  |  |  |
| --- | --- | --- |
| **Experiments that fall under sections A, B, and C require NIH pre-approval. Contact the IBC Office for assistance.** | | |
|  | **III-A-1:** | The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the ability to control disease agents in humans, animals, or plants. |
|  | **III-B-1:** | Experiments involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight. |
|  | **III-C-1:** | Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants. |