# IBC PROTOCOL REGISTRATION FORM

University of Hawaii Institutional Biosafety Committee

| ***Registration Type*** | For UH IBC use only |
|---|---|
| ☐ New IBC Registration .<br>☐ Exempt Protocol (see II:B)<br>☐ Amendment to IBC Protocol No. _____<br>☐ Renewal to IBC Protocol No. _____ | Date Received: _____<br>UH IBC Protocol No.: _____<br>NIH Classification: BSL: _____ RG: _____ |

Registration is required prior to use of recombinant, synthetic nucleic acid activities, biological materials (human and animal blood, body fluids, tissues), animal, human and plant pathogens, and imported live biological materials. Required by NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, University of Hawaii Institutional Biosafety Program, and related Federal, State and University policies.

Technical information relating to this registration is considered confidential.

All Sections of this registration must be completed, with supporting documentation included. This registration document is meant to provide sufficient detailed information regarding each Biohazardous/Recombinant DNA research project so that it may be adequately reviewed by the Institutional Biosafety Committee. Do not provide excess information. Discuss with the Institutional Biosafety Program as needed. Please refer to https://www.hawaii.edu/researchcompliance/Biological-Safety for detailed information on the IBC.

Use Acrobat-compatible software to fill in the form or complete a printed hardcopy of this form.

Email completed PDF or scanned form to UHIBC@hawaii.edu, or fax to 956-3690.

## I. ADMINISTRATIVE DATA

### A. Principal Investigator:

| Name: | | Email Address: |
|---|---|---|
| Address: | | Office Room #: |
| Department: | Phone #: | Other Contact #: |
| ☐ Manoa ☐ Hilo ☐ West Oahu ☐ Maui ☐ Hawaii ☐ Honolulu<br>☐ Kapiolani ☐ Kauai ☐ Leeward ☐ Windward ☐ Other _____ | | |

### B. Project Information:

| Project Title for IBC Registration: | |
|---|---|
| Granting Agency Proposal Title: | |
| Granting Agency: | ORS Project #: |

## C. Amendment Type:

### 1. Major Amendments:

All major changes require a complete registration form and full committee review.

☐ Change in scope of research ☐ Additional research projects/procedures ☐ Change of Principal Investigator

| Reason for Major Change(s): |
|---|
| |

### 2. Minor Changes:

Dependent upon the type of changes, full IBC Review may not be required. Sections III and VI may need to be updated. Contact the Institutional Biosafety Program.

☐ Additional Title ☐ Add/Change Lab Location: *Update Section VI.A.*

☐ Add or Delete Personnel: *Update Section VI.B. Use additional sheets if necessary.*

Update Section III for the following: ☐ Animal Strains ☐ Animal Material ☐ Human Material

☐ Plant Material ☐ Cell Lines ☐ Genetic Constructs ☐ Others (*explain*)

| Description of Minor Change(s): |
|---|
| |

## D. Summary of Biomaterials

**This project utilizes:** *(Check all that apply)*

| | | | |
|---|---|---|---|
| ☐ | Biologically Derived Toxins | ☐ | Plants/Plant Parts/Algae |
| ☐ | Prions and Related Biomolecules | ☐ | Large-scale (>10 L) production |
| ☐ | Recombinant Activity/Synthetic Nucleic Acid | ☐ | Environmental Samples (soil, water) |
| ☐ | Microorganisms | ☐ | Diagnostic/Clinical Samples (blood, urine, etc.) |
| ☐ | Infectious Materials | ☐ | Human Origin Material (contact IRB) |
| ☐ | Cell Lines/Tissues | ☐ | Engineered Nanomaterials |
| ☐ | Invertebrate Animals | ☐ | Select Agents (www.selectagents.gov) |
| ☐ | Vertebrate Animals | ☐ | DURC Concerns or Other |

# II. PROJECT CLASSIFICATION

## A. Brief Project Description for the Layman

Briefly describe the purpose of the project using non-scientific language (layman's terms) so that a person with a high school education can understand. <u>This project description, title, and PI name will be in the publicly available IBC minutes.</u>

| Please restrict to 3-5 sentences. |
|---|
| |

## B. Determine if Exempt per NIH Guidelines, Section III-F

| Item # | NO | YES | Question |
|---|---|---|---|
| B.1 | ☐ | ☐ | This project ONLY includes rDNA manipulation involving *E. coli* K12, *S. cerevisiae*, and *B. subtilis* host vector systems (with the exception of DNA from Risk Group 3, 4, or restricted agents). |

**IF YES, THEN** this registration is exempt and you may **Proceed to Section III**. Exempt registrations are reviewed by an expedited process. An HDOA Import and Use permit is required if importing into the state**.**

| Item # | NO | YES | Question |
|---|---|---|---|
| B.2 | ☐ | ☐ | Does this project NOT utilize organisms or viruses (PCR or sequencing only, no inoculation into cells, cloning into competent cell, viral vectors, etc.)? |
| B.3 | ☐ | ☐ | Does this project ONLY consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent? |
| B.4 | ☐ | ☐ | Does this project ONLY consist entirely of DNA from a 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 host by well-established physiological means? |
| B.5 | ☐ | ☐ | Does this project ONLY consist entirely of DNA 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)? |
| B.6 | ☐ | ☐ | Does this project ONLY 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? A list of such exchangers can be found in the NIH Guidelines Section IV-C-1-b-(1)-(c), Major Actions. For a list of natural exchangers that are exempt from the NIH Guidelines, see NIH Guidelines Appendices A-I through A-VI, Exemptions under Section III-F-5--Sub lists of Natural Exchangers. |
| B.7 | ☐ | ☐ | Does this project NOT present a significant risk to health or the environment (see NIH Guidelines Section IV-C-1-b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment? See NIH Guidelines Appendix C, Exemptions under Section III-F-6 for other classes of experiments which are exempt from the NIH Guidelines. |
| B.8 | ☐ | ☐ | Does this project ONLY involve the purchase or transfer of transgenic rodents for experiments that require Biosafety Level 1 containment (The Purchase or Transfer of Transgenic Rodents, Appendix C-VII)? |
| B.9 | ☐ | ☐ | Does this project ONLY involve the breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at Biosafety Level 1 containment? |

**IF any YES box is checked, THEN** this registration is Exempt and you may **Proceed to Section III**. Exempt registrations are reviewed by an expedited process.

| Item # | NO | YES | Question |
|---|---|---|---|
| B.10 | ☐ | ☐ | Does this project ONLY involve the breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at Biosafety Level 1 containment<br>AND |
| | ☐ | ☐ | Both parental rodents can be housed under BL1 containment;<br>AND |
| | ☐ | ☐ | neither parental transgenic rodent contains the following genetic modifications:<br>(i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses;<br>OR<br>(ii) incorporation of a transgene that is under the control of a gamma-retroviral long terminal repeat (LTR);<br>AND |
| | ☐ | ☐ | the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses. (Generation of BL1 Transgenic Rodents via Breeding - Appendix C- VIII). |

**IF ALL YES boxes are checked, THEN** this registration is Exempt and you may **Proceed to Section III**. Exempt registrations are reviewed by an expedited process.

## C. Description of Non-Exempt Projects:

| Item # | Please check all boxes that apply. | |
|---|---|---|
| C.1 | ☐ | Include deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (Section III-A*)? |
| C.1a | ☐ | If answered "YES" for C.1 (above), could such a transfer compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture? |
| C.2 | ☐ | Include cloning toxin molecules with an LD50 of less than 100 nanograms per kilogram body weight (Section III-B*)? |
| C.3 | ☐ | Include experiments involving the deliberate transfer of recombinant DNA, synthetic nucleic acids, or DNA or RNA derived from recombinant DNA, into one or more human research participants (Section III-C*)? |
| C.4 | ☐ | Include experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Select Agents as host-vector systems (Section III-D-1*)? |
| C.5 | ☐ | Include experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Select Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems (Section III-D-2*)? |
| C.6 | ☐ | Include experiments involving the use of replication-competent recombinant DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems (Section III-D-3*)? |
| C.7 | ☐ | Include experiments with recombinant influenza virus? |
| C.8 | ☐ | Include experiments involving whole animals in which the animal's genome has been altered by introduction of DNA into the germ line (i.e. transgenic animals) (Section III-D-4, III-E-3*). |
| C.8a | ☐ | If answered "YES" for C.8 (above), does the animal contain a transgene encoding more than 50% of the genome of an exogenous eukaryotic virus? |
| C.8b | ☐ | If answered "YES" for C.8 (above), Is the transgene under the control of a gamma-retroviral promoter? |
| C.9 | ☐ | Include experiments involving viable rDNA-modified microorganisms tested on animals (Section III-D-4, III-E-3*)? |
| C.10 | ☐ | Include experiments involving genetically engineered whole plants (Section III-D-5, III-E-2*)? |
| C.11 | ☐ | Include experiments involving more than 10 liters of culture (Section III-D-6*)? |
| C.12 | ☐ | Include experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus and propagated in tissue culture (Section III-E-1*)? |
| C.13 | ☐ | Utilizes Select Agents (defined by HHS/CDC/USDA Select Agent Program) |
| C.14 | ☐ | Require biosafety level 3 containment (BSL3)? |
| C.15 | ☐ | Dual Use Research of Concern Agents or Toxins |
| C.16 | ☐ | Requires Federal or State import permit (HDOA, DLNR, CDC, USDA, NFWS, Commerce) |
| C.17 | ☐ | Utilizes unmodified Genomic Material only (e.g., DNA or RNA for sequence or expression analysis) |

## D. Suggested NIH Classification

Derived from NIH Guidelines (http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines).
Applicant-determined designation may change upon IBC review.

| Please check all boxes that apply: | | | NIH Guidelines reference |
|---|---|---|---|
| D.1 | ☐ | Use of animal cells/cell lines or tissues (e.g. tissue culture research) | II-A-3, Appendix C-1 |
| D.2 | ☐ | Use of human cells/cell lines or tissues (e.g. Human blood, 293 cell lines, CSF) | II-A-3 |

| | | | |
|---|---|---|---|
| D.3 | ☐ | Transfer of Drug Resistance trait to microorganisms | III-A-1-a |
| D.4 | ☐ | Use or cloning of toxin molecule genes | III-B-1 |
| D.5 | ☐ | Use of or the cloning of genes from, or into a Risk Group 2, 3, 4 or restricted agent | III-D-1, 2 |
| D.6 | ☐ | Use of virus or viral particles | III-D-3, III-E-1 |
| D.7 | ☐ | Propagating culture volumes exceeding 10 liters | III-D-6 |
| D.8 | ☐ | Creation or Use of c-DNA/genomic libraries | III-E, III-F |
| D.9 | ☐ | Cloning and vector construction in bacteria and yeasts | III-E, III-F |
| D.10 | ☐ | Use of rDNA molecules for detection purposes (e.g. probes) | III-F |
| D.11 | ☐ | Expression of rDNA products in cultured cells | III-E, III-F |
| D.12 | ☐ | Administration of rDNA product into humans (e.g. Gene Transfer Protocol) | III-C-1 |
| D.13 | ☐ | Administration of rDNA material into animals (e.g. transformed cells, vectors) | III-D-4 |
| D.14 | ☐ | Experiments involving transgenic rodents | III-E-3 |
| D.15 | ☐ | Experiments involving whole transgenic plants | III-D-5 |
| D.16 | ☐ | This is an EXEMPT project, per Section II.B. | III-F |
| D.17 | ☐ | Select Agent or Toxins | |
| | | | |

# III. DESCRIPTION OF BIOLOGICAL MATERIALS

## A. Nanomaterials

The CDC defines a technology as engineered nanotechnology only if it involves all of the following:

- Research and technology development involving structures with at least one dimension in the range of 1 to100 nanometers (nm), frequently with atomic/molecular precision
- Creating and using structures, devices, and systems that have unique properties and functions because of their nanometer-scale dimensions
- The ability to control or manipulate on the atomic scale

see: http://www.cdc.gov/niosh/nas/RDRP/appendices/chapter7/a7-2.pdf and http://www.niehs.nih.gov/health/topics/agents/sya-nano/

This project uses engineered nanomaterials? ☐ NO: ☐ YES

| IF YES, THEN please describe the nanomaterials and how they will be utilized |
|---|
| |

## B. Biotoxins

Does the project require possession of, use of, or transfer of acute biological toxins (mammalian LD50 <100 µg/kg body weight) or toxins that fall under the Federal Select Agent Guidelines, as well as the organisms, both natural and recombinant, which produce these toxins? ☐ NO ☐ YES

IF Yes THEN *Complete this section, describe the work & relevant SOPs in an attachment.*

Name of Toxin: _____ Current Inventory: _____

**Comment [SS1]:** are we really asking for SOPs here and with animal handling? We will get volumes of useless info

1. Attach a biotoxin-specific plan for storage, handling, waste disposal/neutralization.
2. Biological toxin will be commercially acquired ☐ or produced in the laboratory ☐.
3. Experiments involve cloning a biological toxin gene. ☐
4. Will be used in animals (dosing). ☐

## C. Recombinant and Synthetic Nucleic Acids

**Refer to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules***

Does this work involve Recombinant/Synthetic Nucleic Acid Molecule Activity?

☐ YES *Complete this section.* ☐ NO *Do not complete this section. Go to Section III.D.*

### 1. Source of Nucleic Acid Sequence

| Name (Gene/siRNA Name, e.g. GFP green fluorescent protein) | Source (species, strain, cell line, cultivar, Vendor/Supplier) | Function of the genetic element |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

### 2. Nature of the Modified DNA

Describe the functional and structural elements of the recombinant DNA, including the regulatory and/or coding regions, percentage of the entire genome, promoter, synthetic antisense sequence, etc. Will this element be expressed? What is your risk assessment of the sequence (*tumor suppressor, oncogene, etc)?*

| |
|---|
| |

### 3. Vectors

List the cloning and delivery vector(s) used, including selectable marker(s), reporter genes(s), oncogenes, promoters, packaging cell line, assay system for detection, quantification, and/or host range of packaged viral vector. Vector packaged in competent cells (E. coli), other host microbes must have a HDOA import permit. Detail the Risk Attenuation Phenotype (e.g. replication defective, helper virus, disarmed, K-12 derived, potential for reversion, etc…). *****Reference any literature from commercially available vectors*****

| Name (include the genus species if derived from plasmid/virus) | Type (plasmid, phage, virus, etc…) | Source (Vendor/Supplier) | Generation ($1^{st}$ , $2^{nd}$, $3^{rd}$, $4^{th}$, etc..) | Risk Attenuation Phenotype |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

### 4. Recipient Organism

*Specify the type of organism, species, strain, cell line, or cultivar receiving the nucleic acid.*

| |
|---|
| |

**5. Will you express a toxin or oncogene?**

☐ NO ☐ YES *Specify*

**6. Will the vector host range be altered?**

☐ NO ☐ YES *Describe below*

***7.*** **Will the project use infectious DNA/RNA viruses, defective DNA/RNA viruses, or phages in the presence of helper virus in a tissue culture system?**

☐ NO ☐ YES *Provide details on the pathogenicity, host range or generation system*

## D. Microorganisms

Identify and describe microorganisms to be employed by this protocol.

| Microorganism Name (genus, species, strain name) | Source | Human Pathogen | Animal Pathogen | Plant Pathogen | Produce Toxin | *In Vivo* Use | Receive rDNA material |
|---|---|---|---|---|---|---|---|
| | | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

## E. Cell Lines and Tissues

Identify and describe cells and tissues to be employed by this protocol.

| Cell Lines/Tissue Name | Source | Technical Name (e.g. NIH3T3) | Passage (Primary/ Established/ Immortalized) | In Vivo Use | Receive rDNA construct | Receive microorganism | Chemically altered |
|---|---|---|---|---|---|---|---|
| | | | | ☐ | ☐ | ☐ | ☐ |
| | | | | ☐ | ☐ | ☐ | ☐ |

☐ YES ☐ NO Does this Cell line contains latent, adventious, or inherent microorganisms or virus (e.g., HEK and adenovirus)

## F. Animals

### 1. Will you use animals?

☐ NO *(Proceed to Part III.G)* ☐ YES *(Complete this section. Attach relevant animal use SOP)*

☐ Vertebrate ☐ Invertebrate

### 2. List all animal species and research locations.

| Animal Species/Strains | Location of Animal Research | ABSL designation |
|---|---|---|
| | | |
| | | |
| | | |

### 3. Hazards from animals

Do any of the strains or manipulated animals present a hazard that would require more than ABSL-1 (BSL1-N) housing?

☐ NO ☐ YES (complete entire animal part of IBC registration)

### 4. List all transgenic animals

Include animals to be acquired and/or breeding/cross-breeding. (Attach an additional sheet if needed)

| Background Strain: | Line Designation to be Crossed | Source of Line |
|---|---|---|
| | | |
| | | |
| | | |

### 5. Description of Transgenic Animals

| Please check all boxes that apply: | | |
|---|---|---|
| III.F.5.a | ☐ | The animals contain more than one-half of the genome of an exogenous eukaryotic virus. |
| III.F.5.b | ☐ | If cross-breeding, the offspring have transgenes under the control of LTR and contain more than one-half of the exogenous viral genome |
| III.F.5.c | ☐ | Transgenes are under control of gamma-retroviral long terminal repeat (LRT). |

### 6. Acquisition and Breeding of Transgenic Animals

| Please check all boxes that apply: | | | |
|---|---|---|---|
| III.F.6.a | ☐ | Transgenic animals will be purchased. | VENDOR: |
| III.F.6.b | ☐ | Transgenic animals will be generated in-house. | |
| III.F.6.c | ☐ | A colony of transgenic animals will be maintained. | |
| III.F.6.d | ☐ | Transgenic animals will be cross-bread to generate new strains | |

### 7. Will biological materials* be inserted/inoculated/introduced?

☐ NO ☐ YES *(Describe below)*

*If biological material is infectious, use of BSC, negative pressure and restricted entry during manipulation is REQUIRED

### 8. Will there be a potential of biological material being shed from the animal?

☐ NO ☐ YES *(Describe below)*

**9. Does animal waste/bedding require decontamination?**

☐ NO ☐ YES (Attach reference and recommended protocol)

**10. PPE Use**

Describe PPE and biosafety containment use by Laboratory Animal Services. Respond in the Risk Management Section, VI.D.

**11. Will you use venomous, dangerous, endangered or threatened wild animals?**

☐ NO ☐ YES (List below, describe PPE and Biosafety Containment in attachment, and attach a *copy of the permits from DLNR, CITES/NFWS.)*

## G. Plants and Derived Biological Materials

**1. Will you use plants, including plant parts, plant cell lines, but excluding fungi?**

☐ NO *(*Proceed to Part IV.) ☐ YES *(Complete this section. Attach relevant plant use SOP)*

☐ Whole Plant ☐ Plant Part ☐ Plant cell lines

**2. Will you use commercially available de-regulated transgenic plants only?**

☐ NO ☐ YES

**3. Will biological materials be inserted/inoculated/introduced?**

☐ NO ☐ YES *Describe below.*

**4. List all plant species and research locations.**

IF field testing provide location (field allocation no., GPS location of all four corner points).

| Plant Species *(include genus species or variety)* | Has this plant been altered? How? | Location of Research | Greenhouse/ Screen house (Yes/No) | BSL of Greenhouse | Growth Chamber/ Room (Location) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| Field Location: | | | | | |

**5. Will you be using poisonous, dangerous or endangered/threatened plants?**

☐ NO ☐ YES (List below, describe PPE and Biosafety Containment in attachment, and attach a *copy of the permits from DLNR, CITES/NFWS.)*

## IV. EXPERIMENTAL DESIGN

Provide a concise description or summary of your project procedures, placed in sequential order of performance. Attach an additional sheet if needed. **Please do not attach entire protocols.**

## V. RISK ASSESSMENT

### A. Risk Group Classification:

The PI should review *(http://oba.od.nih.gov/oba/rac/Guidelines/APPENDIX_B.htm)* and propose a risk group

☐ Does not apply. No microorganisms, pathogens, or biomaterial are being used that will cause human, plant or animal disease.

☐ **RG1:** Agents that are not associated with disease in healthy adult humans. This group includes a list of animal viral etiologic agents in common use. These agents represent no or little risk to an individual and no or little risk to the community.

☐ **RG2:** Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. These agents represent a moderate risk to an individual but a low risk to the community.

☐ **RG3:** Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. These agents represent a high risk to an individual but a low risk to the community.

**RG4:** Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. These agents represent a high risk to the individual and a high risk to the community.. **NO RG-4 RESEARCH IS AUTHORIZED AT THE UNIVERSITY OF HAWAII SYSTEM.**

### B. Host Range of the Biological Material(s).

Required only if RG2 or RG3 was selected above:

### C. Support for Risk Classification

Identify biosafety risks. What would be the impact of a release to the environment? Extract, condense and describe the pertinent biosafety content from your protocol. Cite supporting references and/or URLs as needed (assist the reviewers):

### D. Hazardous Process?

☐ Centrifuge ☐ Sharps ☐ Animal Injection ☐ Sonication ☐ Tissue Harvesting ☐ Pipetting

☐ None ☐ Other (please state): _____

### E. Possible Exposure Routes?

☐ Ingestion ☐ Percutaneous *(i.e. needle puncture)* ☐ Direct Contact ☐ Mucous Membrane ☐ Inhalation

☐ None ☐ Other (please state): _____

## VI. RISK MANAGEMENT

### A. Designated Work Areas

| Building | Room Number | Biosafety Designation (BSL-, ABSL-, BL-P, BL-N…) | Date of Most Recent Biosafety Inspection |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

### B. Movement and Storage

Concisely describe protocol-specific movement and secure storage plans. Attach an additional sheet if needed.

### C. Personnel Training.

Detail all personnel performing manipulations. The PI must be fully trained. *(Separate sheet may be attached if necessary.)*

| Name | Type of Training | Date of Training |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

### D. Personal Protective Equipment (PPE)

☐ Safety Glasses/Goggles ☐ Gloves ☐ Lab Coat ☐ Pipetting ☐ Disposable Lab Gown

☐ Hair Bonnet ☐ Disposable Booties ☐ Pipetting ☐ Surgical Mask ☐ N-95 Respirator* ☐ PAPR*

☐ Other *Describe* _____

* Requires respirator use clearance, fit testing, and training.

### E. Engineering Controls

☐ Biosafety Cabinet ☐ Fume Hood ☐ Centrifuge Rotor Covers

☐ Other *Describe* _____

### F. Equipment Certifications

| Type of Equipment | Manufacturer/Model | Location | Last Certification Date |
|---|---|---|---|
| Biosafety Cabinet | | | |
| Any HEPA equipment | | | |
| Aerosol generating equipment | | | |
| Autoclave | | | |
| How often is an autoclave quality control test (biological indicator test) performed? | | ☐ Annually ☐ Quarterly ☐ Monthly ☐ Not routine | |
| TYPE of Biological Indicator: ☐ spore ☐ Class 5 integrator . | | | |

| | | | |
|---|---|---|---|
| Laminar Flow Clean Bench | | | |
| DO NOT USE a Laminar Flow Clean Bench for Infectious Agents. Laminar Flow Clean Benches are not for worker or environmental protection. They are for Product Protection only | | | |

### G. Decontamination and Waste Disposal

In addition to any attached protocol-specific SOPs, describe how biohazardous materials, waste, carcasses, and bedding will be decontaminated and disposed. Include type of chemical disinfectant, concentration, and time.

## VII. INCIDENT RESPONSE PLAN

### A. Does a written protocol-specific incident response plan exist?

Incidents would include spill, exposure, injury, fire reporting, security breech, etc.

☐ NO ☐ YES (you need NOT attach)

### B. Occupational Health Program

| Item # | NO | YES | Question |
|---|---|---|---|
| B.1 | ☐ | ☐ | Are personnel enrolled in an occupational health or medical surveillance program? |
| B.2 | ☐ | ☐ | Respiratory protection occupational health program (required for any person using a respirator) |
| B.3 | ☐ | ☐ | Tuberculosis testing / surveillance (required for persons who enter the tuberculosis lab) |
| B.4 | ☐ | ☐ | Blood-borne pathogen training and HepB vaccine |
| B.5 | ☐ | ☐ | Other (vaccine, medical surveillance, etc.) |

Describe. Attach an additional sheet if needed

## VIII. SECTION XI – SELECT AGENTS AND TOXIN/TIER 1

☐ NO ☐ YES This research uses Tier 1 select agents and toxins.
(see https://www.selectagents.gov/SelectAgentsandToxinsList.html ).

## IX. SECTION XII – DUAL USE RESEARCH OF CONCERN (DURC)

Biological research is considered 'dual-use research of concern' if the methodologies, material or results could be used in a manner to cause public harm. To ensure all research is given due consideration as to whether the planned experiments include DURC, the following questions must be answered. *(Full policy at: oba.od.nih.gov/.../United...of_DURC_FINAL_version_032812.pdf)*

| Dual Use Questionnaire | Yes | No |
|---|---|---|
| Will an intermediate or final product of your research make a vaccine less effective or ineffective? | ☐ | ☐ |
| Will the intermediate or final product of your research confer a drug resistance trait to microorganism(s) in the study that could compromise the use of appropriate or conventional drugs to control these microorganism(s) as disease agents in humans, veterinary medicine, or agriculture? | ☐ | ☐ |
| Will your work enhance the virulence of a pathogen or render a non-pathogen virulent? | ☐ | ☐ |
| Will the results of your work increase the transmissibility of any pathogen? | ☐ | ☐ |

| | | |
|---|---|---|
| Will your research result in the alteration of the host range of the pathogen? | ☐ | ☐ |
| Will your research result in an intermediate or final product that may prevent or interfere with the diagnosis of infection or disease? | ☐ | ☐ |
| Does your research enable *weaponization** of an agent or toxin? | ☐ | ☐ |
| Will synthetic biology techniques be used to construct a pathogenic organism, toxin or potentially harmful intermediate product? | ☐ | ☐ |
| Even if your planned research does not involve *any* of the aforementioned eight criteria, and recognizing that your work product or results of your research could conceivably be misused, is there the potential for your data/product to be *readily* utilized to cause public harm? | ☐ | ☐ |

*In this context, weaponization refers to the enhanced dispersion, deliverability, survivability or pathogenesis of a potentially harmful agent or toxin.

[+]Synthetic biology includes, but is not limited to, techniques of molecular biology, chemistry and genetics that would allow for the *de novo* synthesis or reverse engineering of genes, gene products or entire functional organisms.

## X. FEDERAL/STATE PERMITS AND OTHER APPROVALS

### A. Federal and State Permits

☐ NO ☐ YES Do the activities/materials for this project require a federal/state permit?

If yes, please provide the permit information below and include a copy of the current federal/state permit with this IBC protocol registration application.

- There will be No Authorization without a copy of the permit or authorization.
- For **NEW** protocols, if a permit is pending, you must submit a copy of the final approved permit to the Biosafety Office before you may begin work.
- For **RENEWA**L protocols, please provide most current approved permit with the registration form.
- To obtain a federal/state permit, contact *uhpermit@hawaii.edu*.

| Type *(HDOA, CDC, USDA)* | Permit No. | Biological Materials listed on permit | Importation / Inoculation | Exp. Date |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

### B. Other UH Review Committee Approvals:

☐ NO ☐ YES Is this work subject to ☐ UH IACUC, ☐ IRB, ☐ Radiation Safety (EHSO), ☐ Chemical and Physical Hazards Committee, or ☐ Office of Export Control? Please provide basic information in the table below.

***The PI should submit applications to these other review entities as appropriate.***

| Protocol # | Exempted | Protocol Title | Exp. Date |
|---|---|---|---|
| | ☐ | | |
| | ☐ | | |
| | ☐ | | |

## XI. MISCELLANEOUS

| Item # | NO | YES | Question |
|---|---|---|---|
| A | ☐ | ☐ | Will your experiments involve large scale culture? (bioreactors or >10 Liters in one container) |
| B | ☐ | ☐ | Will your experiments involve transfer of an antibiotic resistance gene into the host in addition to those contained in vectors? |
| C | ☐ | ☐ | Human Gene Transfer Experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human subjects (Human Gene Transfer) require NIH/RAC registration |

| | | | |
|---|---|---|---|
| | | | and Institutional Biosafety Committee (IBC) and IRB approval before initiation.<br>Has this approval been obtained? |
| D | ☐ | ☐ | Will you be using human pluripotent stem cells derived from human embryos (human embryonic stem cells) or human fetal tissue (human embryonic germ cells)? |
| E | ☐ | ☐ | Will your research/experiment involve the need to share confidential or proprietary information? |
| F | ☐ | ☐ | Will your research/experiment involve the need to transfer materials and/or data to other institutions, organizations, or foreign countries? |

If any Yes box was selected for items A - D, attach a complete description of the research.

***The information provided may be shared with other institutional programs and offices for their review and assessment. It is intended that the disclosure of information to other UH compliance entities will not interfere with the independent IBC review and approval process.***

## XII. CERTIFICATION

As Principal Investigator, I understand the risks associated with recombinant and synthetic nucleic acid molecules, use of biological hazard materials (human pathogens, human blood, body fluids, or tissues, animal pathogens, blood, body fluids or tissues, plant pathogens), and imported biological materials. I will notify the Biosafety Program and IBC immediately should related activity produce an unanticipated product that increases virulence or toxicity, or otherwise confers a phenotypic change that could be biologically hazardous.

Furthermore, I certify I have read the relevant sections of the NIH Guidelines and CDC/USDA requirements, have or will have appropriately trained and advised my staff of the requirements outlined in the NIH Guidelines or CDC/USDA requirements prior to initiation of the project, acknowledge I have reviewed this form, and I am responsible for this project.

I am familiar with and agree to abide by all provisions of IBC, PBBP, CDC, OSHA, NIH, USDA and other applicable State and Federal Guidelines/regulations pertaining to the proposed project.

I understand that I bear the responsibility for ensuring that all personnel are adequately trained and informed of any risks with the research activity.

I agree to comply with all applicable requirements pertaining to:

- Reporting of all personnel exposures of regulated biological material
- Reporting any transgenic/knockout/knock-in/ biological material release/escape.
- Transport/transfer of for import/export of Biological commodities

The information in this application is accurate and correct.

_____ _____

Principal Investigator Date