IBC Ref. ID #_____

IBC Form 1A

PURDUE UNIVERSITY
Institutional Biosafety Committee

APPLICATION FOR: BIOHAZARDOUS AGENTS AND RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULE RESEARCH

Section A: Lab Information and Personnel

☐ **This is a new application**
☐ **This is a protocol renewal -- Provide Reference No._____**

Application Date: _____ (*MM/DD/YYYY*)

Protocol Title: _____

Principal Investigator (PI): _____

PI Campus Phone: _____ **Email:** _____

Department: _____ **Campus:** _____

Laboratory (Bldg./Room): _____ **Lab Phone:** _____

Office (Bldg./Room): _____

Personnel: Please supply information for all personnel working with recombinant/synthetic nucleic acids and/or biohazardous materials:

- *Verify the completion of all online training before submitting the protocol.*
- *If this form does not contain enough spaces for all personnel, please attach a spreadsheet with your submission.*

Name (First, Last)	**Purdue E-mail Address**	**Training Completed?**	**Personnel Role**
		☐ **Yes** ☐ **No**	Principal Investigator
		☐ **Yes** ☐ **No**	Select
		☐ **Yes** ☐ **No**	Select
		☐ **Yes** ☐ **No**	Select
		☐ **Yes** ☐ **No**	Select
		☐ **Yes** ☐ **No**	Select
		☐ **Yes** ☐ **No**	Select
		☐ **Yes** ☐ **No**	Select
		☐ **Yes** ☐ **No**	Select
		☐ **Yes** ☐ **No**	Select

Protocol Description: IMPORTANT: Provide attachments if needed):
At a minimum, please provide a summary that includes Purpose/Aims, Experimental procedure(s), Staff safety and agent awareness training, containment and storage, decontamination methods/materials, transportation procedures (as applicable).

Section B: Experiments in Categories, III-A, III-B, or III-C, or Select Agents

These categories require approval from external government agencies prior to the start of the experiments. For the proposed research in this protocol, please answer each question.

☐ **Yes** ☐ **No**	1. The deliberate transfer of drug resistance trait to microorganism that are not known to acquire the trait naturally, if such acquisition could compromise use of the drug to control disease agents in humans, veterinary medicine or agriculture. **III-A-a** (IBC, RAC, NIH).
☐ **Yes** ☐ **No**	2. Experiments involving the deliberate formation of recombinant or synthetic nucleic acid molecules containing **genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight** (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin). **III-B-1** (IBC, OBA, NIH)
☐ **Yes** ☐ **No**	3. 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. **III-C-1** (IBC, IRB, RAC)
☐ **Yes** ☐ **No**	4. Use of a Select Agent (IBC/CDC/APHIS approval needed.)
☐ **Yes** ☐ **No**	5. Are any permits from external agencies (APHIS, USDA, CDC, DEA, DOT, FDA, etc.) required to conduct your research? If Yes, Choose from Dropdown
☐ **Yes** ☐ **No** ***(Check Yes only if both agent/toxin and category are true.)***	**6. Use of an agent or toxin from this list:** a) Avian influenza virus (highly pathogenic) b) Bacillus anthracis c) Botulinum neurotoxin d) Burkholderia mallei e) Burkholderia pseudomallei. f) Ebola virus g) Foot-and-mouth disease virus h) Francisella tularensis. i) Marburg virus. j) Reconstructed 1918 Influenza virus. k) Rinderpest virus l) Toxin-producing strains of Clostridium botulinum m)Variola major virus n) Variola minor virus o) Yersinia pestis **To conduct any of the following categories of research:** a) Enhances the harmful consequences of the agent or toxin b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification c) Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin e) Alters the host range or tropism of the agent or toxin f) Enhances the susceptibility of a host population to the agent or toxin g) Generates or reconstitutes an eradicated or extinct agent or toxin

Section C: Classification – Use of Recombinant/Synthetic Nucleic Acids

☐ **Recombinant** ☐ **Synthetic** ☐ **No,** **(If no, move to Section 6)**	**1. Will Recombinant and/or Synthetic Nucleic Acids be used?** **(Check all that apply)** *In the context of the* NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:* *(i) molecules that a) are constructed by joining nucleic acid molecules* ***and*** *b) can replicate in a living cell, i.e., recombinant nucleic acids;* *(ii) (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or* *(iii) (iii) molecules that result from the replication of those described in (i) or (ii) above.*
For Synthetic Nucleic Acids Please Answer All Questions.	**2. For Synthetic Nucleic Acid Use:** Will the synthetic nucleic acid molecules contain an origin of replication or elements known to interact with either DNA or RNA polymerase? ☐ **Yes** ☐ **No** Can the synthetic nucleic acid molecules replicate or generate nucleic acids that can replicate in any living cell? ☐ **Yes** ☐ **No** Are the synthetic nucleic acid molecules designed to integrate into DNA? ☐ **Yes** ☐ **No** Do the synthetic nucleic acid molecules produce (or code for) a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight? ☐ **Yes** ☐ **No** **If all answers are No, (III-F-1)**
☐ **Yes** ☐ **No**	3. Does this protocol include organisms containing recombinant or synthetic nucleic acids in large scale (more than 10 Liters) of culture? **III-D-6 (IBC)** *If yes, please attach any safety, spill, and decontamination methods specifically associated with the large-scale culture(s).*
☐ **Yes** ☐ **No**	4. Do experiments involve influenza viruses generated by recombinant and/or synthetic means? **III-D-7 (IBC)** *If yes, please describe the work that will be conducted with influenza virus(es)in the Protocol Description above. Please include all strain names, information about any virus(es) used as the source of the majority of the segments. Also include information about the generation of the virus (e.g. generation by reverse genetics of chimeric viruses with reassorted segments, introduction of specific mutations.*

5. Vectors Used: Please indicate the name and type of any Recombinant/Synthetic Nucleic Acid vectors used for this protocol. Attach a spreadsheet with these fields if there are not enough spaces below. If this area is not applicable, please check the "N/A" box.

☐ **N/A**

Vector Name	Type (e.g. plasmid, phage, viral)	Features: For example, drug resistance for selection, high efficiency, molecular tags, expression system

6. Inserted Sequences Used: Attach a spreadsheet with these fields if there are not enough spaces below. If this area is not applicable, please check the "N/A" box.

☐ **N/A**

Gene Name	Protein Produced (full name)	Gene Origin (e.g. human, murine, plant)

7. For any use of Recombinant/Synthetic Nucleic Acids with a host system	
☐ Yes ☐ No	7a. Do the proposed experiments use risk group 2, 3, 4, or Restricted Agents as Host-Vector Systems? **III-D-1-a, b, c, d (IBC)**
☐ Yes ☐ No	7b. Does this protocol include experiments in which DNA from risk group 2, 3, 4 or Restricted Agents is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems. **III-D-2** (IBC)
☐ Yes ☐ No	7c. Does this protocol include experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper viruses in tissue culture systems? **III-D-3 or III-E-1 (IBC)** **Please reference Risk Groups 2,3,4**
8. For any use of Recombinant/Synthetic Nucleic Acids without a host system	
☐ Yes ☐ No	8a. Have the recombinant/synthetic nucleic acid molecules been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes? (**III-F-2)**
☐ Yes ☐ No	8b. Do the experiments include molecules that consist entirely of nucleic acids 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? (**III-F-3)**
☐ Yes ☐ No	8c. Do the experiments include molecules 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-4)**
☐ Yes ☐ No	8d. Do the experiments include molecules that consist 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-5)**
☐ Yes ☐ No	8e. Do the experiments include molecules that consist of genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA? (**III-F-6)**

<table>
<tr><th colspan="2">9. How will transgenic organisms/cells be contained and destroyed?</th></tr>
<tr><td>Please name the host system used.
If necessary for classification and pathogenicity assessment, please add strain names. Please check "N/A" box if not applicable to this protocol.</td><td>Note: the appropriate percentages for the following reagents: Bleach 10% solution, Ethanol 70% solution. List any alterations to these percentages below.
Include the use of bleach (or equivalent) as the primary method for liquid culture disposal.
Ultraviolet light is approvable as a secondary method of decontamination for safety cabinets/hoods.</td></tr>
<tr><td><u>Bacterial:</u> ☐ N/A</td><td><u>Liquid Cultures/Waste</u>
☐Autoclave ☐ Bleach ☐Ethanol ☐ Other
Describe:

<u>Solid Materials and Surfaces</u>
☐Autoclave ☐ Bleach ☐Ethanol ☐ Other
Describe:</td></tr>
<tr><td><u>Vertebrate host system (including cell lines):</u>
☐ N/A</td><td><u>Liquid Cultures/Waste</u>
☐Autoclave ☐ Bleach ☐Ethanol ☐ Other
Describe:

<u>Solid Materials and Surfaces</u>
☐Autoclave ☐ Bleach ☐Ethanol ☐ Other
Describe:</td></tr>
</table>

Invertebrate/Insect (including cell lines): ☐ **N/A**	**Liquid Cultures/Waste** ☐**Autoclave** ☐ **Bleach** ☐**Ethanol** ☐ **Other** **Describe:** **Solid Materials and Surfaces** ☐**Autoclave** ☐ **Bleach** ☐**Ethanol** ☐ **Other** **Describe:**
Fungal/Yeast: ☐ **N/A**	**Liquid Cultures/Waste** ☐**Autoclave** ☐ **Bleach** ☐**Ethanol** ☐ **Other** **Describe:** **Solid Materials and Surfaces** ☐**Autoclave** ☐ **Bleach** ☐**Ethanol** ☐ **Other** **Describe:**
Plant: ☐ **N/A**	☐**Autoclave** ☐ **Other** **Describe:**
Other System: ☐ **N/A**	☐**Autoclave** ☐ **Bleach** ☐**Ethanol** ☐ **Other** **Describe:**

10. Please list any cell lines, cells, viral, fungal, bacterial agents not already described in other sections of this protocol.	
Organism name **If necessary for classification, please add strain names.**	**Origin (e.g. bacterial, human, fungal, viral)**

Section D: Use of Whole Animal Systems

☐ The experiments do not involve whole animal (vertebrate or invertebrate/insect) models. **(Move to Section 5)** ☐ The experiments in this protocol involve nucleic acid modified whole animals (either vertebrate or invertebrate. Answer question in this section.) **III-D-4** or **III-E-3**	
☐ **Yes** ☐ **No**	1. Do the experiments use whole animals 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 animals).**
☐ **Yes** ☐ **No**	2. Do the experiments involve experiments involving viable recombinant or synthetic nucleic acid molecule modified microorganisms tested on whole animals?
For vertebrates, include Institutional Animal Care and Use Committee (IACUC) Reference **IACUC Reference Number(s):** **IACUC Approval Date(s) or "pending"**	

Section E: Use of Whole Plants or Organisms Associated with Plants

☐ The experiments do not involve plant models or organisms associated with plants **(Move to Section 6.)** ☐ The research will involve whole plants modified with recombinant or synthetic nucleic acids.	
☐ **Yes** ☐ **No**	1. Based on current understanding, will the use of recombinant or synthetic nucleic acid molecules alter plants to have the potential for detrimental impact on the managed or natural ecosystems? **III-D-5 or III-E-2**
☐ **Yes** ☐ **No**	2. Do experiments involve plants containing cloned genomes of readily transmissible exotic infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystem in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation *in planta*? **III-D-5-b**
☐ **Yes** ☐ **No**	3. Does the research involve experiments with a small number of readily transmissible exotic infectious agents, such as the soybean rust fungus (*Phakospora pachyrhizi*) and maize streak or other viruses in the presence of their specific arthropod vectors, that have the potential of being serious pathogens of major U.S. crops? **III-E-2-c**
☐ **Yes** ☐ **No**	4. Will any experiments involve sequences encoding potent vertebrate toxins introduced into plants or associated organisms? **III-E-2-d**
☐ **Yes** ☐ **No**	5. Will research involve experiments with microbial pathogens of insects or small animals associated with plants if the recombinant or synthetic nucleic acid molecule-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems? **III-E-2-e**

Section F: Biosafety Without Use of Recombinant/Synthetic Nucleic Acids

☐ **Yes** ☐ **No**	1. Do the experiments involve use of a Risk Group II or III biohazardous agent without the use of recombinant or synthetic nucleic acids? (IBC notification)
☐ **Yes** ☐ **No** ☐ **N/A**	2. If permits from external agencies (APHIS, CDC, DEA, DOT, etc.) are required to conduct your research, have these permits been granted?
☐ **Yes** ☐ **No**	3. Will the experiments involve use of unfixed human blood, blood products, tissue, cell lines, or other body fluids without the use of recombinant or synthetic nucleic acids? (IBC, IRB)
Please ensure that the protocol description in Section 1 reflects the specific decontamination procedures, personal protective equipment (PPE), and affirm that specific training will be completed.	

Section G: Principal Investigator (PI) Responsibility Certification

Checking and signing the indicated areas of this section affirms that you understand and have initiated all the related safety policies and procedures related to the protocol and use of biological agents. **Protocols are not accepted without this recognition and PI signature.**

☐ **Regulatory**: The following applicable biosafety guidelines have been reviewed:
- Purdue University Biological Safety Manual
- NIH Guidelines for Research Involving Recombinant DNA Molecules
- CDC Biosafety in Microbiological and Biomedical Laboratories manual, 5th Edition
- USDA/APHIS
- NIH Dual Use Research of Concern

☐ **Awareness:** All laboratory staff and non-staff who could be exposed to biohazardous agents associated with this protocol have been made aware of the potential exposure routes, post exposure signs and symptoms, and safe handling procedures.

☐ **Safety:** All personnel participating in this project are knowledgeable and have been trained in the required laboratory techniques, decontamination, security, and are familiar with biohazard containment policies and procedures. The PI will ensure continuous training and safety protocols.

☐ **Biohazard Exposure Occupational Health:** Occupational Health Biohazard Exposure: It is important that lab staff be made aware of potential complications that may occur during research with bio-agents. Lab staff that; have autoimmune or chronic disease (no matter how well managed), have heart disease, are taking immune suppressing medications (e.g., chemotherapy, systemic steroids, etc.), are a female of child bearing age or are pregnant or planning conception are at higher risk of complications. REM provides bio-agent information sheets and respirator fit tests. REM also provides any required vaccinations and post exposure follow-up through an Occupational Healthcare provider.

☐ **Sharing**: If biological agents are shared with other labs not associated with my protocol, I must first contact the Biosafety Officer. I understand that other Purdue University processes (e.g. contracts, permits) may be necessary and that the Principal Investigator has responsibility to follow these processes. Biological materials may be subject to shipping and export requirements and university policies outside of IBC requirements addressed in this protocol.

☐ **Renewal:** Protocols are renewed on a triennial basis. Changes in the project beyond the scope of this current protocol require the submission of an application for revision.

Biological agents and materials approved in IBC protocols are regulated by Federal guidelines and can pose significant risks to human, animal, and/or plants. Your signature below attests that you certify all personnel listed in this protocol as well as any individuals having access to the agents and materials in question have received appropriate training for the handling, storage, and disposal of these agents and will be managed in a way that upholds this protocol and associated regulations.

Typed PI Name: _____

PI Signature: _____ **Date:** _____