Section 1. General Project Details

Sec. 1-A. Principal Investigator (PI) Information

Principal Investigator (PI):

Position:

Email:

Phone:

Campus:

Department:

Campus/Office Address:

Sec. 1-B. Protocol Information

This submission is a (*check [X] one):*

☐ New Pprotocol ☐ Resubmission: Previous Protocol Number: ☐ Amendment

Project Title:

Sec. 1-C. Other Compliance Committee Approvals

- Animal Research (IACUC):
  - Currently approved protocol(s):
    - Date(s) of expiration:
    - PI(s) of Record:
  - Pending protocol(s):
    - Date(s) of submission:
    - PI(s) of Record:

*Note: IACUC approval must be granted prior to initiation of any vertebrate animal research**

- Human Subjects Research (IRB):
  - Currently approved protocol(s):
    - Date(s) of expiration
    - PI(s) of Record:
  - Pending protocol(s):
    - Date(s) of submission:
    - PI(s) of Record:

Sec. 1-D. Investigators (List ALL personnel involved in this project)

Last Name, First Name <E-mail Address>	***Title/Job Description***	***OFFIC USE ONLY***	***NIH Guidelines***	***Bloodborne Pathogens***	***Biosafety***	***N95 Fit Test***	***Dual Use***	***Other***

Example: Doe, Jane <jdoe@memphis.edu>	Associate Professor / PI / Performs all experiments, Oversees Lab	**Required:** **Complete:**	☒ ☐	☐ ☐	☒ ☐	☐ ☐	☐ ☐	☐ ☐
		Required: **Complete:**	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
		Required: **Complete:**	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
		Required: **Complete:**	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
		Required: **Complete:**	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
		Required: **Complete:**	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
		Required: **Complete:**	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
		Required: **Complete:**	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐

Note: To add additional lines to the table, please click the "+" sign on the left-hand side of the last row.

☐ **Investigator Acknowledgement:** By checking this box, the PI is ensuring that all personnel listed on this protocol have access to the protocol, read it, agree to participate in said research activities, and will complete all necessary training requirements.

Sec. 1-E. Research Location(s) Please list the building, room numbers, research activities performed in that space, and the highest biosafety level for that space and research activity. Please specify where all biological material is being used or stored.

Building	***Room #***	***Research Activities Performed***	***Biosafety Level***
Example: Life Science	1	Human cell culture	BL-

**Note: Please include Core Facility locations in the table.*

Note: To add additional lines to the table, please click the "+" sign on the left hand side of the last row.

Sec. 1-F. Additional Information Will your project involve any of the following things:

☐ Viral Vectors
☐ Dual Use Research of Concern
☐ Select Agents or Toxins
☐ Human Gene Transfer
☐ Biohazardous Agents (includes human cells) *Fill out form B*
☐ Whole Animals

Checking any of the above blocks where there are no additional notes will require additional approvals

Section 2. Research Description

2-A. Describe the research in layman's terms (~250 words)◊:

2-B. Describe planned experiments (technical). Include disinfection procedures and PPE used. Use additional pages if necessary in a separate document. Description should not exceed 2 pages total.

Section 3. Experiments Covered by the *NIH Guidelines*

Section 3-A. Sections of the *NIH Guidelines*

** Note: Choose ALL appropriate sections of the NIH Guidelines that apply to the proposed research**

☐ **III-A. Experiments that Require NIH Director Approval and Institutional Biosafety Committee (IBC) Approval Before Initiation** (See Section IV-C-1-b-(1), Major actions)

- **III-A-1**: Major Actions under the *NIH Guidelines*
- **III-A-1-a**: The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally (See Section V-B, *Footnotes and Reverences of Sections I-IV* of the *NIH Guidelines*), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will require the NIH Director approval

☐ **III-B. Experiments that require NIH Office of Science Policy (OSP) and IBC Approval Before Initiation**

- **III-B-1**: Experiments Involving the Cloning of Toxin Molecules with LD_{50} of Less than 100 Nanograms per Kilogram Body Weight
- **III-B-2**: Experiments that have been Approved (Under Section III-A-1-a) as Major Actions under Sec. III-A-1-a of the *NIH Guidelines*

☐ **III-C. Experiments Involving Human Gene Transfer that Require IBC Approval Prior to Initiation**

- **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

  Human gene transfer is the deliberate transfer into human research participants of either:

  a. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
  b. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
     i. Contain more than 100 nucleotides; or
     ii. Possess biological properties that enable integration into the genome (e.g., *cis* elements involved in integration); or
     iii. Have the potential to replicate in a cell; or
     iv. Can be translated or transcribed.

Note: No research participant shall be enrolled until IBC and IRB approval has been granted

☐ **III-D. Experiments that Require IBC Approval Before Initiation**

☐ **III-D-1**: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the *NIH Guidelines*) **Part B also required**

☐ **III-D-2**: Experiments in which DNA from RG2, RG3, RG4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems

☐ **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

☐ **III-D-4**: Experiments Involving Whole Animals:

- *Note: The breeding and cross breeding of registered transgenic rodents is exempt from the NIH Guidelines. (see Appendix C-VIII). The generation of transgenic rodents that require BL-1 containment are described under Sec. III-E-*
  - *The purchase/transfer of transgenic rodents is exempt from the NIH Guidelines (See Appendix C-VII). **

    - Involving whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or DNA derived therefrom, into the germ-line (transgenic animals other than rodents), or

    - Experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals, including rodents

    - **Appendix M**: Experiments involving large animals

☐ **III-D-5**: Experiments involving whole plants at BL-2 or higher practices

☐ **III-D-6**: Experiments involving more than 10 liters of culture *(in one container)*

☐ **III-D-7**: Experiments involving influenza viruses generated by recombinant or synthetic methods

☐ **III-E. Experiments that Require IBC Notice Simultaneous with Initiation** ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required.

☐ **III-E-1**: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than $^{2}/_{3}$ of the genome of any Eukaryotic virus.

☐ **III-E-2**: Experiments involving whole plants at BL-1 or BL-2.

☐ **III-E-3**: Experiments involving transgenic rodents: 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. Only experiments that require BL1 containment are covered under this section; experiments that require BL2 or higher containment fall under section III-D-4 above.

** Note: Only experiments that require BL-1 containment are covered under Sec III-E-3. **

☐ **III-F. Experiments that are exempt from the *NIH Guidelines***

☐ **III-F-1**: Uses synthetic nucleic acids that:

- Can neither replicate nor generate nucleic acids that can replicate in any living cell, and
- Are not designed to integrate into DNA, and
- Do not produce a toxin that is lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram of body weight.

☐ **III-F-2**: Those that are not in organisms, cells, or viruses and that have not been modified or manipulated 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 prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or closely related strain of the same species), or when transferred to another 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, with the advice of the RAC, and following appropriate notice and opportunity for public. (You **MUST** check one of the *Appendix C* exemptions below)

- **Appendix C-I**: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than ½ of the genome of any Eukaryotic viral genome that are propagated and maintained in cells in tissue culture

Host-Vector System Exemptions:

- **Appendix C-II: *Escherichia coli K-12* Host-Vector Systems***
- **Appendix C-III: *Saccharomyces* Host-Vector Systems***
- **Appendix C-IV: *Kluyveromyces* Host-Vector Systems***
- **Appendix C-V: *Bacillus subtilis* OR *Bacillus licheniformis* Host-Vector Systems***
- **Appendix C-VI: Extrachromosomal Elements of Gram Positive Organisms***

***Exemptions do not apply to experiments described in Section III-B which require NIH OSP and IBC approval before initiation or experiments involving DNA from Risk Groups 3, 4, or restricted organisms.**

Transgenic Rodent Exemptions:

- **Appendix C-VII**: The purchase or transfer of transgenic rodents at BL-1
- **Appendix C-VIII**: Generation of BL1 transgenic rodents via breeding

Note: See also the Animal Experiments Covered under the NIH Guidelines Reference Table

☐ **Experiments with Risk Group 2 agents otherwise exempt from NIH guidelines Part B also required**

Section 3-B. Recombinant DNA (rDNA) and Synthetic Nucleic Acid Molecule Information

In the table below, please provide the original source of inserted DNA, the vector(s) (recombinant viruses), used to insert into the host, all hosts, including intermediate, in which it will be inserted, and the gene or transcription product to follow. Also, if the gene or transcription product is known to be harmful (e.g. oncogenic, toxic, mutated gene), please provide details. Please list only recombinant DNAs or synthetic nucleic acids in this table.

Source Species of inserted DNA	***Plasmid and/or Vector(s)*** *(recombinant viruses)* ***to be used***	***Host(s) to be used*** *(Please include all intermediate hosts)* ***E.g.: human cells, mouse cells***	***What is the gene or transcription product***	***Is it known to be harmful*** *(e.g. Oncogenic, Toxic, Mutated Gene)* ***to researcher or environment? If yes, please describe:***
Example: Human	pcDNA3.1	E. coli, drosophila cells	RalGDS1	No
Example: HIV and VSV	Packaging plasmid (pRSV-Rev), gag/pol plasmids (pMDLg/pRRE), env plasmid (pMD2.G)	Human cells	Gag, pol and env	Yes. Potentially oncogenic.

Note: To add additional lines to the table, please click the "+" sign on the left-hand side of the last row.