

Carnegie Mellon University
**Institutional Biosafety Committee (IBC) Recombinant or Synthetic Nucleic
Acid Molecules Research Application**

Please fill out **ALL** sections of this application as it relates to your research. Incomplete or missing information may delay approval of your research. Once completed, please submit an electronic copy to safety@andrew.cmu.edu. If you have any questions, please contact safety@andrew.cmu.edu or call (412) 268-8405.

SECTION I: GENERAL PROJECT DETAILS

Application Type:

- New project
- Modification of existing project (**Note: Please indicate all modifications in ALL CAPS**)
- Renewal **WITHOUT** modifications
- Renewal **WITH** modifications (**Note: Please indicate all modifications in ALL CAPS**)

Please indicate the protocol number you are modifying or renewing:

Investigator Name:

Department:

Campus Address:

Email:

Phone:

Fax:

Title of Protocol:

Anticipated start date:

Anticipated completion date:

Funding:

Internally funded

Externally funded

Source:

Grant/sponsor number:

Other Institutional Reviews/Approvals Related to this Protocol:

- Human Subjects Research (IRB)
Protocol number:
Most recent approval date:
- Animal Research (IACUC)
Protocol number:
Most recent approval date:

Section II: LAB PERSONNEL

Please list all personnel who will be working on this project and indicate who will be the primary contact for this project if it will be someone other than the Principal Investigator.

Name	Title	Responsibilities	Email

SECTION III: EXPERIMENT CATEGORY

Please choose the appropriate section(s) of the [NIH Guidelines](#) under which your research falls (**check all that apply**):

III-E: Experiments that require IBC notice simultaneous with initiation

- III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than two thirds of the genome of any eukaryotic virus
- III-E-2: Experiments involving whole plants
- III-E-3: Experiments involving transgenic rodents (**Note:** Only experiments that require BL1 containment are covered under this section; experiments that require BL2, BL3, or BL4 containment are covered under [Section III-D-4, Experiments Involving Whole Animals](#). Experiments involving the breeding of certain BL1 transgenic rodents are exempt under [Section III-E-3, Experiments Involving Transgenic Rodents](#).)

III-D: Experiments that require IBC approval before initiation

- III-D-1: Experiments using Risk Group (RG) 2, 3, 4, or restricted agents as host-vector systems
- III-D-2: Experiments in which nucleic acids from RG 2, 3, 4, or restricted agents are 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
- III-D-5: Experiments involving whole plants
- III-D-6: Experiments involving >10 liters of culture

III-C: Experiments that Require IBC, IRB, and RAC review before research participant enrollment

- III-C-1: Experiments involving the deliberate transfer of recombinant or synthetic nucleic acids into one or more human research participants

III-B: Experiments that require NIH/OBA and IBC approval before initiation

- III-B-1: Experiments involving the cloning of toxin molecules with LD50 of <100ng per kg body weight

III-A: Experiments that require IBC approval, RAC review, and NIH Director approval before initiation

- III-A-1-a: The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromised the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. (Note that antibiotic resistance markers used for selecting and propagating plasmids in *E.coli* are not included)

Other:

None of these categories apply (Please proceed to the [Exempt Application](#))

SECTION IV: EXPERIMENT DESCRIPTION

A. In the space below, provide a description of the experimental design. Include information on procedures, methods, and/or manipulations with biological materials. (Provide information such that the IBC can understand and assess biological risk. If following a well-recognized procedure, a link to an example of that protocol may be provided.)

B. Describe the **SOURCE** of the DNA including the type of organism, species, strain, cultivar/cell line, and the company information (if applicable). If possible, please provide links to the source information.

C. Describe the **NATURE** of the inserted nucleic acid sequences including regulatory or coding regions, entire genome, synthetic antisense sequences, etc.

D. List the **VECTOR(S)** to be used and briefly specify their purpose. Note: If using a lentiviral vector, you must also complete [Section V](#) of this application.

E. Describe the **RECIPIENT ORGANISM(S)** (host) for the DNA. Specify the type of organism, species, strain, cultivar/cell line, origin etc.

F. If the genetic alteration will result in expression of a toxin or oncogene, alter the host range or cell tropism or allow the sequence to integrate into the host genome, please provide details below.

G. Will there be an attempt to express a foreign gene?

Yes No

Will the foreign gene be something other than a fluorescence tag (e.g. GFP or RFP, mCherry, etc.) or a purification tag (e.g. xHis, GST, FLAG, etc.)?

Yes No

If **"YES"**, list the genes in the space below:

If **"YES"**, describe the protein that will be produced (morphological or structural characteristics, physiological activities and processes, growth characteristics).

Could this expression produce adverse health effects on humans?

Yes No

If **"YES"**, please describe these risks:

H. Describe the potential biosafety risks of this research proposal. Address each of the following as it relates to the biological materials used in this proposal:

- a) Pathogenicity:
- b) Route(s) of transmission:
- c) Agent stability:
- d) Infectious dose (indicate host):
- e) Concentration (identify as stock concentration or concentration employed in experiment such as dose, etc.):
- f) Volume of cultures used:
- g) Origin (i.e. USA, ATCC, etc.):
- h) Availability of effective prophylaxis:

SECTION V: LENTIVIRUS WORK

A. Are you using a lentiviral vector system, such as HIV-1?

No. Continue to [Section VI](#).

Yes, I am using a _____ lentiviral vector. Continue to [Section VI](#).

Yes, I am using an HIV-1 lentiviral vector.

Check the appropriate box to indicate how you will acquire the lentiviral vector (a 3rd generation system is encouraged):

The vector will be produced in my laboratory

The vector will be obtained from outside supplier/vendor. Source:

Please provide all relevant documentation such as literature references, information regarding vector replication status and results of replication status testing.

I have reviewed the following NIH Guidance: "[Biosafety Considerations for Research With Lentiviral Vectors](#)"

B. What is the amount of vector to be produced or used (choose one)?

- Less than 1 liter
 1 liter or greater (must check BSL-2+ in [Section VI](#))

C. What is the nature of the vector packaging system (choose one)?

- Vector will be packaged on two plasmids or fewer (must check BSL-2+ in [Section VI](#))
 Vector will be packaged on three or more plasmids

D. What is the nature of the transgene (choose one)?

- Non-oncogenic
 Oncogenic (must check BSL-2+ in [Section VI](#))

E. If animals will serve as hosts, what is the nature of the animal(s) used (check all that apply):

- Animals WILL NOT be used
 Animals will be used that are engrafted with human cells (must check BSL-2+ in [Section VI](#))
 Animals which are permissive for the lentiviral vector will be used (must check BSL-2+ in [Section VI](#))
 Animals will be used, but none of the above applies

SECTION VI: BIOSAFETY LEVEL OF EXPERIMENT

A. Based on the above information, please check the HIGHEST appropriate physical containment for this protocol.

Refer to the most recent [NIH guidelines](#);

Or [CDC guidelines](#);

Or [ABSA Risk Groups](#)

- BSL-1 (Proceed to [Section VIII](#))
 BSL-2 (Proceed to [Section VII](#))
 BSL-2+ (Proceed to [Section VII](#))

SECTION VII: SAFETY PRACTICES AND PROCEDURES

If your protocol requires BSL-2 containment or higher, you must complete the following section:

A. Aerosol Generating Procedures

Please indicate which of the following activities will be conducted on this protocol (check all that apply):

- Centrifuging Vortexing Pipetting Blending Sonicating
 Use of a shaker Necropsy Vacuum Cell Sorting
 Other (please describe):

Please indicate how the potential creation of aerosols will be controlled (check all that apply):

- Biological Safety Cabinet Last certification date:
 Safety centrifuge cups Other (please describe):
 None

B. Use of Sharps

Please indicate all sharps that will be used in this protocol (check all that apply):

- Needles Scalpels Glass Razor blades Knives Lancets
 Microtome blades Other (please describe):
 None

Has the use of sharps been minimized to the greatest extent feasible?

- Yes No N/A

Are sharps with integrated safety devices used when practical, feasible, and available?

- Yes Please describe device (Type, Model, Brand):
 No
 N/A

C. PERSONAL PROTECTIVE EQUIPMENT (PPE)

Please indicate all personal protective equipment that will be used in this protocol (check all that apply):

- Gloves Lab coat Gown Safety glasses Safety goggles
 Face shield Other (please describe):

D. Disinfectants Used

Please indicate which disinfectants will be used for routine decontamination and for spill cleanup (check all that apply):

Bleach Cidex Iodophor Ethanol Other (please describe):

SECTION VIII: PROJECT LOCATION

Please list all locations (room number and building) where the project will be conducted, and describe the type of recombinant DNA work performed at each site (e.g. transfection of cells, administration of rDNA materials to study subjects, etc).

Room and Building	Type of Work Performed	Biosafety Level

SECTION IX: Principal Investigator (PI) Experience

Do you have a current CV or biosketch on file?

Yes No

If no, the PI on this project must attach to this protocol a CV or biosketch and any other information that demonstrates experience working with the materials listed above.

SECTION X: ASSURANCE INFORMATION

- a. I certify that the information provided in this application is complete, accurate and consistent with any proposal(s) submitted to a funding agency.
- b. I agree that I will not begin this project until receipt of official approval from the appropriate committee(s).
- c. I agree that modification to the originally approved project will not take place without prior review and approval by the appropriate committee(s), and that all activities will be performed in accordance with all applicable federal, state, local and University policies.
- d. I will follow applicable biosafety level requirements, comply with all shipping requirements and required waste management practices.
- e. I will ensure that all personnel have appropriate training including but not limited to: biosafety principles and techniques, hazard identification, management of accidental spills, shipping regulations, proper handling of biohazardous materials and waste management.
- f. I am aware that the IBC reserves the right to conduct inspections of the research facilities at any time.
- g. I understand that yearly renewal is required for continuing approved projects
- h. I have read and understood the document, "[Principal Investigator Responsibilities](#) under the NIH Guidelines."
- i. The electronic submission and acceptance of this document at the Biosafety Office is agreement with the statements a-g (above)

Signature of Principal Investigator

Date