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 submi app fBhm ys1h8i(a)1(yp-4.9 (o)10 (.(D1u)1 >ppl)1(ypt)4-4.9 (o). ay)59 (o) fEMC BT/Span <</MCI

☐ Renewal **WITH** modifications **(Note: Please indicate all modifications in ALL CAPS)**

Please indicate the protocol number you are modifying or renewing:

Source'

Investigator Name:
Department:
Campus Address:
Email:
Phone:
Fax:

Title of Protocol:

Anticipated start date:
Anticipated completion date:

Funding:

☐

Other Institutional Reviews/Approvals Related to this Protocol:

☐ Health Canada (if applicable)

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

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) Communicability:

☐ I **have reviewed the following NIH Guidance: "Biosafety Considerations for Research With Lentiviral Vectors"**

B.

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