Institutional Biosafety Committee
SUNY - Downstate Medical Center –
450 Clarkson Ave, Brooklyn, NY 11203

IBC #_____

Descriptive Title:

Principal Investigator:

SUNY Downstate Academic Title:

Department and Mail Stop:

Tel: Fax:

E-mail:

Other Investigators [List all personnel working on this project list experience pertinent to this application (include co-investigators, technicians, post docs, fellows, residents, students, clinical coordinators, research nurses, and others who have access to the laboratory)]:

NAME	EXPERIENCE

All laboratory locations where the proposed work will be conducted:

Please check the items to be used in this project:

☐Autoclave: No ☐ Yes ☐
Location:

Biosafety cabinet: No ☐ Yes ☐
Location:

Date of certification:

Biosafety centrifuge: No ☐ Yes ☐

Location:

Fume hood: No ☐ Yes ☐

Location:

Date of certification:

Project Description provide a succinct (<250 words) description/summary, in layperson's terms, of *what* and *how* (**not why**) you plan to do in a chronological sequence. Address each of the IBC protocol sections (I to X) that are applicable to your work. Spell all abbreviations once.

Please check the items applicable to this project:
(Section IX must be completed in all applications)

☐ **Human Samples - Complete Section I**
(submit a separate protocol to the Institutional Review Board)

☐ **Animals - Complete Section II**
(submit a separate protocol to the Institutional Animal and Use Committee)

☐ **Transgenic Animals - Complete Section III** (for non-exempt transgenic animals as defined in [http://www.gpo.gov/fdsys/pkg/FR-2011-01-19/pdf/2011-1037.pdf]

☐ **Radioisotopes/Ionizing Radiation - Complete Section IV**
(submit a separate protocol to Radiation Physics)

☐ **Infectious Agents - Complete Section V**

☐ **Recombinant DNA - Complete Section VI**

☐ **Toxic/Hazardous Substances - Complete Section VII**
(include **M**aterial **S**afety **D**ata **S**heet for each substance)

☐ **Flow Cytometric Hazard Assessment - Complete Section VIII**

☐ **Disposal of Biological Materials and Hazardous Substances - Complete Section IX**
(to be completed in all applications)

☐ **Shipment of Biological Materials - Complete Section X**
(includes animal or human tissues/fluids for research or diagnostic purposes)

Section I - Human Samples ☐ **Not Applicable**
(submit a separate protocol to the Institutional Review Board)

IRB Protocol Number & Title: **Approval Date**:
(Describe the procedures and techniques, equipment to be used and its location, storage conditions and location of specimen)

Specimen type:

☐ Blood

☐ Body fluid
Name:

☐ Cell/Organ/Tissue
(Both primary and commercially procured)
Name:

☐ Cell line/culture
Name:

Known hazards (e.g., HIV-1, HBV, HCV)**:**

Describe measures to protect personnel:

Section II - Animals
(submit a separate protocol to the Institutional Animal and Use Committee) ☐ **Not Applicable**

IACUC number: **Approval Date**:

IACUC Protocol Title:

Name of animal species: _____

The animals will be administered with:

☐ Recombinant DNA

☐ Infectious Agent: _____
(complete section V)

☐ Biological specimen of animal origin: _____
(including cells and fluids)

☐ Biological specimen of human origin: _____
(including cells and fluids, complete section I)

☐ Chemical (hazardous) substance:
(complete section VII)

☐ Radioisotope:

Route of administration:

Quantification of the injected material:

What is the likelihood that the infectious agent or the chemical substance or its metabolites will be passed in animal urine/feces or other body fluids/secretions?

Who will be responsible for changing animal bedding?

Provide an assessment of the risk of exposure of other animals/other investigators/ animal handlers:

Will animals undergo surgery? ☐ Yes ☐ No

(if yes, provide details)

Where will surgery be performed?

Where will animals be housed?

How will animals be transported to the laboratory?

Describe measures to protect personnel:

Section III - Transgenic Animals (includes both use and creation) ☐ **Not Applicable**

Does the project involve *on site* breeding or crossbreeding of genetically-modified vertebrate animals)?

No ☐ Yes ☐

Does the project involve rodents (parental or offspring) that contain more than 50% of the genome of an exogenous eukaryotic virus from a single virus family?

No ☐ Yes ☐

Does the project involve rodents where a transgene is under the control of a gammaretroviral long-terminal repeat (LTR) and where the LTR is functional?

No ☐ Yes ☐

Section IV - Radioisotopes/Ionizing Radiation
(submit a separate protocol to Radiation Physics) ☐ **Not Applicable**

License number:

Radioisotope	Chemical Form	Amount used in procedure (mCi)	Maximum amount on hand (mCi)

Does your work involve radioiodinating compounds? Yes ☐ No ☐

Will you be using radioisotopes in animals? Yes ☐ No ☐

Section V - Infectious Agents **☐Not Applicable**

(Use separate form for each infectious agent)

Purpose: ☐ Research ☐ Instruction/Education

Identify all personnel who will work on this project, providing documentation indicating their level of training and experience in working with infectious agents:

If used in education, provide documentation on its safe use in the classroom

Name of the Infectious Agent: _____

Is this agent infectious to animals? ☐ No ☐ Yes

☐ No ☐ Yes

Is this agent infectious to humans? ☐ No ☐ Yes

Does this agent elaborate a toxin?

Is there a vaccine available for use in humans against this agent or its components?

☐ No ☐ Yes

Identify any precautionary medical practices (e.g., vaccines, health surveillance) that will be implemented, if any:

Will live animals be infected with this agent? ☐ No ☐ Yes
(complete section II)

What is the LD_{50} of this agent in the animal model you plan to

use? Will this agent be subjected to ionizing radiation?

☐ No ☐ Yes

If a bacterial agent, provide an antibiogram:
(attach additional sheets of paper as needed)

How is the infectious agent propagated in the laboratory?

Specify methods of inactivation/decontamination and disposal of the agent or contaminated materials:

How is the agent stored in your laboratory?

Provide room location where agent is stored:

Section VI - Recombinant DNA ☐ **Not Applicable**

Are recombinant DNA procedures used in your laboratory limited to PCR amplification of DNA fragments (i.e., no subsequent cloning of amplified DNA)?

☐ Yes (Your recombinant DNA studies are exempt from restrictions described in the *NIH Guidelines for Research Involving Recombinant DNA Molecules*).

☐ No (Please provide the following information using a separate table for each gene):

Biological source of DNA or gene (1):			
Name and function of the gene:			
Selectable marker			
Host:			
Cell/animal recipient:			
Assessment of levels of physical and biological containment (consult current *NIH Guidelines for Research Involving Recombinant DNA Molecules* at http://www.nih.gov/od/orda/toc.html)	☐ Risk group 1 ☐ Risk group 2 ☐ Risk group 3	☐ BSL - 1 ☐ BSL - 2 ☐ BSL - 3	☐ Animal BSL-1 ☐ Animal BSL-2 ☐ Animal BSL-3

Biological source of DNA or gene (2):	
Name and function of the gene:	
Selectable marker	
Host:	
Cell/animal recipient:	

Assessment of levels of physical and biological containment (consult current *NIH Guidelines for Research Involving Recombinant DNA Molecules* at http://www.nih.gov/od/orda/toc.html)	☐ Risk group 1 ☐ Risk group 2 ☐ Risk group 3	☐ BSL - 1 ☐ BSL - 2 ☐ BSL - 3	☐ Animal BSL-1 ☐ Animal BSL-2 ☐ Animal BSL-3

Biological source of DNA or gene (3):

Name and function of the gene:			
Selectable marker			
Host:			
Cell/animal recipient:			
Assessment of levels of physical and biological containment (consult current *NIH Guidelines for Research Involving Recombinant DNA Molecules* at http://www.nih.gov/od/orda/toc.html)	☐ Risk group 1 ☐ Risk group 2 ☐ Risk group 3	☐ BSL - 1 ☐ BSL - 2 ☐ BSL - 3	☐ Animal BSL-1 ☐ Animal BSL-2 ☐ Animal BSL-3

Name of the antibiotic:

Is a toxin produced? ☐ No ☐ Yes

Name of the toxin:

- Biosafety Level 1 (BSL-1) experiments are not automatically exempt.
- All experiments in *Escherichia coli* are not necessarily exempt or safe.
- Commercial kits or well-worn host-vector systems are not necessarily exempt or safe.
- Exempt experiments are not necessarily safe, that is, a higher BSL and/or other precautions and/or practices may be required by the IBC.

Section VII - Toxic/Hazardous Substances ☐ **Not Applicable**
(include Material Safety Data Sheet for each substance)

Name of the toxic/hazardous substance:
(include carcinogenic, mutagenic, teratogenic substances)

Is this substance to be given to animals? ☐ No ☐ Yes
(complete section II)

Dose and route of administration:
Amount of the substance to be kept in the laboratory:

Storage location: Use location:

Inventory control procedure:

Method of deactivation:

Risk of human exposure and containment procedure?
(describe measure to protect personnel)

Section VIII - Flow Cytometric Hazard Assessment ☐**Not Applicable**

1. Cells to be used:

☐ Fresh or frozen animal cell
☐ Fresh or frozen human cells
☐ Cell lines

2. If a cell line to be used, indicate name(s)/designation(s):

3. If the cells are from human donors, were the donors screened for bloodborne pathogens?

☐ Yes; proceed to # 4 ☐ No; proceed to # 6

4. Any pathogens the sample may contain?

☐ None ☐ HIV ☐ HCV
☐ HBV ☐ Other

5. Has the infectious agent been inactivated?

☐ No ☐ Unknown ☐ Yes; describe method

6. Do the cells contain infectious agents such as viruses, bacteria, fungi, protozoa?

☐ No ☐ Yes; give name(s):

7. Were the cells genetically engineered?

☐ No

☐ Yes

Was a virus used?

☐ Adenovirus ☐ Retrovirus
☐ Lentivirus ☐ Herpes virus

Provide a description of the construct/virus and the procedure:

8. Are the cells fixed? ☐ No ☐ Yes

9. Are cells to be sorted? ☐ No ☐ Yes

10. Make and model of the instrument:

11. Serial number: 12. Location:

12. Name the operator:

13. Is the instrument used for diagnostic purpose(s): ☐ No ☐ Yes

Section IX - Disposal of Biological Materials and Hazardous Substances

Does your research generate waste that would be considered "regulated waste"?
[**Regulated Waste** means liquid or semi-liquid blood or other potentially infectious materials, chemical waste or hazardous substances; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.]

☐ No ☐ Yes (Provide a detailed description of the waste disposal procedures)

Will the waste be autoclaved before leaving the institution?

☐ No ☐ Yes

Provide the location of the autoclave to be used:

Will the waste be "red bagged" before leaving the institution?

☐ No ☐ Yes

Do you have sharps disposal containers appropriately placed in your laboratory?

☐ Yes ☐ No

Section X - Shipment of Biological Materials ☐ **Not Applicable**

Has anyone been trained in packaging and shipment of biologic specimens?
Date of training:
(attach certification)

Applicant's assurance. I certify that:

a. All persons conducting this work, including my collaborators, have received instruction on the specific hazards associated with the work and the specific safety equipment, practices, and behaviors required during the course of the work and use of these facilities. My records documenting this instruction may be reviewed.

b. Any spill of infectious agents, any equipment or facility failure (e.g., ventilation failure), and/or any breakdown in procedure that could result in potential exposure of laboratory personnel and/or the public to infectious material will be reported to the IBC immediately (IBC@downstate.edu or 718-270-3912).

c. Any changes in the protocol that would result in an increased level of biohazard will have to be reviewed and approved by the IBC before the change is implemented.

d. If use of infectious agents involves human body fluids or tissues, all personnel working with such agents have been given the opportunity to receive immunization against Hepatitis B at no cost, and their immunization records are current at the employees health service.

e. Research involving use of infectious agents/biohazardous materials and recombinant DNA/transgenic animals will not be initiated until reviewed and approved by the IBC.

f. Upon discontinuation of the research or protocol expiration, all infectious agents/biohazardous materials and recombinant DNA will be disposed of according to the procedures outlined in the protocol.

g. The information provided herein is accurate to the best of my knowledge. I also understand that, should I use the project described above as a basis for a funding proposal (either intramural or extramural), it is my responsibility to ensure that the description of the work in the funding proposal is identical to that contained in this application.

h. Universal precautions will be used throughout the proposed research by all personnel.

Print name	Signature of Faculty Member	Date
Print name	Signature of Department Chairperson	Date

Submit this completed application to the IBC via IBC@downstate.edu

For IBC use only **IBC # _____**

☐ Exempt ☐ Non-Exempt

☐ Disapproved ☐ Modifications Required

☐ Approved

Biosafety Level Approved: ☐ BSL-1 ☐ BSL-2

☐ BSL-3

Laboratory inspection required: ☐ No ☐ Yes (Research can only be initiated after the laboratory has been inspected and approved)

_____ _____

IBC Reviewer Date

_____ _____

IBC Chairperson Date