

IBC PROJECT # _____

Office Use Only: Exempt / Not exempt / no recombinant DNA / Approval Date:

Application for Review of Recombinant or Synthetic Nucleic Acid Molecules and Bio-hazardous, Infectious Agent Activities, or Use of Non-native Organisms

A. Principal Investigator

Name and Degrees:	
Telephone:	
Email:	
Department:	
Office Location (bldg/room):	
Project Title:	
* Experience (insert applicable letters below):	

***Experience:**

- a) Prior hands on experience in working with infectious agents (include number of years)
- b) Prior hands on experience in working with recombinant DNA (include number of years)
- c) No prior hands on experience, but will receive training from:

NOTE: Refer to the **NIH Guidelines** for Research Involving Recombinant DNA Molecules at: <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>

B. Laboratory Specifications

1. Specific laboratory location(s) where this work will occur:

If the work will be conducted at another institution, the IBC of that institution must review and approve the activity as well.

2. Will a Biosafety Cabinet (Tissue Culture Hood) be used for this project?

NO YES → specify **Location:**

BSC Class:

Date of most recent certification:

3. Will a Cold Room/Environmental Chamber be used for this project?

NO YES → **specify location:**

4. Will any biological material used for this project be stored outside of the lab listed above?

NO YES → **specify location:**

C. Summary of Proposed Work

Provide a comprehensive summary of the project to be conducted. ***This summary should be understandable to a scientist who is not an expert in your field.*** If applicable, include a detailed description of the recombinant DNA aspect of your proposed work. If the project involves infectious material, the summary should emphasize the potential pathogenicity of the microorganisms and recombinants to be used, and the safety precautions to be taken.

D. Information on Biological Material Used for Recombinant DNA Work - N/A (If N/A, go to section E)

1. a). Describe the host cells to be used (cells in which you will express your gene of interest). Include species of origin. Please be specific:

b). Describe the vector to be used. Include species tropism of vector:

c). For viral vectors, please describe the packaging system. **In addition**, for commercially prepared viral vectors, please also attach the product specification/data sheet.

d). Is there any possibility that the biological materials to be used could affect human cells? Please provide specific information:

2. Additional information for projects using Lentiviral Vectors: **N/A** (If N/A, go to question 3)

* Refer to the Recombinant DNA Advisory Committee (RAC) Guidance at:

http://osp.od.nih.gov/sites/default/files/resources/Lenti_Containment_Guidance_0_0.pdf

a). Please specify the origin of lentiviral vector constructs to be used (eg HIV, FIV, SIV)

b). Please describe the vector design:

Specify the number of viral plasmids used for generation of the viral vector particles and the viral genes deleted (in order to assess the potential for generation of replication-competent virus from the vector components). Include any additional safety features (e.g., they do not encode Tat). Include information on the virus coat protein expressed on the viral particles (e.g. VSV-G pseudotyping) to allow an assessment of host cell range of tropism.

c). Describe the nature of the transgene insert, specifying whether it's oncogenic or toxic when expressed in human cells. This would include genes for shRNA/siRNA that would decrease expression of tumor suppressor genes or otherwise toxic to human cells.

d). What is the vector titer and the total amount of vector to be produced locally or commercially obtained?

e). For Animal Studies, are the animals engrafted with human cells? Are the animals capable of supporting replication of infectious lentivirus?

3. Will a helper virus be used?

NO YES → specify:

4. a). Describe the DNA to be inserted into the recombinant vector:

b) Is expression of this gene associated with any human disease?

c) Specify the origin of the DNA:

5. Where will you obtain this DNA? Provide the name of the commercial or other source and product number, if applicable:

6. a). Is the DNA derived from a potential pathogen, human oncogene, or does it encode a potential toxin?

NO → Proceed to question 7

YES, specify: Human Vertebrate Plant

b). Check a Risk Group:

Risk Group 1: Agents that are not associated with disease in healthy adult humans

Risk Group 2: Agents that are associated with human disease which are rarely serious and for which preventive or therapeutic interventions are often available.

Risk Group 3: Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).

7. Will you be cloning DNA encoding molecules toxic to vertebrates with an LD₅₀ less than 100 ng/kg of body weight? NO YES*

* If yes, please note that NIH/OBA **and** Institutional Biosafety Committee Approval is required before initiation.

8. Does the experiment involve whole plants? NO YES

9. Does the experiment involve more than 10 liters of culture?
 NO YES

Largest volume used is:

Usual volume used is:

10. Please review section III of the NIH Guidelines (link below) and specify to which category of experiments involving recombinant DNA, this project falls under.
http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf

Category III-

E. Information For Projects involving Biohazardous Agents N/A

(Do not repeat information for recombinant DNA constructs covered in section D)

PLEASE NOTE : Following CDC recommendations, the IBC considers all HUMAN TISSUES OR CELLS (including cultured cell lines) as RISK GROUP 2 AGENTS.

1. Name of the agent(s)

2. Describe the source of the agent (from where the agent was acquired).

3. Provide a hazard assessment (nature of the hazards to personnel - sections of the CDC- NIH Guidelines must be cited when relevant), including use of radiological hazards in conjunction with biohazardous agents.

4. Describe the concentration and amount of agents to be generated.

5. Use of Select Agents:

Note: For assistance in answering these questions, see CDC Select Agent Transfer program <http://www.cdc.gov/od/sap> or USDA Veterinary Services Livestock Pathogens and Toxins List, <http://www.selectagents.gov/agentToxinList.htm>

a). Is the agent you are using on the CDC select agent list?
See <http://www.selectagents.gov/agentToxinList.htm>

NO YES → Identify the select agents:

If yes, please contact the EH&S Officer or staff at 315-470-6896.

b). Are you using a genetic element or genetically modified microorganism that was derived from a select agent?

NO YES → identify the select agents:

c). Do the genetically modified microorganisms or genetic elements, that contain nucleic acid sequences, code for any of the toxins listed in the CDC List of Select Agents, Appendix A, or their toxic sub units?

NO YES → identify the toxin(s)/toxic sub-units:

F. Physical Containment Level to be used in this protocol (refer to grid below):

BSL1 BSL 2 BSL 3

Physical containment is achieved through the use of laboratory practices, containment equipment, and special laboratory design. Emphasis is placed on primary means of physical containment, which are provided by laboratory practices and containment equipment. Special laboratory design provides a secondary means of protection against the accidental release of organisms outside the laboratory or to the environment. Special laboratory design is used primarily in facilities in which experiments of moderate to high potential hazard are performed.

Biosafety Level	Agents	Practices	Safety Equipment	Facilities
1	Not known to cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink required.
2	Associated with human disease. Hazard=	BSL1 Plus: -Limited access -Biohazard warning	Biosafety Cabinet for all manipulations of agents that cause	BSL1 Plus: - Autoclave available

	percutaneous injury, ingestion, mucous membrane exposure	signs -Sharps precautions -Biosafety manual/SOPs defining any needed waste decontamination or medical surveillance policies.	splashes or aerosols of infectious materials. PPE – lab coats, gloves, face protection as needed	
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL2 Plus: -Controlled access -Decontamination of all waste -Decontamination of lab clothing before laundering	Biosafety cabinet for all open manipulations of agents. PPE – protective lab clothing, gloves, respirator protection as needed.	BSL2 Plus: - Physical separation from access corridors - Self-closing, double door access - Exhausted air not re-circulated - Negative airflow into lab.

*Refer to the NIH Guidelines, Appendix G. Physical containment at:
<http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>

G. Information For Projects involving Non-Native Organisms N/A

1. Name of the organism(s)

2. Describe the source of the organism (from where the organism was acquired).

2. Provide a hazard assessment

4. Describe the number/amount of organisms.

5. Attach relevant government permits.

H. Funding

Funding Status: Internally Funded Seeking Internal Funding
 Externally Funded Seeking External Funding

Sponsor:	
Grant Title:	
Grant Number: (if funded)	

Is this grant administered through the Research Foundation on behalf of SUNY ESF?

NO → What is the administrative authority?

YES → RF Account (i.e., project/task/award #):

If you have received funding, or are seeking funding, for this activity, please include a copy of the grant with your submission to IBC.

Investigator Assurance of Compliance

By signing below, I attest to the accuracy of the information contained within this application. I assure that I will follow all applicable College policies and relevant government regulations and guidelines governing this activity. I will file an amendment with the IBC prior to implementing any change in the protocol from that described in this application.

Signature of Principal Investigator

Date

Signature of Department Chair

Date