Syracuse University
Institutional Biosafety Committee
Protocol Application Form

The Syracuse University Institutional Biosafety Committee (IBC) has been established to protect the health of University employees, students, visitors and the community from hazards of biological origin and ensure compliance with applicable federal, state and local requirements. The IBC reviews all protocols involving the use of biohazardous materials to understand the associated risks and how safety parameters will be managed at the University.

To complete this application answer all questions that apply and sign. Attach additional items that will aid committee members during the review process (e.g., specific vector information, cell lines, ATCC product description) and submit to the Biosafety Officer, Tim Coughlin, at tmcoughl@syr.edu. Note that no work should begin until the PI receives approval from the IBC. If you have any questions regarding this application, please call the EHSS Office at 315-443-2447.

A complete application and maintenance of an active protocol requires a biosafety review of the designated work area to ensure the containment level are appropriate for the proposed research. EHSS staff, the IBC Chairperson, and additional IBC members may participate in a laboratory biosafety review. Any biosafety concerns identified during this review will be discussed with the Principle Investigator (PI). Laboratory personnel are encouraged to conduct biosafety self-audits using the guidelines available on the Syracuse University Biological Safety website: http://ehss.syr.edu/laboratory-safety/biosafety/319-2/.

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EHSS Use Only	
Application #: Biosafety level:	Approved: Expires:

TITLE OF PROTOCOL:

DATE:

☐ **NEW APPLICATION** ☐ **RENEWAL** ☐ **AMENDMENT**

I. PRINCIPAL INVESTIGATOR

Name:	Email:
Department:	Building & room:
Campus phone:	Emergency phone:
Funding source:	Award #:

II. PERSONNEL INFORMATION

Include all lab personnel intended to have authorization to perform the work described in this application.
NOTE: Prior approval and relevant training is required to obtain access to biohazardous materials.

Name	Role (e.g. PI, GA, UG)	Years of Relevant Experience
	PI	

III. SUMMARY OF RESEARCH

1. Research Goals
Provide a succinct description of the proposed research that can be understood by a non-scientist. Avoid using highly technical terminology. Please define all abbreviations and acronyms.

2. Methods

Describe the experimental design; include all procedures involving biohazardous materials with respect to the research goals described in *Section III.1*:

3. Active Protocol Dates

Provide an estimated start and end date for this protocol based on anticipated funding and research timeline.

Start: End:

4. Work Locations

Provide the locations where biohazardous materials will be used. Include equipment rooms, storage areas, biological safety cabinets, etc. if located outside of the laboratory.

NOTE: Biohazardous materials transported between work locations must be, at minimum, in secondary containment.

5. Biological Materials

Indicate whether your protocol will include the following:

☐ Infectious agents - Complete *Section IV*

☐ Recombinant DNA - Complete *Section V*

☐ Human derived material (e.g. blood, bodily fluids, cells, tissues) - Complete *Section VI*

IV. INFECTIOUS AGENTS ☐ Not Applicable

Agent (e.g. bacterium, virus, fungus, toxin)	Genus & species	Strain	Source (e.g. vendor, collaborator) and contact information	CDC / NIH Biosafety Level (BSL)

6. Rationale

Please explain why a less virulent or attenuated agent cannot be used in the proposed research:

7. Training

Have all laboratory personnel working with infectious agents completed Biosafety Training?
Training completion can be verified at: http://ehss.syr.edu/about/training/my-training-history/

☐ YES ☐ NO

Has the laboratory developed an SOP for the proposed protocol?

☐ YES ☐ NO

8. Identification of Hazards

Perform an assessment of the biohazardous potential of the agents and processes involved; include all relevant concerns such mode of transmission, aerosol-producing procedures, prior laboratory-acquired infections, sharps use, etc.

9. Hazard Mitigation

Describe laboratory practices that will reduce the risk of a potential exposure to the agent(s) (e.g. use of a biological safety cabinet, sealed centrifuge rotor, routine decontaminations). Include the method of terminal inactivation (e.g. chemical, autoclave) and how access to biohazardous materials is controlled (i.e. security).

10. Exposure Information
What is the infectious dose?
List the signs and symptoms of exposure:
The treatment available for accidental exposure is (check all that apply): ☐ Antibiotics ☐ Vaccination ☐ Antivirals ☐ No effective treatment
The agent is viable in the environment for: ☐ Hours ☐ Days ☐ Weeks

V. RECOMBINANT OR SYNTHETIC NUCLEIC ACIDS ☐ Not Applicable

Please review the NIH Guidelines concerning the use of recombinant or synthetic nucleic acid molecules: https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf

Vector type (e.g. plasmid, lentivirus, retrovirus)	Source (e.g. vendor, collaborator) and contact information	CDC / NIH Biosafety Level (BSL)	Target recipient

11. Nature of Vectors
Describe the vector(s) to be used in the proposed research. Provide information on the genetic basis of attenuation, replication competency and host range.

12. Nature of Inserts
Provide the genus and species names of the organism(s) from which the insert is derived.

12. Nature of Inserts (cont'd)

Please provide the full names and abbreviations of the gene(s) and/or promoter(s) carried on the insert, and a brief description of the biological function or activity of the product(s).

If the insert is from a eukaryotic virus and it is to be introduced into a eukaryotic host, what percent of the viral genome will be cloned:

% ☐ N/A

13. Training

Have all laboratory personnel working with recombinant DNA completed Biosafety Training?
Training completion can be verified at: http://ehss.syr.edu/about/training/my-training-history/

☐ YES ☐ NO

Has the laboratory developed an SOP for the proposed protocol?

☐ YES ☐ NO

14. Identification of Hazards

Perform an assessment of the biohazardous potential of the transformed product(s); include all relevant information such as antibiotic resistance, toxicity of products, etc.

15. Hazard Mitigation

Describe laboratory practices that will reduce the risk of a potential exposure to the product(s) (e.g. use of a biological safety cabinet, sealed centrifuge rotor, routine decontaminations). Include the method of terminal inactivation (e.g. chemical, autoclave) and how access to biohazardous materials is controlled (i.e. security).

VI. HUMAN DERIVED MATERIAL ☐ Not Applicable

Indicate whether your protocol will include any of the following:		
Blood	Type: N/A	Source:
Bodily fluids	Type:	Source:
Cells / tissues	Type:	Source:
Primary cell lines	Type:	Source:
Established cell lines	Type:	Source:

16. Training

Have all laboratory personnel working with human derived materials completed Bloodborne Pathogens training?
Training completion can be verified at: http://ehss.syr.edu/about/training/my-training-history/

☐ YES ☐ NO

Have all laboratory personnel working with human derived material been offered the Hepatitis B vaccination?

☐ YES ☐ NO

Has the laboratory developed an SOP specific to the proposed protocol?

☐ YES ☐ NO

17. Identification of Hazards

Perform an assessment of the biohazardous potential of the materials and processes involved; include all relevant concerns such mode of transmission, aerosol-producing procedures, prior laboratory-acquired infections, sharps use, etc.

18. Hazard Mitigation

Describe laboratory practices that will reduce the risk of a potential exposure to the material(s) (e.g. use of a biological safety cabinet, sealed centrifuge rotor, routine decontaminations). Include the method of terminal inactivation (e.g. chemical, autoclave) and how access to biohazardous materials is controlled (i.e. security).

VII. ADDITIONAL INFORMATION

Please use this space below to provide any additional information regarding the proposed protocol that may be helpful to the IBC during review.

Assurance Statement

I acknowledge responsibility for all biohazardous materials used in my laboratory. I agree to comply with all Federal, State and Local rules and regulations applicable to this application. I have read and have a copy of the Syracuse University Biological Safety Program. I agree to have this Program readily available to all persons using biohazardous material in my laboratory. I agree to create and provide standard operating procedures for all operations proposed in this application to all personnel working under my supervision.

I assume the responsibility of assuring that all individuals using biological material in my laboratory have completed the required training programs and have received the required supervised training. I also agree to assure that all exposures from biohazardous materials used in my laboratory are avoided. Furthermore, I will assure that all biological material use conducted in my laboratory will be in accordance with the terms and conditions of my application, the Biological Safety Program, and applicable rules and regulations.

I am aware that any additions or modifications to the approved protocol used in my laboratory that could increase or modify the potential exposure hazard or introduce a new hazard must be approved by the Institutional Biosafety Committee.

I certify that all information provided and all statements made in this application are true and complete to the best of my knowledge.

Signature of Applicant:_____Date:_____