Biosafety Protocol Submission Form

All research involving **recombinant or synthetic nucleic acid molecules**, **infectious agents**, **human or animal tissues**, **biological toxins**, or **other biohazardous materials** must be reviewed and approved by the Institutional Biosafety Committee (IBC) prior to initiation. This includes teaching activities and collaborations with external institutions.

Please follow the instructions below when preparing your protocol submission:

I. General Information

1. Principal Investigator (PI):

Name: _____ **Email:** _____
Department: _____ **Phone:** _____
Office Location: _____ **Lab Location:** _____

2. Project Title:

3. Type of Submission *(check one)*:

☐ New Protocol
☐ Renewal
☐ Amendment
☐ Annual Update

4. Proposed Project Start Date: _____

5. Proposed Project End Date: _____

II. Research Personnel

1. List all individuals working with the materials (attach additional sheet if needed):

	Name	Classification	Role/Title	Email	T#	Training (Y/N)
1.						
2.						
3.						
4.						
5.						

2. Will undergraduate or high school students participate in the project?

☐ Yes ☐ No

If yes, please provide details of supervision and training on separate sheet

III. Project Description

1. Brief Abstract (in lay terms):

Describe the goal and significance of the project (*attach sheet if necessary)*

2. Detailed Experimental Procedures:

Attach detailed description of SOPs of all procedures involving biohazards, including: inoculations, culturing, transformations, transfections; animal procedures (if applicable); sample collection and processing. Also state the estimated duration and frequency of experiments.

IV. Biological Materials Used

1. Check all that apply (attach relevant SDS, permits, etc.):

☐ Recombinant or synthetic nucleic acid molecules
☐ Human blood, tissues, or cell lines
☐ Animal blood, tissues, or cell lines
☐ Infectious agents (bacteria, viruses, fungi, etc.)
☐ Select agents or toxins
☐ Transgenic animals/plants
☐ Human gene transfer experiments
☐ Other (specify): _____
_____
_____

2. Provide specific names and characteristic of agents, vectors, or hosts:

3. Are any materials derived from human or non-human primates?

☐ Yes ☐ No

If yes, please explain source and handling procedures on separate sheet

V. Risk Assessment and Biosafety

1. Proposed Biosafety Level (BSL)

☐ BSL-1
☐ BSL-2
☐ BSL-3 *Please provide justification of proposed BSL on separate sheet*

2. Containment Facilities Used (Check all that apply):

☐ Biological Safety Cabinet (Class II or Class III)
☐ Centrifuge with sealed rotors/cups
☐ Animal biosafety housing (e.g., micoisolators)
☐ Other (specify): _____
_____
_____

3. Disinfection and Waste Disposal Procedures:
Describe procedures for decontamination and waste disposal of biohazardous materials.
(attach extra sheet if necessary)

4. PPE and Safety Measures:

Describe the personal protective equipment and additional safety practices used: (*attach extra sheet if necessary)*

VI. Animal or Human Subjects (if applicable)

1. Are vertebrate animals used in this protocol?

☐ Yes IACUC Protocol #: _____

☐ No

2. Are human participants involved?

☐ Yes IRB Protocol #: _____

☐ No

VII. Training and Compliance

1. Have all personnel completed all requires safety training

☐ Yes ☐ No

2. Are any federal permits required (e.g., APHIS, USDA, CDC, NIH)?

☐ Yes *(Attach copy)*

☐ No

VIII. Principal Investigator Assurance

By signing this assurance, I _____, as the Principal Investigator (PI), acknowledge and accept full responsibility for the safe and compliant conduct of the research described in this IBC protocol submission. I certify and agree to the following:

1. **Accuracy of Information**
   I affirm that all information provided in this protocol submission is accurate, complete, and reflective of the actual procedures to be conducted in the laboratory or research setting.

2. **Regulatory Compliance**
   I will ensure that all research activities involving recombinant or synthetic nucleic acid molecules, biohazardous materials, infectious agents, and/or biological toxins are conducted in full compliance with applicable federal, state, and local regulations, including but not limited to:
   - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
   - CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)
   - U.S. Department of Transportation (DOT) and International Air Transport Association (IATA) shipping regulations
   - Any other applicable regulatory or permitting requirements (e.g., USDA/APHIS, EPA)

3. **Adherence to IBC Requirements**
   I will conduct this research in accordance with all institutional biosafety policies and the conditions and stipulations set forth by the IBC. I understand that I must obtain written IBC approval prior to initiating or modifying any covered research activity.

4. **Training and Supervision**
   I will ensure that all personnel, including students, technicians, and collaborators involved in the project:
   - Are properly trained in biosafety, biosecurity, and emergency response procedures
   - Understand and follow the approved protocol, standard operating procedures (SOPs), and safety practices
   - Complete all required institutionally mandated training (e.g., bloodborne pathogens, lab safety, biosafety training)

5. **Incident Reporting**
   I will report any accidents, exposures, spills, or other biosafety-related incidents involving research described in this protocol to the Biosafety Officer and IBC immediately or within the required timeframe, following institutional incident reporting procedures.

6. **Amendments and Continuing Review**
   I agree to submit protocol amendments to the IBC for review and approval prior to

implementing any changes. I also acknowledge my responsibility to submit continuing reviews and renewals as required by the IBC to maintain approval status.

7. **Facility Suitability**
   I confirm that the facilities and equipment to be used for this research are appropriate for the assigned biosafety level and that all required containment measures and procedures will be strictly followed.

8. **Export Control and Dual Use Research of Concern (DURC)**
   I understand that it is my responsibility to identify and disclose any potential export control or DURC considerations associated with this work and consult with the appropriate institutional offices as needed.

9. **Recordkeeping**
   I will maintain all required records related to biosafety training, equipment certifications, waste disposal logs, and protocol-related documentation in accordance with institutional policies.

By signing below, I certify that I have read, understood, and agree to comply with all of the above requirements. I accept full responsibility for the conduct of this research and for ensuring that all personnel associated with the project adhere to approved safety and regulatory practices.

Principal Investigator Name: _____

Department: _____

Email: _____ **Phone:** _____

Signature: _____ **Date:** _____