North Carolina A&T State University
Institutional Biosafety Committee (IBC)
Protocol for Research Involving Biological and Biohazardous Materials

SECTION I

IBC#_____

(To be assigned by IBC)

PI Name: **Date:**

Project Title:

Co PI Name: **Laboratory Personnel:**

Laboratory Personnel: **Laboratory Personnel:**

Note: All investigators and participating personnel must have documentation completion of the Online Biosafety Training Program

Department: **Laboratory address where research will conducted (Building and room):**

Phone:

Biosafety Level of Contamination:

Funding Source

(Check all that apply and provide names as necessary)

☐ NIH	☐ Seed Grant	☐ Institutional Research Support	☐ NSF
☐ State	☐ Departmental	☐ Private Foundation/Association	☐ Commercial
☐ Other	☐ None		

If you chose Commercial, Seed Grant, Private Foundation, or Other provide the Company name or Source:

PI of Grant: **Grant Proposal Number:**

SECTION II

General Biosafety Information

Refer to Instructions to assist in completing this portion of the application

1. **Experiment overview.** *Give a brief overview, in layman terms, of the experiment you will conduct and discuss the use of any hazardous or potentially hazardous agents (i.e. bacteria, virus, cells, etc.) that will be utilized.*

2. **List all biological and/or biohazardous material to be utilized and their Risk Group (RG) classification.** (*Give details on material(s) listed (including genus, species, and strain type).*

3. **Safety practices summary.**

4. **Risk for occupational exposure.** *(Describe precautions to prevent occupational risks)*

5. **Storage of biological/biohazardous materials.**

6. **Special instructions for biosafety level 3 containment.**

7. **List relevant training or experience that qualifies you (the PI) to conduct this proposed research.**

SECTION III
Human Gene Transfer Supplement

(Refer to instructions)

Check the following box if this section is not applicable to the research you are proposing in Section II.

☐ **Not Applicable**

SECTION IV
Animal Use Supplement

Check the following box if this section is not applicable to the research you are proposing in Section II.

☐ **Not Applicable**

1. **List each biological/biohazardous/regulated agent identified in Section II.2 which will be introduced only into animals.**

2. **Has this research use of animals received A&T's Institutional Animal Care and Use Committee (IACUC) approval?**

IACUC Protocol Number **Date Approved**

IACUC Protocol Pending **Date Submitted**

SECTION V
rDNA Registration

Check the appropriate section (s) in Section III of the NIH Guidelines that cover your experiment.

☐ **A** ☐ **B** ☐ **C** ☐ **D** ☐ **E** ☐ **F**

1. **List the source(s) of DNA.**

2. **List the nature of the inserted DNA sequences.**

3. **List the host(s) and vector(s) to be used.**

4. **Identify the protein if an attempt will be made to obtain expression of a foreign gene in the cloning vehicle.**

Are large-scale experiments (more than 10 liters of culture/experiment) planned? ☐ **Yes** ☐ **No**

If the proposed experiments are to be carried out off-campus submit the rDNA assurances for the off-campus site with this form.

5. **Will there be any off campus collaborators involved in this project?** ☐ **Yes** ☐ **No**
   If yes, please list their name, degree(s), title, department, address, email, and phone number below.

SECTION VI
Information and Training

1. **Submit copies of YOUR Lab Safety Plan with this proposal.** In accordance with the Laboratory Standard, information regarding the Laboratory Safety Manual, Laboratory Safety Plan, and Material Safety Data Sheets must be communicated to employees and all those working in the lab. **Indicate the location (building and room number) of these items.**

2. **Identify designated work areas for infectious biological materials, and areas where eating or drinking is allowed, if any.**

3. **<u>Submit a floor plan with this proposal</u> for each laboratory showing locations of infectious material storage, waste storage, lab benches, desks, hoods, spill control supplies, the safety manual, the safety plan, MSDS, and any other items to assist emergency response personnel.**

4. **Describe measures to decontaminate biological waste.**

COMPLETE THE PRINCIPAL INVESTIGATOR'S ASSURANCE AND BE SURE YOUR DEPARTMENT CHAIRPERSON SIGNS THE ASSURANCE BEFORE YOU SUBMIT THIS APPLICATION TO THE IBC.

PRINCIPAL INVESTIGATOR'S ASSURANCE

The signature certifies that the PI understands and accepts the following obligations in this study:

I recognize that as the PI it is my responsibility to ensure that this research and the actions of all project personnel involved in conducting the study will conform with the IBC approved protocol and the provisions of the NIH Guidelines for Research Involving Recombinant DNA, the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories manual, and the Select Agent Rule where appropriate.

I will inform the IBC of any unanticipated biosafety related problems encountered while doing the research.

I will notify the IBC of any change in an RG-1 protocol.

I will not initiate any change in an RG-2 or RG-3 protocol without prior IBC approval.

I will maintain all required research records on file and I recognize that representatives of the IBC are authorized to inspect these records.

I accept responsibility for the safe conduct of the experiments to be conducted and will see that all associated personnel are trained in the safe laboratory practices required to work.

I will oversee the development and implementation of standard biosafety operating procedures for the laboratory.

I understand that the IBC approval is valid for 1 year and an annual IBC update is required in order to maintain approved status.

I understand that failure to comply with all NIH regulations, IBC requirements / policies, and the provisions of the protocol as approved by the IBC may result in suspension or termination of my research project.

For protocols involving the use of Select Agents (as defined by the NIH / CDC):

I will comply with the requirements for the reporting and securing of select agents that fall within the bounds of the PATRIOT Act.

For protocols using animals in research:

I will contact the IACUC and develop standard operating procedures (SOPs) and an Operational Safety Protocol to address relevant operational biocontainment and safety issues for the use of these agents in animals, prior to their introduction into the animal.

_____ _____

PI Signature Date:

_____ _____

Department Chairperson Date:

IBC Approval

The Institutional Biosafety Committee has reviewed the proposed project and has found it to be in compliance with the *NIH Guidelines*, the CDC / *NIH Biosafety in Microbiological and Biomedical Laboratories* manual, the *Select Agent Rule* requirement for research involving biohazardous materials, and the NCA&T Policies and Procedures.

_____ _____

IBC Chairperson Date: