For IBC Use Only Protocol #._____

Florida A&M University
Institutional Biosafety Committee

Room 130 Dyson Building
850-412-5246

PROTOCOL SUBMISSION FORM

For New Protocols or Resubmissions Involving the Use of Biohazardous Materials in Research

All research protocols at Florida A&M University involving biohazards must be submitted to the Institutional Biosafety Committee (IBC) for review. **For purposes of the IBC, biohazards are potentially infectious agents or organisms, recombinant DNA, and other genetically altered organisms and agents.** Protocols are approved for 3 years.

A protocol submission to the IBC includes the **original** of this form, **typed and completed in full.** If items are not applicable, note N/A. The form **must** be signed in section PI by the investigator. The application must be submitted to the Committee, Room 130 Dyson Building1520 S Martin Luther King Jr. Tallahassee, FL 32307. Questions regarding completion of this form may be directed to the Administrator of Regulatory Compliance, at 599-3214. If this work is part of a project being proposed for external funding, this protocol should be submitted to the IBC at the same time as your grant proposal or as soon as possible thereafter so that the funding agency can be informed of Approval in a timely fashion.

Laboratories must have a Biosafety manual. Also, this information must be readily accessible to all lab members. **RG1:** Laboratories working with a Risk Group 1 agent may adopt the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (4th edition) as their principal Biosafety laboratory manual (http://www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm). **RG2 and above:** Section VII of this protocol submission will serve as the Biosafety manual for laboratories working with a Risk Group 2 or 3 agents. **Please note,** if the agent is classified as a Select Agent, a more extensive Biosafety manual, including one that addresses security and other regulatory requirements, will be required.

When any revision to an approved research protocol is desired, an amendment must be filed with the IBC and approved prior to implementation. The amendment submission form must be completed indicating the changes. Forms can be obtained from the Office of Animal Care and Regulatory Compliance office or website, http://research.famu.edu/OACRC

I. PROJECT **Investigator:** *Investigator must be a member of the faculty or a Research Associate with parenthetical rank of Assistant Professor or higher.*	**Appointment:**
Office Address: Include building and room #	
Department: *If more than one department notes primary affiliation only.*	**Section:**
Email:	**Phone:**
Fax	
Location of Proposed Work/Experiments: *Include building and room number*	
Primary Lab Contact	**Phone**
	Email:

Status of Protocol: For amendments, complete an amendment submission form.
☐ New
☐ **Resubmission** *If Resubmission original Protocol #* _____

Project is funded: ☐ Internally* ☐ Externally** ☐ Externally (pending)**

II. Risk Assessment

1. Will you be working with or likely to generate a potentially hazardous agent or organism or a Virus (defective or non-defective)?
If yes, the entire submission form must be complete.
If no, only sections I-VI of this submission form must be completed

2. Will the experiments involve the use of (check all that apply and indicate)?

☐ **Human Subjects** *Contact the IRB office at 412-5246. Special requirements may apply.*
IRB Protocol#_____ **IRB Protocol** Date Approved: _____

☐ **Human Cell Lines**

☐ **Whole animals** *Include a copy of the IACUC supplemental form B with this IBC submission.*
Species _____
IACUC Protocol #_____ **IACUC Protocol Approval Date** _____

Check Biosafety Level ☐ **BL1** ☐ **BL2** ☐ **BL3** ☐ **BL4**
Please refer to the latest version of the NIH Guidelines for Research Involving Recombinant DNA Molecules at Http://www4.od.nih.gov/oba/Rdna.htm

☐ **Animals Tissue Only (Not working with live animals)**
Species _____
IACUC Protocol #_____ **IACUC Protocol Approval Date** _____

☐ **Whole Plants**
Species _____
Check Biosafety Level ☐ **BL1** ☐ **BL2** ☐ **BL3** ☐ **BL4**
Please refer to the latest version of the NIH Guidelines for Research Involving Recombinant DNA Molecules at Http://www4.od.nih.gov/oba/Rdna.htm

☐ **Microorganisms (bacteria, Viruses, etc.)**
Species _____
Check Biosafety Level ☐ **BL1** ☐ **BL2** ☐ **BL3** ☐ **BL4**
Please refer to the latest version of the NIH Guidelines for Research Involving Recombinant DNA Molecules at Http://www4.od.nih.gov/oba/Rdna.htm

☐ **Plant & Animal Tissue Culture**
Species _____
Check Biosafety Level ☐ **BL1** ☐ **BL2** ☐ **BL3** ☐ **BL4**
Please refer to the latest version of the NIH Guidelines for Research Involving Recombinant DNA Molecules at Http://www4.od.nih.gov/oba/Rdna.htm

3. Is the agent being used in this protocol on the CDC list of Select Agents? ☐ Yes ☐ No
Note: work with a Select Agent will require registration with the CDC and therefore special procedures apply Please contact IBC for guidance.

3a. Is the agent being used in this protocol on the CDC list of Select Agents? ☐ Yes ☐ No

If **YES**, has CDC registration been approved? ☐ Yes ☐ No
If **YES**, has CDC registration has been approved, please provide a copy of the approval letter for our records.
If **NO**, please state why:

4. Do experiments involve any release into the environment? ☐ N/A ☐ Yes ☐ No
If yes, please describe.

4a. Has approval for this release been filed with state and federal agencies? ☐ N/A ☐ Yes ☐ No

5. Do experiments involve work with human blood or other potentially infectious materials? ☐ Yes ☐ No
If **YES**, annual Blood Borne Pathogen training is required. If this training has been received, please indicate this in Section VII, question 7. ***Blood means human blood, human blood components, and products made from human blood. Other potentially infectious materials means human body fluids; unfixed tissues or organs (other than intact skin) from a Human (living or dead); HIV-containing cell or tissue cultures, organ cultures and HIV-or HBV-containing culture mediums Or other solutions; and blood organs, or other tissues from experimental animals infected with HIV or HBV.***

III. FOR RECOMBINABT DNA / VIRAL STUDIES:

1. Does this research involve work with rDNA? ☐ Yes ☐ No

2. Please describe the source of rDNA(s): (i.e. organism, clone bank, etc., and literature citation, as appropriate)

3. Please describe the nature of the rDNA (s): *(i.e. specific genes, rDNA, or genomic DNA, etc.)*

3a. Is this a mutated gene? ☐ Yes ☐ No
If **Yes,** please describe

3b. Is this an oncogene? ☐ Yes ☐ No
If **Yes,** please describe

3c. Are the rDNA sequences potentially harmful to humans, animals, or plants? ☐ Yes ☐ No
If **YES,** please describe.

4. Please list and provide a description of all plasmid vectors.

4a. Please list and provide a description of all viral vectors.

4b. Are you using any helper viruses or viral packaging cell lines? ☐ N/A ☐ Yes ☐ No
If **YES,** please describe.

4c. If you are using a virus, is it replication competent? ☐ N/A ☐ Yes ☐ No
Certain recombinant replication-defective viral vectors (e.g. vectors based on adenovirus and murine retrovirus) can produce recombinant replication-competent virus through homologous recombination with packaging genes or endogenous wild-type virus. ***What method are you using to test your viral preparations for the presence of replication-competent virus?***

4d. What host cells are susceptible to viral infection?

5. What microorganism, whole animal, or plant will be used as a host for the vectors described in question 4 and 4a.

5a. Potential host range/In what other organism(s) is the product potentially infectious?

6. Will the experimental procedures involve the deliberate transfer of a drug resistance trait to microorganisms and could this compromise the use of drugs used to control disease agents in humans, veterinary medicine, or agriculture? ☐ Yes ☐ No
*If **YES,** please specify.*

7. Is human gene therapy proposed in this protocol? ☐ Yes ☐ No
Also, please contact the IBC office to determine if there are additional requirements. Please consult the Office of Biotechnology Activities (OBA) website for further details at htt;//www4.od.nih.gov/oba/Rdna.htm.

8. Please check the appropriate physical containment for this protocol.
Please refer to the latest version of the NIH Guidelines for Research Involving Recombinant DNA Molecules at htt://www4.od.nih.gov/oba/Rdna.htm.

☐ **BL1** ☐ **BL1 w/BL2 practices** ☐ **BL2** ☐ **BL2w/BL3 practices** ☐ **BL3** ☐ **BLA**

9. Does this project involve large scale (>10 liters of culture) research or production? ☐ Yes ☐ No
If yes, additional guidelines apply. Please contact the IBC at 412-5246.

IV. PLEASE SUMMARIZE THE PROPOSED RESEARCH.

In particular, describe (in lay language) the recombinant approach used or use of any infectious agent, what systems, you plan to start with, what your endpoint is what types of manipulations you plan to use to achieve that goal, and whether you anticipate any complications in that process. Detailed information such as buffers, significance etc., is not necessary. Also provide any additional supplemental material, including publications, which might be helpful to the IBC in its review process.

V. STAFF GROUP

Please list the name of each staff member (including PI). This should include all individuals who will be directly involved in carrying out the work described in the protocol.

ALL staff members must sign this protocol.

Once the protocol has been approved, any changes in staff should be submitted to the IBC on an amendment form. Note: staff other than the principal investigator may not amend the protocol. If this protocol involves a select agent, please note that all staff members MUST be screened and approved prior to access to the select agent, and other special procedures may apply. Contact the IBC for guidance.

READ BEFORE SIGNING

Your signature indicates the following:

☐ **You have thoroughly read this protocol submission**
☐ **You have sufficient knowledge and are sufficiently trained to perform the responsibilities for which You have been assigned**
☐ **If training is required, this will be completed prior to your involvement in this project hazardous Agents used in this protocol**
☐ **You fully understand the steps necessary following any spills or potential exposures with the Agents described in this protocol**

Name and Responsibilities: *Examples of responsibilities would include: Cell or tissue culture, animal care and use, plasmid prep., cloning, protein prep., viral work, etc*	**Signature**
Responsibilities:	
Responsibilities:	

Responsibilities:	
Responsibilities:	
Responsibilities:	

VI. SIGNATURES

The undersigned investigator is responsible for providing adequate training and supervision of staff in microbiological techniques and practices required to ensure safety and for procedures in dealing with accidents. The investigator is responsible for correcting work errors and conditions that may result in the release of rDNA materials or infectious agents and ensuring the integrity of the physical containment. Any adverse event, such as a work related injury or exposure must be reported to the IBC. The investigator is also responsible for ensuring that co-investigators, if posed by the project. The investigator must ensure that staff has read this protocol.

A copy of section VII (if applicable must be posed in the lab. For further information regarding physical safety issues, laboratory safety, emergency response and training within the University contact Environmental Health and safety office at 599-3442.

Investigator: I understand my responsibility with regard to laboratory safety and certify that the protocol as approved by the IBC will be followed during the period covered by this research project. Any future changes will be submitted for IBC review and approval prior to implementation. I understand that this protocol will be reviewed periodically; it is my responsibility to complete and submit the survey form used for the periodic IBC review in a timely manner.

Signature of Investigator:	**Date:**
Signature of Department Chair:	**Date:**

VII. RISK MANAGEMENT FOR INFECTIOUS AGENTS **:

Potentially infectious to humans, animals, or plants

This section must be posted in the Laboratory.

*****Please note that this Section should be completed only if the infectious agent is Risk Group 2 or greater.***

The following information is to be provided for all research protocols involving infectious agents (potentially infectious to humans, animals, or plants).

Personnel must be advised of special hazards and must be required to read and to follow the required practices and procedures described in this section.

Investigator:
Lab room number (s):
Phone number:

1. Please identify the name of the infectious agent and corresponding Risk Group.

Please refer to the latest version of the NIH Guidelines for Research Involving Recombinant DNA Molecules at htt://www4.od.nih.gov/oba/Rdna.htm

Name of the infectious agent: _____

Risk Group: ☐ **RG2** ☐ **RG3** ☐ **RG4**

1. Please indicate the type of biosafety cabinet that will be used for this project.

Contact Environmental Health and Safety Office if you have questions regarding your biosafety cabinet.

☐ **I** ☐ **IIa** ☐ **IIb1** ☐ **IIb2** ☐ **IIb3** ☐ **III** ☐ **None**

2a. What is the last Date that your biosafety cabinet was certified?
Please note that biosafety cabinets must be certified annually.

3. Please note that the operating instructions for the Biological Safety Cabinet and other applicable equipment (centrifuge, etc., that are operated with the potentially hazardous material) need to be available to staff members. Please note that Appendix A of the BMBL at http://ww.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm contains information regarding the safe operation of the different classes of BSC's.

4. AGENT HAZARD (including recombinant) – *State succinctly the nature of the hazard to which you and your associates will be exposed and the possible consequences of accidental human infection with the agent with which you will be working; include each potential danger and its pathway (contact, inhalation, ingestion).*

5. What are the safety and security policies/procedures for admittance to the work area?
Please indicate which of the following measures are taken upon entry to the laboratory:

☐ Employees wear ID badge at all times
☐ Authorized access only
☐ Laboratory locked when unattended
☐ Keycard access only
☐ Visitor/Guest access recorded
☐ Hazardous agent in locked cabinet
☐ Immunization
☐ Security Background Check
☐ Donning of PPE*, please indicate:
☐ Specific training, please indicate:
☐ Infectious specimen packages opened in a Biosafety cabinet only
☐ Other:

***PPE** stands for **P**ersonal **P**rotective **E**quipment

6. Please indicate the specific policies and procedures that will be followed in the handling of this agent (s). *(This may be accomplished by attaching specific procedure manuals, or by attaching the pertinent sections of the latest edition of the CDC/NIH Biosafety in Biomedical Laboratories at: http://www.cdc.gov/od/ohs/biosfty/bmb14toc.htm*

7. Because of the procedures described or the agents used in this protocol, some specific training or additional requirements may be necessary. Please note the following examples:

OSHA Blood Borne Pathogen Training: Annual training is required of all individuals working with human blood products or potentially infectious human materials.*

OSHA Respiratory Protection and Fit Testing: Required of all individuals who must wear a respirator**.

DOT/IATA Shipping of Infectious Substance*:

Import/Export Permit for Infectious Substance Shipping*

8. PERSONAL PROTECTIVE EQUIPMENT – Please indicate which of the following PPE is required when working with this agent.

☐ Gloves ☐ Safety Glasses ☐ Safety Shower ☐ Lab Coat ☐ Safety Goggles/Shield

☐ Mask ☐ Shoe Covers ☐ Hand wash sink ☐ Respirator ☐ Protective Suit/Gown

☐ Other

9. SPILL PROCEDURES – List the procedures to take, step by step, in the event of a spill containing this agent in the lab. Please include the disinfectant, the concentration used and the amount of contact time.

10. EXPOSURE / NEEDLESTICK – Please indicate which of the following measures are to be taken in the event of an exposure (including needle sticks) to this agent.

☐ Thoroughly was area of needle stick with soap and water

☐ Immunization available and offered

☐ Effective post exposure treatment available (please provide details)

☐ Notify PI

☐ Notify UCOM (UC Office of Occupational Medicine, L-156, 2-6757)

☐ Other/Details:

11. SURVEILLANCE FOR INFECTIONS – Discuss if surveillance is appropriate and justify whether or not sera banking/testing is needed.

12. DECONTAMINATION PROCEDURES – Please indicate which of the following measures are taken during routine decontamination of the work area and of the pertinent equipment:

☐ Treat with fresh bleach (please indicate for the agent being used, the appropriate dilution of disinfectant and exposure time):

☐ UV Light for _____minutes

☐ 70% ethyl/isopropyl alcohol for 10 minutes

☐ Glutaraldehyde (Cidex) per manufacturers instructions
☐ Autoclaving at _____temperature for _____ minutes
☐ Other:

13. DISPOSAL METHODS – Please indicate which of the following methods are utilized during the disposal of the agent:

☐ General Waste and sanitary sewer

☐ Autoclaving at _____ temperature for _____ minutes

☐ Potentially infectious waste is placed in a biohazard waste drum and picked-up and shipped by EVS

☐ Sharps container pick-up and shipped by EVS

☐ Waste incineration required

☐ Other:

14. OVERSIGHT – Who will assume responsibility for the ongoing day-to-day oversight and supervision of laboratory operations and personnel in your absence? Describe the relevant qualifications of the individual.

15. IN CASE OF AN EMERGENCY, CALL – In case of an emergency involving this agent, indicate who should be notified, include the phone number.