For Office Use Only

Protocol #:_____
Date Approved:_____
Signature IBC
Chair_____
rDNA___Infectious Agent__ Exempt___
IACUC____ IRB____ RSC____

XAVIER UNIVERSITY OF LOUISIANA
INSTITUTIONAL BIOHAZARD COMMITTEE
HAZARDOUS AGENTS PROTOCOL

Date:
Project Title:

Principal Investigator(s):
Title:
Department:
Phone No:
Fax No:
Email:
Campus Address:

This is a:
☐ New Protocol ☐ Revised Protocol (revision date) ☐ Amendment

If this submission is a Revised or an Amended Protocol, Please make sure those changes (and only those changes) are in **red** type. Submit with supporting documents, as applicable, and identify the Protocol No. .

Hazard Category: (check all that apply)
☐ Biological ☐ Chemical ☐ Recombinant DNA ☐ Radiation

Will animals be used in this protocol? ☐ Yes ☐ No
Will human subjects, tissues or bodily fluids be used in this project? ☐ Yes ☐ No
Will radiation be used in this project? ☐ Yes ☐ No

If you answered YES to any of the above, please identify:
The IRB Approval number
The IACUC Approval number
or The RSC Approval number

Personnel: List all project personnel and relevant experience. This information is intended to inform the committee of the training background of the investigators and key personnel.

NAME	DEGREE(S)	DUTIES IN THE PROJECT	RELEVANT TRAINING EXPERIENCE

Non-Technical Synopsis: Please give a brief description of the project that is easily understandable by non-scientists. Use phrasing and words that would be easily understood by someone having no knowledge of your project. Avoid using abbreviations and technical vocabulary or phrases. Attach a copy of the grant proposal abstract or project summary if desired.

1. DOES THE RESEARCH INVOLVE THE USE OF ANY OF THE FOLLOWING?

A**.** Biological Hazards (Microbiological or viral agents, pathogens, toxins, select agents as defined in 42 CFR 73, Appendix A, or animals) ☐Yes ☐No

B. Human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines) ☐Yes ☐No

C. Recombinant DNA ☐Yes ☐No

D. Chemicals:

1. Toxic chemicals ☐Yes ☐No
2. Flammable, explosive or corrosive chemicals ☐Yes ☐No
3. Toxic compressed gasses ☐Yes ☐No
4. Acetyl cholinesterase inhibitors or neurotoxins ☐Yes ☐No

E. Controlled substances ☐Yes ☐No

F. Ionizing radiation:
1. Radioactive materials ☐Yes ☐No
2. Radiation generating equipment ☐Yes ☐No

G. Nonionizing radiation:
1. Ultraviolet Light ☐Yes ☐No
2. Lasers (class 3b or class 4) ☐Yes ☐No
3. Radiofrequency or microwave sources ☐Yes ☐No

If the answers to any of these questions is YES, complete all sections of this survey that apply.

If all answers are NO, the project is exempt. *If the research involves human subjects or human tissues, IRB review is required. Use of animals also requires submission to the IACUC.*

2. BIOLOGICAL HAZARDS

A. If you answered YES in Section IA above, list all BIOSAFETY LEVEL 2 AND 3 AGENTS OR TOXINS used in your laboratory. It is the responsibility of each PI to:

(1) Consult either
a) The NIH-Center for Disease Control and Prevention publication entitled Biosafety in Microbiological and Biomedical Laboratories, or
b) The CDC online reference (http://www.cdc.gov)

(2) Identify the Biosafety Level (also called the Risk Group) for each organism, agent, or toxin, and enter it into the following table:

Organism, Agent, or Toxin	Biosafety Level *

B. Are any of the biohazardous agents listed above classified as a "Select Agent" by the CDC? ☐Yes ☐No

C. For each BIOSAFETY LEVEL 2 OR 3 AGENT OR TOXIN listed, complete this section:

BIOLOGICAL HAZARDS-Description of Use (*Photocopy this page as necessary*.)

I. Identify the microbiological agent or toxin (name, strain, etc.):

II. If this is a Select Agent (42 CFR 72.6), provide the CDC Laboratory Registration # and the date of the CDC inspection:
III. Indicate the largest volume and/or concentration to be used:
IV. Indicate whether antibiotic resistance will be expressed, and the nature of this antibiotic resistance:
V. Describe the containment equipment (e.g. protecting clothing, biological safety cabinets, fume hoods, etc) to be used in this research:
VI. Describe the proposed methods to be employed in monitoring the health and safety of personnel involved in this research: .

3. CELLS and TISSUE SAMPLES

If you answers YES to Part 1B, Please answer the following questions:

A. Will personnel work with animal blood, human or non-human primate blood, bodily fluids, organs, tissues, cell lines or cell clones? ☐Yes ☐No

If YES, DESCRIBE THEIR INVOLVEMENT:

B. Will research studies represent a potential biohazard for lab personnel? ☐Yes ☐No

If YES, SPECIFY THE POTENTIAL HAZARD AND PRECAUTIONS EMPLOYED TO PROTECT PERSONNEL IN THE LABORATORY:

4. RECOMBINANT DNA

If you answered YES to Part 1 C, please complete the following:

A. Biological source of DNA insert or gene:
B. Function of DNA insert or gene:

C. NIH classification of rDNA experiment:
D. Will a recombinant protein be expressed? If so, describe the protein and its biohazard potential:
E. Vector(s), including any viruses and biosafety classification:
F. Host cells:
G. Cell/animal/plant recipients:

5. CHEMICALS HAZARDS

A. Does this project involve the use of hazardous chemical agents (known or suspect carcinogens, mutagens, select agents, immunosuppressive agents, neurotoxic agents, toxic drugs, potent steroids, or other chemicals listed as hazardous waste by the E.P.A.? ☐Yes ☐No

B. If YES, COMPLETE THE FOLLOWING STATEMENTS FOR <u>EACH</u> AGENT TO BE USED (*Attach additional sheets if necessary*).

I. Name of Agent:

II. Specify location(s) of use/handling:

III. Specific nature of hazard:

IV. Estimated amount stored in laboratory:

6. CONTROLLED SUBSTANCES

A. Does your research involve the use of any substances regulated by the DEA? ☐Yes ☐No

B. If YES, list the controlled substance(s) to be used:

C. Are all schedule II and II drugs stored in a double-locked vault? ☐Yes ☐No

7. RADIOACTIVE MATERIALS

A. Does your research involve the use of radioactive materials? ☐Yes ☐No

B. If YES, PROVIDE THE FOLLOWING:

I. Identity of the radioactive source(s):

II. Radiation Safety Committee approval date:

8. SAFETY PLANS

This project is exempt from submitting a laboratory-specific chemical and/or biosafety plan for the following reasons:

If NOT EXEMPT, please check one of the following:

☐ I have developed a laboratory-specific chemical and/or biosafety plan for this project. A copy is attached for review.

☐ I have amended the laboratory-specific chemical and/or biosafety plan for this project. A copy is attached for review.

9. LABORATORY SAFETY.

Please check all of the personal protective equipment required for work on this project in the laboratory:

☐ Face shield/goggles/safety glasses (specify type):
☐ Shoe covers
☐ Lab coat
☐ Gloves
☐ Head cover
☐ Mouth/nose/respiratory protection (specify type):
☐ Other(s) (specify):

List locations of biological safety equipment:

BIOLOGICAL SAFETY EQUIPMENT USED	BUILDING	ROOM NUMBER	CERTIFICATION DATE (Required only for biosafety cabinets?

ACKNOWLEDGEMENT OF RESPONSIBILITY

- I certify that the information provided in this application is complete and accurate and consistent with any proposal(s) submitted to external funding agencies.
- I agree that I will not begin this project until receipt of official approval from the appropriate committee(s).
- I agree that modifications to the originally approved project will not take place without prior review and approval by the appropriate committee(s) and that all activities will be performed in accordance with all applicable federal, state, local and Xavier University policies.
- I will follow all applicable biosafety level requirements, comply with all shipping requirements and required waste management practices.
- I will ensure that all personnel have appropriate training including but not limited to: biosafety principles and techniques, accidental spills, shipping regulations, proper handling of biohazardous materials and waste management.
- I am aware that the IBC reserves the right to conduct inspections of the research facilities at any time.

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of Department Chair Date

_____ _____

Signature of IBC Chair Date