Department of Veterans Affairs

BIOHAZARD/CHEMICAL HAZARD INFORMATION INVOLVING RESEARCH

Principal Investigator: **Date:**

PROJECT TITLE: __

If your research activities involve the use of any of the following items, you MUST complete this form. For each item you check, complete the questions in the corresponding section below. In addition, you ARE REQUIRED to complete item G. regarding a Biosafety Plan for this project.

Yes / No		
☐☐	Blood, human tissue samples;	if "YES" Fill in Section A
☐☐	Animals;	if "YES" Fill in Section B
☐☐	Microbial/Viral Agents;	if "YES" Fill in Section C
☐☐	Chemical Hazards;	if "YES" Fill in Section D
☐☐	Recombinant DNA;	if "YES" Fill in Section E
☐☐	Cell Culture;	if "YES" Fill in Section F

****IF ALL QUESTIONS ARE ANWSERD "NO" THE PROTOCOL IS EXPEMPT****

A. BLOOD, HUMAN TISSUE SAMPLES

Yes / No

1. ☐☐ Will you work with blood or body fluids?
   If yes, specify:

Yes / No

2. ☐☐ Will you work with organs or tissues?
   If yes, specify:

Yes / No

3. ☐☐ Will the blood, body fluids, tissues, and/or organs need to be processed beyond collection/transport exclusively by trained clinical personnel using standard clinical methods and following standard universal precautions?

   If the sample needs to be processed beyond collection/transport to the clinical laboratory (e.g. if the specimen tube needs to be opened), then the answer is "Yes".

   A "No" answer will exempt the investigator from submitting a Biosafety plan for this category.

   ********* **If specimens are to be shipped off-site a copy of the International Air Transport Associate (IATA) certificate of training MUST be attached to the back of this form**********

Yes / No

4. ☐☐ Will specimens (blood, body fluids, tissues, and/or organs) be transported to or from an off-site location (e.g. University of Miami) by someone other than a professional shipping company?
   If yes, specify
   1. Off site location(s):

   2. Method of transport:

   3. Double containment system of specimens (fluids must be in a leak proof containment system):

   .

B. ANIMALS

Yes / No

1. ☐☐ Will you inject or otherwise treat animals with infectious agents?
   If yes, specify:

Yes / No

2. ☐☐ Will you work with animal organs, blood, body fluids, or tissues?
   If yes, specify:

Yes / No

3. ☐☐ Do the studies involve nude or SCID mice as recipients of human tissue or fluids?
   If yes, specify:

Yes / No

4. ☐☐ Do the studies involve use of hazardous chemical agents with animals? (known carcinogens, mutagens, immunosuppressive agents, toxic drugs, potent steroids, agents of unknown pharmacological activity, and other chemicals listed as hazardous waste by the Environmental Protection Agency (EPA)).
   If yes, specify:

C. MICROBIAL OR VIRAL AGENTS

Yes / No

☐☐ Is agent potentially infectious to humans?
IF YES, COMPLETE THE FOLLOWING STATEMENTS FOR EACH AGENT TO BE USED (attach additional sheets, if necessary).

1. Name of agent:

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

3. Biosafety Classification of Agent:

D. CHEMICAL HAZARDS:

Yes / No

☐☐ Do studies involve 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.)?
IF YES, COMPLETE THE FOLLOWING STATEMENTS FOR EACH AGENT TO BE USED (attach additional sheets, if necessary).

1. Name of agent:
2. Specify location(s) of use/handling:
3. Specific nature of hazard:
4. Estimated amount stored in laboratory:

E. RECOMBINANT DNA

Yes / No

☐☐ Do studies involve use of recombinant DNA?

1. Biological source of DNA insert or gene:
2. Function of DNA insert or gene:
3. NIH classification of recombinant DNA experiment:
4. Will a recombinant protein be expressed? If so, describe the protein and its biohazard potential:
5. Vector(s), including any viruses and biosafety classification:
6. Host cells:
7. Cell/animal/plant recipients:

F. **CELL CULTURE**

Yes / No

1. ☐☐ Will you use cell culturing procedures?

Yes / No

2. ☐☐ Do you work with human cell lines?
   If yes, complete the following:
   a. Name:
   b. Hazard:
   c. BSL level:

Yes / No

3. ☐☐ Do you work with animal cell lines or primary tissue cultures?
   If yes, complete the following:
   a. Name:
   b. Hazard:
   c. BSL level:

G. **SAFETY PLANS**

Studies involving the use of biohazardous materials or chemical hazards described in Sections A through F require a Laboratory-Specific Chemical and/or Biosafety Plan, unless specifically exempt. Please choose one of the following options:

****IF ALL QUESTIONS IN SECTIONS A-G ARE ANWSERD "NO" THE PROTOCOL IS EXEMPT****

☐ I have submitted a written laboratory-Specific Chemical and/or Biosafety Plan for a previous study, which was approved by the Chemical Hygiene and Biosafety Subcommittee on . Because the biohazardous materials or hazardous chemicals to be used in the current study are similar to those used in the previous study, the safeguards described in my laboratory-Specific Chemical and/or Biosafety Plan are applicable to the current studies and do not require a new laboratory-Specific Chemical and/or Biosafety Plan. Please see attached copy of my approved laboratory-Specific Chemical and/or Biosafety Plan.

☐ I have developed a laboratory-Specific Chemical and/or Biosafety Plan for this project. A copy is attached for review and approval by the Chemical Hygiene and Biosafety Subcommittee.

☐ I have amended the laboratory-Specific Chemical and/or Biosafety Plan for this project. A copy of the amended Safety Plan is attached for review and approval by the Chemical Hygiene and Biosafety Subcommittee.

☐ I am exempt from submitting a laboratory-Specific Chemical and/or Biosafety Plan for this project for the reasons cited below (be specific):

ACKNOWLEDGEMENT OF RESPONSIBILITY

I certify that my protocol will be conducted in compliance with all Federal, State, and Local policies and regulations governing the handling, use, and proper disposal of biohazardous materials or hazardous chemicals. I further certify that all technical and incidental workers involved in this project will be made aware of the potential exposure hazards, and that they will be instructed and trained in the proper handling, use, and disposal of all biohazardous materials or hazardous chemicals, and that appropriate personal protection equipment will be provided.

_____	_____	_____
Principal Investigator	Signature	Date

MIAMI VA MEDICAL CENTER RESEARCH SERVICE CHEMICAL
HYGIENE AND BIOSAFETY SUBCOMMITTEE

The Chemical Hygiene and Biosafety Subcommittee has reviewed the Biohazard/Chemical Information Involving Research submitted by the Principal Investigator named above.

☐ We have reviewed the laboratory-Specific Chemical and/or Biosafety Plan previously submitted and approved for another project, and find it to be acceptable for the current project.

☐ We have reviewed the laboratory-Specific Chemical and/or Biosafety Plan submitted for this research project and find it to be in compliance with current Federal, State, and Local policies and regulations governing the use, handling, and proper disposal of biohazardous materials or hazardous chemicals. Resources necessary for the safe performance of these proposed studies are available and adequate.

☐ We have reviewed the amendment to the laboratory-Specific Chemical and/or Biosafety Plan submitted for this research project and find it to be in compliance with current Federal, State, and Local policies and regulations governing the use, handling, and proper disposal of biohazardous materials or hazardous chemicals. Resources necessary for the safe performance of these proposed studies are available and adequate.

☐ A laboratory-Specific Chemical and/or Biosafety Plan is currently under review. Studies cannot begin until plan is approved.

☐ We have reviewed and approved the request for exemption submitted by the Principal Investigator. No laboratory-Specific Chemical and/or Biosafety Plan is required for this project.

Certification of Research Approval
The safety information for this application has been reviewed and is in compliance with Federal, State, and local policies, regulations, and CDC/NIH Guidelines governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. Copies of any additional review forms used locally are available from the Research Office.

_____

Chair, Subcommittee on Research Safety **Date**
Micheline McCarthy, MD

_____

Chair, Research & Development Committee **Date**
Maria Llorente, MD.

_____

Radiation Safety Officer (if applicable) **Date**
Edgar Reyes, M.S.

_____

Research Safety Officer **Date**
John C. Hackman, Ph.D