

**BIOHAZARD/CHEMICAL HAZARD  
 INFORMATION INVOLVING RESEARCH**

Principal Investigator

Contact No.

Date

Protocol Title

Personnel: Provide the name of all employees and collaborators who will be working in the laboratory.


List all rooms, including Veterinary Medical Unit space (if applicable), where research activities will take place. Specify room number(s), building(s) and campus.

Complete the following checklist.

- |     |    |   |
|-----|----|---|
| Yes | No |   |
|     |    | Human blood, tissues, organs, and/or body fluids; If "Yes", complete Section A        |
|     |    | Animal blood, tissues, organs, and/or body fluids; If "Yes", complete Section B       |
|     |    | Sample transportation; If "Yes", complete Section C                                   |
|     |    | Microbial/Viral agents and biological toxins; If "Yes", complete Section D            |
|     |    | Are you working with chemical?  |
|     |    | Are Chemicals <b>Highly Hazardous</b> (see Appendix 1)?; If "Yes", complete Section E |
|     |    | Recombinant DNA; If "Yes", complete Section F   |
|     |    | Cell Culture; If "Yes", complete Section G  |
|     |    | Radiation hazards; If "Yes", complete Section H                                       |

**\*\*\* If all questions are answered "No", then your protocol is exempt. Complete Sections I & J and return this form to the Research Office. \*\*\***

**SECTION A. HUMAN BLOOD, TISSUES, ORGANS, AND/OR BODY FLUIDS**

Yes No

1. Will you work with human blood or body fluids? If yes, specify below.

Yes No

2. Will you work with human organs or tissues? If yes, specify below.

Yes No

3. Will the human blood, body fluids, tissues, and/or organs need to be processed/manipulated beyond the collection point?

If yes, specify

a) Collection room:

b) Processing room:

c) Procedure(s) to be performed:

**Note: All protocols involving human subjects and samples require IRB's approval. Contact the IRB Coordinator for more information at (305) 575-7000 ext. 4465. A laboratory-specific biohazard exposure control plan is required if human specimens are processed in a VA Research Service laboratory. Contact the Chemical Hygiene and Biosafety Coordinator for more information at (305) 575-7000 ext. 4395.**

**SECTION B. ANIMALS**

**Yes No**

1. Will you inject or otherwise treat animals with infectious agent? If yes, specify below.

**Yes No**

2. Will you work with animal organs, blood, body fluids, or tissues? If yes, specify below, including species.

**Yes No**

3. Does this protocol involve nude or SCID mice as recipients of human tissues or fluids? If yes, specify below.

**Yes No**

4. Does this protocol involve the use of hazardous chemical agents (known carcinogens, mutagens, immunosuppressive agents, toxic drugs, potent steroids, agents of unknown pharmacological activity, and other chemicals listed as hazardous agents by the EPA) with animals? If yes, specify below.

**Note: All protocols involving animals require IACUC's approval. Contact the IACUC Coordinator for more information at (305) 575-7000 ext. 3444. A laboratory-specific biohazard exposure control plan is required. Contact the Chemical Hygiene and Biosafety Coordinator for more information at (305) 575-7000 ext. 4395.**

**SECTION C. SAMPLE TRANSPORTATION**

**Yes No**

Will specimen be transported to or from an off-site location? If yes, specify below.

a) Type of samples:

b) Off-site location(s):

c) Method(s) of transport:

d) Method(s) of containment:

**If specimens are to be shipped off-site via courier service, a copy of the International Air Transport Association (IATA) certificate of training must be submitted with this application. Note: If specimens are being transported by lab personnel to a local affiliate university, IATA training is not required but detailed descriptions of methods of transport and containment are required. This information must be included in the laboratory-specific biohazard exposure control plan.**

**SECTION D. MICROBIAL OR VIRAL AGENT(S) AND TOXIN(S)**

Yes No

Is agent potential infectious or highly toxic to humans? IF YES, COMPLETE THE FOLLOWING FOR **EACH** AGENT TO BE USED. Use additional sheet(s), if more space is required.

a) Identify agent or toxin (name, strain, etc.):

b) Location of use and storage:

c) Biosafety classification:

Is agent or toxin a Select Agent? Yes No  
If Yes, is quantity exempt? Yes No

For more information on Select Agents and Toxins go to <http://www.selectagents.gov/index.html>

d) Largest volume and/or concentration used:

e) Identify containment equipment requirements (PPE, biosafety cabinets, etc.):

f) Describe methods for monitoring health and safety of employees working with agent/toxin:

g) Describe method of inactivation of the agent/toxin:

h) Describe waste disposal procedures:

**Note: A laboratory-specific biohazard exposure control plan is required. This information must be included in the laboratory-specific biohazard exposure control plan. Contact the Chemical Hygiene and Biosafety Coordinator for more information at (305) 575-7000 ext. 4395.**

**SECTION E. CHEMICAL HAZARDS**

Yes No

Does this protocol involve the use of highly hazardous chemical agents (see Appendix 1)?  
IF YES, COMPLETE THE FOLLOWING STATEMENTS FOR **EACH** AGENT TO BE USED. Use additional sheet(s), if more space is required. **DO NOT ATTACH A CHEMICAL INVENTORY AS A RESPONSE TO THIS SECTION.**

Name of agent:	
Location of storage/use:	
Nature of hazard:	
Estimated amount:	
Is this a controlled substance?	Yes No For more information go to <a href="http://www.deadiversion.usdoj.gov/schedules/">http://www.deadiversion.usdoj.gov/schedules/</a>

Name of agent:	
Location of storage/use:	
Nature of hazard:	
Estimated amount:	
Is this a controlled substance?	Yes No For more information go to <a href="http://www.deadiversion.usdoj.gov/schedules/">http://www.deadiversion.usdoj.gov/schedules/</a>

Name of agent:	
Location of storage/use:	
Nature of hazard:	
Estimated amount:	
Is this a controlled substance?	Yes No For more information go to <a href="http://www.deadiversion.usdoj.gov/schedules/">http://www.deadiversion.usdoj.gov/schedules/</a>

Name of agent:	
Location of storage/use:	
Nature of hazard:	
Estimated amount:	
Is this a controlled substance?	Yes No For more information go to <a href="http://www.deadiversion.usdoj.gov/schedules/">http://www.deadiversion.usdoj.gov/schedules/</a>

**Note: A laboratory-specific chemical safety plan is required. Contact the Chemical Hygiene and Biosafety Coordinator for more information at (305) 575-7000 ext. 4395.**

**SECTION F. RECOMBINANT DNA**

Yes No

Does this protocol involve the use of recombinant DNA (beyond that of PCR) at the Miami VA Medical Center?

a) Biological source of DNA insert or gene

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b) Function of DNA insert

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c) Vector used

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d) Host cells and/or virus used

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e) Cell/animal/plant recipients

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f) Location of storage and use

--

g) NIH Classification of rDNA experiment

h) Biosafety classification

i) Will a recombinant protein be expressed?  
If so, describe the protein and its  
biohazard potential.

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j) Describe containment equipment  
requirements

--

k) Describe method(s) of inactivation of the  
DNA insert or gene

--

l) Procedure(s) of waste disposal

--

m) Describe method(s) for monitoring health  
and safety of employees

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**Note: All protocols involving rDNA require UM IBC's approval. See the following website for more information and required forms: <http://uresearch.miami.edu/regulatory-compliance-services/ibc>. A laboratory-specific biohazard exposure control plan is required. This information must be included in the laboratory-specific biohazard exposure control plan. Contact the Chemical Hygiene and Biosafety Coordinator for more information at (305) 575-7000 ext. 4395.**

**SECTION G. CELL CULTURE**

Yes No

- Does this protocol involve working with human cell lines or primary human tissue cultures?  
If yes, complete the following for **EACH** primary human cell culture or human cell line (attach additional sheets, if necessary).

Name	Vendor If None, enter N/A	Cell Line? (Y/N)	BSL Level	Location of storage and use (Room #, building, and campus)

Yes No

- Does this protocol involve working with animal cell lines or primary animal tissue cultures?  
If yes, complete the following for **EACH** primary animal cell culture or animal cell line (attach additional sheets, if necessary).

Name	Vendor If None, enter N/A	Cell Line? (Y/N)	BSL Level	Location of storage and use (Room #, building, and campus)

**Note: This information must be included in the laboratory-specific biohazard exposure control plan. Contact the Chemical Hygiene and Biosafety Coordinator for more information at (305) 575-7000 ext. 4395.**

**SECTION H. RADIATION HAZARDS**

Yes No

- Does this protocol involve the use of radioactive isotopes? If yes, describe all isotopes to be used in this protocol in the table below (attach additional sheets, if necessary).

Radionuclide	Physical Half-Life	Chemical Name/Formula	Location of storage and use (Room #, building, and campus)	Name of User(s)

- Provide a brief description of the procedure(s) involving radioactive isotopes. Specify whether radioactive isotopes will be used on animals or cell cultures, if applicable.

Yes No

- Does this protocol involve the use of X-ray emitting machine? If yes, provide the type and name of the equipment and the location of storage and use of this equipment.

**Note: Approval from the Radiation Safety Officer is required prior to the use and handling of all radioactive material and equipment for each protocol. Contact the Radiation Safety Officer for more information at (305) 575-7000 ext. 3591. This information must be included in the laboratory-specific chemical safety plan.**

**SECTION I: SAFETY PLANS**

Studies involving the use of biohazardous materials, chemical hazards, or radiation hazards described in Sections A-H require a Laboratory-Specific Chemical Safety Plan and/or a Laboratory-Specific Biohazard Exposure Control Plan, unless specifically exempt. Please choose one of the following options.

**\*\*\*\*\* IF ALL QUESTIONS ON THE CHECKLIST ARE ANSWERED "NO", THE PROTOCOL IS EXEMPT. \*\*\*\*\***

I have submitted a written Laboratory-Specific Chemical Safety Plan and/or a Laboratory-Specific Biohazard Exposure Control 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 approved Laboratory-Specific Chemical Safety Plan and/or Laboratory-Specific Biohazard Exposure Control Plan are applicable to the current study and this study does not require a new Laboratory-Specific Chemical Safety Plan and/or Laboratory-Specific Biohazard Exposure Control Plan. I have included a copy of my approved:

Laboratory-Specific Chemical Safety Plan                      Laboratory-Specific Biohazard Exposure Control Plan

I have developed a  
Laboratory-Specific Chemical Safety Plan                      Laboratory-Specific Biohazard Exposure Control Plan  
for this project. A copy is included for review and approval by the Chemical Hygiene and Biosafety Subcommittee.

I have amended the  
Laboratory-Specific Chemical Safety Plan                      Laboratory-Specific Biohazard Exposure Control Plan  
for this project. A copy is included for review and approval by the Chemical Hygiene and Biosafety Subcommittee.

I am exempt from submitting a Laboratory-Specific Chemical Safety Plan and/or Laboratory-Specific Biohazard Exposure Control Plan. Provide justification below.

**SECTION J. PRIVACY AND DATA SECURITY PLAN**

**Yes No**

Has a Privacy and Data Security Plan already been submitted?

If yes, submit a copy of the plan.

If no, complete and submit a copy of the plan using the following link: [http://www.sfvafre.org/images/forms/HumanStudiesForms/HS\\_InitialApplicationForms/MVAHCS\\_Privacy\\_and\\_DataSecurityPlan.pdf](http://www.sfvafre.org/images/forms/HumanStudiesForms/HS_InitialApplicationForms/MVAHCS_Privacy_and_DataSecurityPlan.pdf)

**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, transport, and disposal of all biohazardous materials or hazardous chemicals, and that appropriate personal protective equipment will be provided. I also certify that all technical and incidental workers involved in this project will have access to the Research Biosafety Plan and Manual, Chemical Hygiene Plan and Safety Manual, Infection Control Policy and Exposure Control Plan for Bloodborne Pathogens, and Animal Research Safety Manual.

\_\_\_\_\_  
PI's Signature

\_\_\_\_\_  
Date

**MIAMI VA MEDICAL CENTER RESEARCH SERVICE  
CHEMICAL HYGIENE AND BIOSAFETY SUBCOMMITTEE**

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

We have reviewed the Laboratory-Specific Chemical Safety Plan and/or Laboratory-Specific Biohazard Exposure Control Plan previously submitted and found it to be acceptable for the current project.

We have reviewed the Laboratory-Specific Chemical Safety Plan and/or Laboratory-Specific Biohazard Exposure Control Plan submitted for this project and found it to be compliance with all Federal, State and Local policies and regulations governing the handling, use, and proper disposal of biohazardous materials or hazardous chemicals. Resources necessary for the safe performance of the proposed study are available and adequate.

A Laboratory-Specific Chemical Safety Plan and/or Laboratory-Specific Biohazard Exposure Control Plan is currently under review. The study cannot begin until the plan is approved.

We have reviewed and approved the request for exemption submitted by the Principal Investigator. No Laboratory-Specific Chemical Safety Plan and/or Laboratory-Specific Biohazard Exposure Control Plan is/are required for this project.

**Certificate 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.

\_\_\_\_\_  
Chairperson, Chemical Hygiene and Biosafety Subcommittee

\_\_\_\_\_  
Date

\_\_\_\_\_  
Research Safety Officer

\_\_\_\_\_  
Date

\_\_\_\_\_  
Radiation Safety Officer, If Applicable

\_\_\_\_\_  
Date



## APPENDIX 1. COMMONLY LISTED HAZARDOUS AGENTS

This is not a complete and exhaustive list. For a complete list of hazardous agents as defined by EPA or OSHA, visit

<http://www.epa.gov/osw/hazard/wastetypes/listed.htm> or

[https://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_id=9761&p\\_table=STANDARDS](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=9761&p_table=STANDARDS)

- Peroxide forming chemicals
- Radionuclides
- Nicotine
- Solvents (e.g., xylene, acetone, ethyl acetate, N-butyl alcohol, methanol, toluene, etc.)
- Fixative (e.g., paraformaldehyde, formaldehyde, formalin, etc.)
- Highly corrosive solutions (e.g., sulfuric acid, hydrochloric acid, phosphoric acid, etc.)
- Sodium azide
- Sodium cyanide
- Hydrogen fluoride
- Chemical amounts that could potentially exceed permissible exposure limits (PELs). For more information visit:  
[https://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_id=9992&p\\_table=STANDARDS](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=9992&p_table=STANDARDS)