

Institutional Biosafety Committee Protocol for Research Involving Biological Hazards

Protocols for all research at Georgetown University involving **Biological Hazards** must be submitted to the **Institutional Biosafety Committee (IBC)** for review. **For purposes of the IBC, Biological Hazards include: A) Infectious Agents, B) Toxins, and C) Recombinant DNA .**

Research protocols involving the use of any of these entities must contain a detailed description of potential danger(s) posed by the agent(s), **AND** a summary of safeguards, training, and procedures which will be employed to protect both laboratory personnel and the GU community.

Will this protocol involve the use of Radioactive Materials?⁽¹⁾ **Yes** **No**

Will this protocol involve the use of Animals?⁽²⁾ **Yes** **No**

⁽¹⁾For research involving the use of Radioactive Materials or Radiation Producing Equipment (i.e. Irradiator, linear accelerator and/or x-ray equipment), a copy of this protocol must also be submitted to the Radiation Safety Office.

⁽²⁾For research involving Animals, a copy of this protocol must also be submitted to the GUACUC.

Investigators must be members of the faculty, senior research associates, or research associates.

The form must be signed by the investigator and the department chair.

The application must be completed in full. If items are not applicable, please note N/A.

Completed forms should be delivered to: Administrator, EH&S
LM12 Preclinical Science Building
Phone: 687-4712/Fax: 687-5046

Forms available for download at: <http://ehs.georgetown.edu>

Protocol Number: _____

I. INVESTIGATOR / PROJECT INFORMATION

Investigator: _____ Net ID _____

Appointment: _____

Name Degree

Office Address: _____ Phone: _____

Fax: _____

Department: _____

Division: _____

(If more than one department, note primary affiliation only.)

Location(s) of Proposed Research:

(Rm./Bldg.) _____

Title of Protocol: _____

Co-Investigators: _____

Select One:

New Protocol Amendment

If amendment, original protocol no.: _____

If 'Amendment,' please provide the specific changes made to the original protocol.

This protocol is part of an externally funded project: Yes No

If **Yes**, please complete the following section:

Agency: _____

Division or program: _____

Grant/contract proposal title:

Proposed dates of project: From: _____ To: _____

PI for grant or contract (if different from investigator responsible for this protocol):

II. PROTOCOL OVERVIEW

A. Please provide a brief overview (350 words or less) of the project. Include the following:

1. Specific information about how the biological agent will be used.
2. Procedures that involve the agent.
3. Concentrations and amounts that will be used in each technique.
4. Potential Dangers (biological hazards, exposure potentials, infectious doses).
5. Required Safeguards to alleviate these potential hazards (physical and biological containment, protective equipment, disposal procedures, decontamination, staff training, etc.).

Protocol Number: _____

B. Does this research require use any of the following Core Facilities:

- Histopathology & Tissue
- Flow Cytometry/Cell Sorting
- Cytogenetics
- Tissue Culture
- Microscopy & Imaging
- RRF (Animals)*

***If 'Yes', will the research involve the creation of transgenic animals. Yes No**

When working with animals, complete the GUACUC "Use of Hazardous Materials in Animal Research" form (<http://ora.georgetown.edu/guacuc/guacucForms.htm>)

GUACUC Protocol Number, (if available): Protocol No. _____ Pending _____

Animal Biological Safety Level (ABSL) to be employed: _____

(ABSL) I II [III and IV not permitted at Georgetown University]

III. BIOHAZARDOUS MATERIAL(S)

A. INFECTIOUS AGENTS

Does this research involve the use of infectious agents ? Yes No

(e.g., prions, bacteria, viruses, fungi, parasites, and rickettsiae)

Biological Safety Cabinet (BSC) Available? Yes No

If yes, provide the location: _____

Information regarding agent:

Agent(s) - specify genus, species, and/or strain	Largest Volume Used	Company, Source, and/or Catalog No.	Biosafety Level

B. HUMAN CELL LINES

Will this research involve the use of human cell lines? Yes No

Cell Line Name	Company, Source, and/or Catalog Number	BioSafety Level

C. BIOLOGICALLY-DERIVED TOXINS

Does this research involve the use of toxins? Yes No

(e.g., botulinum toxin, tetrodotoxin, cholera toxin, aflatoxin, lipopolysaccharides from all species, conotoxin)

Guide: Toxins of Biological Origin (<http://www.ehs.ufl.edu/bio/toxin.htm>)

Vented BSC or fume hood available? Yes No

If yes, provide the location: _____

Information regarding toxin:

Toxin	Company, Source and/or Catalog Number	LD ₅₀	Amount on hand

Protocol Number: _____

D. RECOMBINANT DNA

Does this research involve the use of recombinant DNA? Yes No

If yes, please complete the following. Use specific names or designations for the vector and give the original virus or plasmid under “backbone.”

BSC or fume hood available? Yes No

If yes, provide the location: _____

Vector(s) (Include specific vector maps):

Vector	Company, Source, and/or Catalog Number	Backbone	Biosafety Level

Host Strains (List all, use strain designation in the appropriate box):

E coli	Other bacteria	Retroviral Packaging Lines

Nature of inserted DNA sequences: _____

Source(s) of DNA (organisms): _____

Will a deliberate attempt be made to obtain expression of a foreign gene? Yes No

If yes, what protein will be produced? _____

IV. HAZARDOUS/CARCINOGENIC CHEMICAL INFORMATION

Does this research involve the use of particularly hazardous substances (includes carcinogenic, teratogenic, acutely highly toxic and various antineoplastics)?

<http://ehs.georgetown.edu/chemsafe/procedures/SOPs1.html>

Yes No

If Yes, a Chemical Safety Review Protocol Application must be submitted to EH&S/CSR Committee.

<http://ehs.georgetown.edu/chemsafe/forms/CSRFill.pdf>

V. ACKNOWLEDGMENT

I _____ agree to work with the biological agents, toxins, and/or recombinant materials according to information given on this application and according to the GUMC Manual. I agree to train, provide direction to, and monitor the activities of all individuals performing this research. If recombinant materials are used, I agree to observe the current NIH Guidelines for Research involving Recombinant DNA Molecules as described in the materials found at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html. Any future changes will be submitted for IBC review and approval prior to implementation.

Investigator: _____ **Date:** _____

Chair: *I have reviewed the above protocol and approve its submission to the IBC.*

Chair: _____ **Date:** _____

IBC Use Only:

Date Received: _____
Preliminary Approval Date: _____
Final Approval Date: _____