Application for Research/Teaching Involving Biohazardous Materials

Instructions:
Please save this form to your computer. When completing this document please retain the format as near as possible and answer questions thoroughly. Complete the appropriate sections as outlined below.

Required. Every Principal Investigator must complete the following:
- Section 1 General Information
- Section 2 Laboratory Information
- Section 3 Project Description
- Section 8 Certification and Signatures

Research Specific Sections. Complete the following sections if they are applicable to your research as indicated below.
- Section 4 Use of rDNA; for research involving recombinant DNA technology.
- Section 5 Biological Agent Use; for research involving viable microorganisms.
- Section 6 Use of Human Source Materials; for research involving human materials including human tissues and human derived cell lines.
- Section 7 Use of Select Agent Toxins; for research involving the listed toxins.

When you have completed the form, print a copy of the whole document, sign section 8, and send the signed copy along with any required supporting documentation to the Compliance Coordinator, ORSSP, PO Box 8005 for review or email to IBC@georgiasouthern.edu (If you do not have electronic signature, the signature page may be sent by separate mail or fax 912-478-0719.)

Section 1 General Information:

1a. Project Approval No. ____________ (leave blank if new project)

1b. Biosafety Level (indicate all that apply): exempt BSL1 BSL2

1c. Project Title:

d. Principal Investigator:

Department: Campus Address:

Office Phone: Lab Phone:

Fax: email:

1e. Please indicate all laboratory personnel working on this project at Georgia Southern University, to include faculty, technical staff, post-docs, and graduate students.

1f. The IBC requires that ALL staff who will physically handle the biohazardous agents or recombinant DNA molecules and are conceivably at risk from research procedures involving the use of these biological materials be required to take Chemical Specific Right to Know training. Collaborators are exempt unless they are conducting research in the laboratory(s) listed on this protocol. Students in teaching laboratories are also exempt from certificate submission; it is the instructor’s responsibility to
determine the appropriate mode of training for students in a classroom setting. Please attach copies
of Chemical Specific Right to Know training certificates to this application. This application WILL NOT
be processed without these documents. If you do not have training certificates for Chemical Specific
Right to Know, please see the following link: http://www.usg.edu/ehs/training/chemical/

Section 2  Laboratory Information:

2a. Is this project part of a course or teaching lab? YES ___  NO ___

b. List ALL laboratories/facilities where research is to be conducted and the corresponding biosafety
level: include cold/warm rooms, equipment rooms as appropriate. Please indicate room(s) where
biosafety cabinets (BSC) are located.

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<tr>
<th>Room Number</th>
<th>Biosafety Level</th>
<th>BSC</th>
<th>Warm/Cold Room</th>
<th>Equipment Room</th>
<th>Human Materials Used</th>
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Check box if applicable

c. Will animals be used for this project? YES ___  NO ___

IACUC Approval No(s) ____________________________

(Please see section 4.c. if transgenic or knockout animals are generated.)

d. Will human source materials be used for this project? YES ___  NO ___

IRB Approval No(s) ____________________________ (See section 6)

e. Will radioactive materials be used? YES ___  NO ___

(If yes, contact the Radiation Safety Officer at (912) 478-1151.)

f. Will mixed waste be generated (radioactive/biological or chemical/biological)? YES ___  NO ___

(If yes, for information on waste management, please contact the Georgia Southern
University Environmental Safety Officer at (912) 478-7161.)
g. Does your research involve shipment or receipt of biohazardous materials? YES ___ NO ___

If your research involves shipping or receiving biological or infectious materials, the person(s) who will be responsible for signing the shipping and receiving documents are required by Federal law to have training before materials are shipped or received. Training is available from the Environmental Safety Officer.

h. Did you complete a Biological Safety Laboratory Self Audit? YES ___ NO ___

The IBC requires that a completed form be attached to the application BEFORE the protocol will be reviewed. Print form at http://academics.georgiasouthern.edu/research/

i. Did you complete a BSL-1 or 2 Safety Standard Operating Procedure (SOP)? YES ___ NO ___

The IBC requires that a completed SOP be attached to the application BEFORE the protocol will be reviewed. Sample SOPs are available at http://academics.georgiasouthern.edu/research/. Modify or adapt to your laboratory needs.

Section 3 Project Description:

3a. Provide a brief project description.

3b. Outline the overall goal(s) of the project in the space below; Please be concise and give enough information to assure that the purpose of the experiments and the techniques used are clear.

3c. Describe the handling of biohazardous materials associated with the project. Include detailed descriptions of the biosafety and personnel safety precautions to include: microbiological practice and containment, personal protective equipment, containment, spill procedure, waste storage and disposal, sharps management, decontamination procedures, accident follow up, and training provided to participants.

(If several methods or project elements are employed divide the narrative by project element to maintain a clear timeline and attach precautions to methods.)
Section 4  *Use of rDNA:*

(Please complete this section if you use or generate recombinant microorganisms, cells, animals, etc.)

4a. **Source of Gene, Insert or Clone:**

   1. Specify DNA/RNA source (or probe), nature of insert, is a protein expressed, and percent of any viral genome in construct.
   2. Do any sequences code for toxins? If yes, please specify.
   3. Is the DNA source from a USDA-regulated plant or animal? If the regulated organism is grown or stored at Georgia Southern University, please include a copy of the USDA permit. (Link to USDA site: [http://www.aphis.usda.gov/brs/index.html](http://www.aphis.usda.gov/brs/index.html))

4b. **Vectors and Host Cells:**

   1. Identify cloning/expression/transfection vectors used, recipient bacterial strains, and recipient host cell lines (human, mouse, plant, etc.). Provide a restriction map of vector unless this is a commercially available vector. Describe the location and type of promoters and other control sequences and percent of any viral genome in construct.
   2. If using viral vectors, indicate packaging cell lines and assay system used to measure helper virus titre or titre of replication competent virus (background) generated. Include host range of packaged viral vector.

c. **Use of Recombinant DNA in Animals:**

   1. Will transgenic or “knockout” animals be generated or used in the project? If so, indicate injected gene and vector as well as the recipient animal/mouse strain.
   2. What is the expected phenotype of the animal, (e.g. immunodeficient, early disease onset/resistance, etc.)?

d. **Large-Scale Research:**

   Do experiments involve growth of more than 10 liters of culture at a time? If YES, identify culture room and type of equipment used for large scale culture growth and handling.
Section 5 Biological Agent Use:

(Please complete this section if you work with viable microorganisms)

a. Agent identification. List biological agent(s)/microorganism(s) (i.e., H. pylori, EBV, E.coli 0157, B.subtilis, S. cerevisae, etc.) and recommended Biosafety Level (CDC):

b. Agent hazard. Is the agent infectious to humans, animals or plants? Y ___ N ___ (If the answer is “NO”, skip to Section 6)

1. Source of infectious agent (i.e., new isolate from human tissue, blood, animal, tissue culture, another laboratory, ATCC, etc.):

2. Host range: Can this agent infect humans? Has it been passaged in animals?

3. Is the agent classified as a Select Agent (http://www.cdc.gov/od/sap/docs/salist.pdf)? If yes, please contact the Georgia Southern University Compliance Officer at 912-681-5465 for further instructions.

c. Experimental Procedures:

1. Describe procedures involving use of infectious agent (indicate culture volume, maximum concentration). How and at what stage of the experiment is the infectious agent inactivated or lysed?

2. Will experiments result in acquisition of new characteristics such as enhanced virulence, infectivity, drug resistance, or change in host range? If so, explain:

d. Safety Procedures:

1. Outline protective equipment required to minimize exposure of laboratory personnel during all procedures requiring handling or manipulation of infectious agent:

2. Outline procedures for decontamination of work surfaces, instruments, equipment, liquid containing infectious materials and glassware:

3. Outline disposal/decontamination procedures for contaminated sharps, contaminated solid waste, tissues, pipette tips, etc.

e. Medical Surveillance:

1. Are pre-project serum samples or is immunization advisable? If yes, explain:

2. Will there be a need for medical monitoring or surveillance? If yes, explain:
Section 6 *Use of Human Source Material.*

(Please complete this section if you work with human source material, including human cell lines and human tissues.)

a. List the source and types of human material (i.e., blood, bone, sputum, cell culture). For tissue culture, list cell types and names. Please include where you plan to obtain the material:

b. Has the material been treated prior to use in the lab (such as formalin fixing or heat treatment)? Please describe:

c. Do you have an Exposure Control Plan (ECP) on file with the Environmental Safety Officer?
   
   YES ____  NO ____  N/A ____
Section 7 *Use of Select Agent Toxins of Biological Origin:*

Do you plan to store or use any of the following toxins? If so, please indicate which one(s) and the approximate maximum amount stored at any time in your laboratory.

Note: The following toxins are required to be secured at all times, preferably in lockable container. Inventory logs must also be kept noting quantity used, quantity remaining, and destruction/disposal method used.

### HHS Toxins

<table>
<thead>
<tr>
<th>Toxin</th>
<th>Regulatory Threshold Quantity Requiring CDC certificate of registration</th>
<th>Your maximum quantity</th>
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<tbody>
<tr>
<td>Abrin</td>
<td>100 mg</td>
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<tr>
<td>Contotoxins</td>
<td>100 mg</td>
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<tr>
<td>Diacetoxyscirpenol</td>
<td>1000 mg</td>
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<tr>
<td>Ricin</td>
<td>100 mg</td>
<td></td>
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<tr>
<td>Saxitoxin</td>
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<tr>
<td>Tetrodotoxin</td>
<td>100 mg</td>
<td></td>
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<tr>
<td>Shiga-like ribosome inactivating proteins</td>
<td>100 mg</td>
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</tbody>
</table>

### Overlap Toxins (HHS and USDA)

<table>
<thead>
<tr>
<th>Toxin</th>
<th>Regulatory Threshold Quantity Requiring CDC or USDA certificate of registration</th>
<th>Your maximum quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botulinum neurotoxins</td>
<td>0.5 mg</td>
<td></td>
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<tr>
<td>Clostridium perfringens epsilon toxin</td>
<td>100 mg</td>
<td></td>
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<tr>
<td>Shigatoxin</td>
<td>100 mg</td>
<td></td>
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<tr>
<td>Staphylococcal enterotoxins</td>
<td>5 mg</td>
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<tr>
<td>T-2 toxin</td>
<td>1000 mg</td>
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</table>
Section 8 Certification and Signatures

The information contained in this application is accurate and complete. I am familiar with and agree to abide by the provisions of the current NIH Guidelines for work with recombinant DNA and biohazards, specific NIH instructions pertaining to the proposed project, if any, local, state and federal regulations, and any applicable Georgia Southern University policies and procedures.

In addition, I agree to abide by the following requirements:

a. I will initiate no recombinant DNA research subject to the NIH Guidelines until that research has been reviewed and approved/registered with the Institutional Biosafety Committee (IBC).

b. I will follow appropriate biosafety level laboratory techniques in the research.

c. I will comply with all shipping requirements for biological materials.

d. I will make available to the laboratory staff copies of the approved procedures that describe the potential biohazards and the precautions to be taken.

e. I will train staff in best microbiological practices and techniques required to ensure safety for this project, in the procedures for dealing with accidents, and in waste management procedures.

f. I will supervise staff, and correct work errors and conditions that could result in breaches of the NIH Guidelines, local, state or federal regulations, or any applicable Georgia Southern University policies or procedures.

By signing below, I certify that I have read and understand this form and that the information I have provided is true to the best of my knowledge. Further, I agree to adhere to the requirements within this document and understand that I will be held responsible and may be subject to disciplinary action for any omissions or misrepresentations.

Principal Investigator (Print) ___________________________ Department ___________________________

Principal Investigator (Sign) ___________________________ Date ___________________________

Department Chair (Sign) ___________________________ Date ___________________________

If this project involves the use of animals or human tissue/human subjects, you must contact the IACUC or IRB, respectively at 912-478-5465. IRB or IACUC approval will be required before your submission will be reviewed by the IBC.

If this project involves the use of radioactive materials, you must contact the Radiation Safety Officer at (912) 478-1151.