

**Biological Agent Registration Application**

This application must be completed by the Principal Investigator (PI) and must be approved by the Biological Safety Officer (BSO) and/or the Institutional Biosafety Committee (IBC) prior to acquiring biological materials.

For information, registration process or assistance with this form, please contact BSO, Don Sibley at [Don.Sibley@ucf.edu](mailto:Don.Sibley@ucf.edu) or 407-823-1526.

**Protocol Title:**

**Grant Title(s) if Applicable (may be same as the Protocol title as above).**

**Type of Protocol:**

New                      Amendment                      Resubmission

For resubmissions, enter IBC #: \_\_\_\_\_

Resubmissions are required every three (3) years.

For amendments, enter IBC #: \_\_\_\_\_

*Modifications involving the following items require amendments to existing IBC protocols: addition of a new viral vector, use of primary human and non-human primate cell lines, addition of pathogens (Risk Group 2 or Risk Group 3) or toxins (BSL-2 or higher containment), addition of recombinant DNA work, addition of in vivo work.*

**Summary of Change(s):**

Indicated in	Section III B1 # _____	Section III B2	Section III B3
	Section III B4	Section III B5	Section III B6
	Section III B7		



Research description and goals, cont'd.

B. Indicate category of material(s) used in the project

1. **Recombinant or synthetic DNA/RNA** Yes  No

Consult the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines

[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html)). Information in the parenthesis refer to the specific section of the Guidelines where additional information can be found.

a. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally; such acquisition could compromise the use of the drug to control disease in human, veterinary medicine or agriculture. **(III-A)**

**Example:** Transfer of Erythromycin resistance into *Borrelia burgdorferi*.

Yes  No

b. Experiments involving cloning of toxin molecules with LD<sub>50</sub> of less than 100 ng/kg body weight. **(III-B)**

**Example:** Cloning toxin genes (or using plasmids that express genes that encode toxins with low LD<sub>50</sub>) for the biosynthesis of microbial toxins such as botulinum toxin, tetanus toxin, diphtheria toxin and *Shigella dysenteriae* neurotoxin).

Yes  No

c. Human gene transfer experiments **(III-C)**

Yes  No

d. Experiments involving the introduction of rDNA or synthetic nucleic acid molecules into human and animals Risk Group 2 (RG2) or Risk

Group 3 (RG3) agents. **(III-D-1)**(An abbreviated list found in **Appendix B** of the *NIH Guidelines*[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html#\\_Toc351276291](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276291)))

- |  | Yes | No |
|--|-----|----|
| e. Experiments in which DNA from human and animal RG2 and RG3 agents is cloned into nonpathogenic prokaryotes or lower eukaryotic host-vector systems. <b>(III-D-2)</b>  | Yes | No |
| f. Experiments involving the use of infectious DNA/RNA Viruses <b>OR</b> Defective DNA/RNA viruses in the presence of helper virus in tissue culture systems. <b>(III-D-3)</b><br><b>Example:</b> viral vectors including lentivirus, adenovirus, baculovirus in tissue culture. | Yes | No |
| g. Experiments involving whole animals. <b>(III-D-4)</b><br><b>Example:</b> Use of any rDNA modified organisms, use of any RG2 and RG3 agents, creation of transgenic animals, etc.)   | Yes | No |
| h. rDNA or synthetic nucleic acid molecule-modified experiments involving whole plants <b>(III-D-5)</b>  | Yes | No |
| 1. Experiments involving arthropods with recombinant or synthetic nucleic acid molecule modified microorganism associated with them  | Yes | No |
| i. Experiments involving cultures of more than 10 liters. <b>(III-D-6)</b>   | Yes | No |
| j. Experiments involving influenza viruses. <b>(III-D-7)</b><br><b>Example:</b> Generation of influenza viruses by reverse genetics of chimeric viruses with reassorted segments and introduction of specific mutations  | Yes | No |
| k. Experiments involving the formation of rDNA or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus. <b>(III-E)</b>  | Yes | No |

Provide explanation for any "YES" indicated above. Include the following information in 1-2 paragraphs:

Describe use of recombinant or synthetic DNA or RNA; Source of DNA, host/vector to be used, nature of the insert (i.e. oncogene) and brief experimental procedures.

Viral Vectors used-check all that apply:

- Adenovirus N/A
- Adeno-Associated virus (AAV); helper virus used
- Espstein-Barr Virus (EBV)
- Herpesvirus
- Retrovirus; ecotopic amphotrophic
- pseudotype virus
- MMLV
- Lentivirus: helper virus genes separated on separate plasmids
- pseudotype (VSV-G)
- Poxvirus-Vaccinia Virus
- Sindbis (alpha) virus; helper virus
- Baculovirus

How did you obtain the viral vector?

- Commercial kit List Source: \_\_\_\_\_ Product name: \_\_\_\_\_
- All components made in the lab
- Assembled in lab from components made/obtained otherwise
- Received packaged virus
- Received transduced cells

Describe the safety features of the viral vectors (e.g. gene deletions, expression of packaging genes on multiple plasmids, self-inactivating LTR, limited tissue tropism)

Viral vector safety features, cont'd.

2. **Infectious Agent/Pathogen** Yes                  No  
 (If yes, list below. Also, describe the use of agent and the source of the material (i.e. ATCC))

Any work involving a biological agent classified as a Risk Group 2 (RG2) or 3 (RG3) agent (abbreviated list found in Appendix B of the NIH Guidelines ([http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html#\\_Toc351276292](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276292))) must be registered with the IBC. This includes commercially acquired lentiviruses (RG2) to infect cells/animals.

Infectious agent/pathogen will be used in animal Yes                  No

3. **Biological Toxin** Yes                  No  
 (If yes, list below. **For exempt quantities of Select Toxin, fill out the next section**)

All biological toxins which include biosafety containment level 2 (BSL-2) or above must be registered with the IBC. These toxins include diphtheria toxin, pertussis toxin, tetanus toxin, ricin, botulinum toxin, shiga toxin, *E. coli* heat labile enterotoxin, etc.

Biological toxin will be commercially acquired Yes                  No

Biological toxin will be produced in the laboratory Yes                  No

Biological toxin will be used in animal	Yes	No
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4. Select Agents	Yes	No
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**The use, possession or transfer of a biological material listed as a Select Agent and/or Select Agent Toxin are strictly regulated under 7 CFR 331, 9 CFR 121 and 42 CFR 73 and require registration through the Federal Select Agent Program. Researchers considering work with any select agents/toxins MUST contact the BSO, Brian Butkus at [brian.butkus@ucf.edu](mailto:brian.butkus@ucf.edu) or 407-823-5498. An updated list of select agents/toxins can be found at <http://www.selectagents.gov/SelectAgentsandToxinsList.html>**

Each PI may possess exempt quantities of Select Agent Toxin(s) and not be required to register with CDC. It is important to ensure that the total amount of each toxin per PI is maintained below these limits **at all times** in order to remain exempt from registration requirements with the CDC. Due to the severe penalties associated with non-compliance with the Select Agent regulations, it is UCF policy that each laboratory in possession of exempt quantities of Select Toxins maintain current inventory for these materials. Contact BSO at [brian.butkus@ucf.edu](mailto:brian.butkus@ucf.edu) or 407-823-5498 to request an inventory sheet.

Exempt quantities of Select Toxins	Yes	No
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A table listing the exempt quantities of select toxins can be found at <http://www.selectagents.gov/PermissibleToxinAmounts.html>

Name of Select Toxin

Indicate the source from where the toxin will be acquired and the amount

Indicate storage location for the Select Toxin (Building and room)

Animals will be exposed to Select Toxin	Yes	No
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If yes, indicate the location where the animals will be exposed to the Select Toxin and housed

All Select Toxins and any cultures, stocks, and materials coming into contact with a Select Toxin will be inactivated prior to disposal

Yes No

Describe method of inactivation:

Select Toxin will be transferred to other individuals/PI outside the laboratory.

Yes No

5. Animal Use

Yes No

If yes, IACUC approval #: \_\_\_\_\_

Transgenic

Yes No

Species: \_\_\_\_\_ IACUC approval #: \_\_\_\_\_

**Note:** Use of **ANY** recombinant materials (e.g. human tumor cells, rDNA modified microorganisms, lentivirus, etc.) in animals require IBC approval.

Briefly describe the use of animals in this research including description of any transgene, protein product, source, promoter, tissue, specificity, etc.



6. Human and non-human primate blood, tissue, or body fluid including cell lines Yes                  No

If yes, briefly list and describe use of human and non-human primate blood, tissue, or body fluid. Include all (primary or characterized) human and non-human primate cell lines.

Human stem cells or induced pluripotent stem cells (embryonic or adult) Yes                  No

If yes, briefly describe source (i.e. commercial, human subjects, etc.) of the material and how it will be used.

7. Human Participant Use: Yes                  No  
If yes, IRB Approval #: \_\_\_\_\_  
Samples will be collected from human: Yes                  No  
Studies will be performed on human: Yes                  No

Briefly describe the use of humans/human samples in this research:

**C. Risk Assessment and Containment Procedures**

1. Experimental Risks and Mitigation Plan

a. Use of sharps (parenteral hazard) Yes No

If yes, check all used in experimental procedures

needles & syringes      razors      scalpels      blades  
glass      microtome      other: \_\_\_\_\_

Sharps mitigation:

sharps container      broken glass container  
engineered sharps      other: \_\_\_\_\_

b. Aerosol generating procedures (inhalational hazard)

Yes No

If yes, check all used during experimental procedures

centrifugation      vortex      sonicating      pipetting  
flow cytometry analysis/sorting      other: \_\_\_\_\_

Aerosol mitigation:

class II biosafety cabinet      chemical fume hood  
sealed rotor      HEPA-filtered animal caging  
local exhaust-snorkel      other: \_\_\_\_\_

c. Personal Protective Equipment (PPE):

safety glasses      goggles      face shield      gloves  
protective clothing (lab coat, Tyvek)

respirator (*Respirator (N-95) requires participation in the Medical Surveillance Program. Please call 407-823-0324 for more information*)

other: \_\_\_\_\_

2. Describe decontamination/disinfection process

3. Describe biological waste disposal method

a. Solid waste

b. Liquid waste

4. Describe the management of personnel and/or environmental risks

a. Spill response procedures (including inside the biosafety cabinet and outside, if applicable)

b. Exposure control measures (describe steps in the event of accidents or unintended exposures to biologicals i.e. animal bites, needle sticks, sharps injury, splash, etc. etc.)

**IV. Collaboration**

Will this research involve collaboration within UCF? Yes  No

If yes, please provide information for the Co-PI(s).

Name: \_\_\_\_\_ Dept: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Email: \_\_\_\_\_

Name: \_\_\_\_\_ Dept: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Email: \_\_\_\_\_

Will this research involve collaboration with any organization outside of UCF? Yes  No

If yes, has approval for this project been granted by the outside organization? Yes  No   
 Pending

Please provide the contact information for the organization that will be participating with this research.

Name: \_\_\_\_\_ Title: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Email: \_\_\_\_\_

Will biological material be transferred to any organization outside of UCF? Yes  No

I understand that I will be responsible to comply with federal, state and local regulations that pertain to all my research and laboratory activities. I am familiar with the relevant provisions of the current *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* ([http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html)) and agree to comply with these relevant provisions and all Institutional Policies and Procedures. Also, I accept responsibility for providing, through scheduling or teaching, training to all personnel involved in my laboratory. The information in this application is accurate and complete.

Print Name \_\_\_\_\_

PI Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## IBC Committee Use Only

Registration # \_\_\_\_\_

Review Date: \_\_\_\_\_ Approval Date: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

- Application reviewed by:  **Full Committee**  **BSO**
- Approved**                       **Modifications required for approval**
- Deferred**                         **Denied**

Biosafety Level Required:	Exempt	BSL-1	ABSL-1
		BSL-2	ABSL-2
		BSL-3	ABSL-3
Biosafety Cabinet Required:		Yes	No
If yes, is the BSC currently certified:		Yes	No
Biosafety lab audit has been completed by EH&S:		Yes	No

**Note:** The biosafety audit must indicate that all lab personnel are up to date on training with EH&S, and that appropriate waste containers and PPE for the listed biohazards are present in the lab. If not, the PI must indicate when these requirements will be added /completed.

Lab personnel are up to date on training EH&S:	Yes	No
Appropriate waste containers and PPE present in lab:	Yes	No
PI has conducted risk assessment and proposed standard operating procedures (SOPs) including decontamination/spill clean-up, and waste disposal methods.	Yes	No

**Committee Notes:**

IBC Chair Signature: \_\_\_\_\_ Date: \_\_\_\_\_

BSO Signature: \_\_\_\_\_ Date: \_\_\_\_\_