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 or 407-823-1219.

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

I. **Authorized User Information** (Principal Investigator who will be responsible for the biological material)

Name: _____ **Date:** _____ **Building** _____

UCF Title: _____ **Office room #** _____ **Lab room #** _____

Phone: _____ **Email:** _____

II. **Laboratory Description**

Biosafety Level Proposed: ☐ Exempt ☐ BSL-1 ☐ ABSL-1
☐ BSL-2 ☐ ABSL-2
☐ BSL-3 ☐ ABSL-3

Indicate building and room where the work will be performed:

Building: _____ Room(s): _____

Biosafety Cabinet Required: ◯ Yes ◯ No
If yes, BSC is currently certified: ◯ Yes ◯ No

The PI has conducted risk assessment and proposed standard operating procedures (SOPs) including decontamination, spill response, and waste disposal methods. **Provide details in Section III-C.**

◯ Yes ◯ No

III. **Research Description (select all that apply)**

A. Briefly describe (1-2 paragraphs) the proposed work in lay, non-technical terms. Include (a) summary, (b) research goal(s)) and (c) importance of the work. Please avoid use of acronyms and scientific jargon.

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). 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_{50} 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_{50}) 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))

◯ 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. **(III-D-2)**

◯ Yes ◯ No

f. Experiments involving the use of infectious DNA/RNA Viruses **OR** Defective DNA/RNA viruses in the presence of helper virus in tissue culture systems. **(III-D-3)**
Example: viral vectors including lentivirus, adenovirus, baculovirus in tissue culture.

◯ Yes ◯ No

g. Experiments involving whole animals. **(III-D-4)**
Example: 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 **(III-D-5)**

◯ 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. **(III-D-6)**

◯ Yes ◯ No

j. Experiments involving influenza viruses. **(III-D-7)**
Example: Generation of influenza viruses by reverse genetics of chimeric viruses with reasserted 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. **(III-E)**

◯ 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: ☐ N/A

- ☐ Adenovirus
- ☐ 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)) 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

4. Select Agents ◯Yes ◯No

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 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 or 407-823-5498 to request an inventory sheet.

Exempt quantities of Select Toxins ◯Yes ◯No

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

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)

For biological spills inside the biosafety cabinet (BSC):
1) Cover the spill with absorbent material, i.e paper towels
2) With appropriate PPE (lab coat, gloves and eye protection), pour disinfectant (list disinfectant with appropriate dilution, Example: 1:10 freshly prepared bleach solution) onto the paper towels by working from the outside to the inside and let it sit for ____ minutes (If using bleach, the contact time is 20 minutes, for all others, consult manufacturer's directions on the label)
3) After ____ minutes, dispose the paper towels and gloves into the red Biohazard container.
4) Notify Biosafety Officer (407-823-0324) if it involves recombinant materials or potential exposure to such materials

For biological spills outside the BSC:
1) Close the area to traffic and notify all co-workers
2) Leave the area for 30 minutes to allow for any aerosols to settle
3) Wear appropriate PPE (lab coat, gloves, eye protection)
4) Cover the spill with absorbent material, i.e. paper towels
5) Flood the area with (name the disinfectant and dilution) working from the outside to the center of the spill for ____ minutes (contact time; 20 minutes for bleach)
6) Discard the paper towels and gloves into the red Biohazard box. If glass is present, use forceps to pick up broken glass and dispose in a sharps or a broken glass container.
7) Notify Supervisor and the Biosafety Offcer (407-823-0324)

   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.)

For emergencies, call 911 or report to nearest ER
For all other potential exposures:
1) Administer first aid, if necessary.
   -Wash the area with soap and water or flush eyes, nose or mouth with large amounts of water for 15 minutes
2) Notify Supervisor and Biosafety Officer (407-823-0324)
3) If applicable, notify AmeriSys at 1-800-455-2079 to initiate treatment

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) 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: _____

Project Personnel

The individuals listed below will be involved in the experimentation described above. They are familiar with and agree to abide by the current University of Central Florida guidelines as outlined in the Biological Safety Manual and the NIH Guidelines (for Research Involving Recombinant or Synthetic Nucleic Acid Molecules). **All participants must be up to date with EH+S trainings.**

Name	Title

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) 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. I understand and acknowledge my right to address in person the IBC meeting during which my BAR application will be reviewed for the purpose of discussing and addressing any questions the committee may have regarding my application.

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: _____