Biological Agent Registration

The following require registration & approval BEFORE you begin the research:

1) Biosafety level 2 (BSL-2) or BSL-3 human, animal, or plant pathogens. ***BSL-4 agents may not be used at UF.***
2) Unknown human and animal pathogens - these are considered BSL-2 until identified.
3) Cell lines or cultures that have been immortalized with a virus (such as EBV or a retrovirus) or are primary human tumor cells. These items must be handled at a **minimum** of BSL-2.
4) Human blood or other tissues that are known to be positive for any human disease-causing virus(es) or other agent(s).

Project submissions are reviewed by the Biosafety Office. BSL-3 projects or those using select agents will require additional information & are forwarded to the Institutional Biosafety Committee (IBC) for review, comment, and approval. The IBC is composed of scientists that *may not be experts in your particular field of research*. **Please tailor your project description accordingly.** We must obtain sufficient information from you to be able to determine the required containment level, facilities, procedures, practices, and expertise/training necessary for the safe conduct of the project, so **please be thorough**. Insufficient information will delay the approval process and the form will be returned to you for revision. **Please utilize the fillable document and type the form; hand written forms are not accepted. If you have any questions, please contact the Biosafety Office at 392-1591 or bso@ehs.ufl.edu**

The Biosafety in Microbiological and Biomedical Laboratories (5th Edition) is a valuable resource for details on containment, risk assessment, agent summary statements, etc. and can be found at:
http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

University of Florida
Environmental Health & Safety
Biological Safety Office
bso@ehs.ufl.edu
phone: (352)-392-1591
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Biological Agent Registration

#BA -

Section 1 – Basic Information

PI Name:		Title:
Department:		Address/Box:
Office Phone:	Lab Phone:	Email:
Project Title:		
Project Location: Building(s):		Room(s):
Sponsor:		

Section 2 – General Project Information

2.1 Will human subjects and/or human clinical specimens be used in this research? Yes ☐ No ☐
If yes, have you received IRB approval?
- ☐ No Date of intended submission:
- ☐ Yes IRB#:
- ☐ Approval pending – date submitted to IRB:

2.2 Will you use isotopes? Yes ☐ No ☐
If yes, please provide RSC approval date:

2.3 Will you transport or ship biological agents/infectious substances/diagnostic specimens? Yes ☐ No ☐

2.4 Will you use Select Agents (http://www.ehs.ufl.edu/Bio/select.htm)? Yes ☐ No ☐

2.5 Will you use agents subject to export controls (http://www.ehs.ufl.edu/bio/export_list.htm)? Yes ☐ No ☐

2.6 Are permits (import, transport, release to environment) required to work with this material? Yes ☐ No ☐
If yes, please submit a copy of all permits with this registration.

2.7 Does any aspect of your work have "dual-use potential", defined as research that can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, or the environment? Yes ☐ No ☐

If yes, provide a detailed explanation:

Section 3 – Animal Use

3.1 Will animals be infected with or exposed to the pathogen? Yes ☐ No ☐ (if no, skip to Section 4)

3.2 Please list the animals you will be using:

3.3 Route of infection? *Check all that apply*.
☐ Intravenous ☐ Intraperitoneal ☐ Subcutaneous ☐ Intracerebroventricular ☐ Intramuscular
☐ Intranasal ☐ Other:

3.4 Has this protocol received approval from the UF IACUC?
☐ No Date of intended submission:
☐ Yes IACUC #:
☐ Approval pending – date submitted to IACUC:

3.5 Where do you plan to house your animals? Building: Room:

3.6 Where will you perform procedures using animals? Building: Room:

3.7 How will animals be disposed of upon completion of experiments?

Section 4 – Plant Use

4.1 Will plants be infected with or exposed to the pathogen? Yes ☐ No ☐ (if no, skip to Section 5)

4.2 Please list the plants you will be using:

4.3 Is this species a noxious weed, invasive plant, or exotic plant? Yes ☐ No ☐

4.4 How will plants be infected?

4.5 Where will infected plants be kept?
☐ Laboratory Location:
☐ Growth chamber Location:
☐ Greenhouse Location:
☐ Field Release Location:

4.6 Describe procedures for containment of infected plants:

4.7 How will infected plant materials be disposed of upon completion of experiments?

Section 5 - Biological Agent/Pathogen Details

5.1 Detail biological agents used in this project below, one column per agent (insert sheets as necessary). For guidance see https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html, http://www.cdc.gov/biosafety/publications/bmbl5/index.htm, http://www.absa.org/riskgroups/index.html or http://www.phac-aspc.gc.ca/msds-ftss/index-eng.php. If information is not known (e.g. diagnostic specimens) or is not applicable (human cell lines), indicate that on the form.

	Agent	**Agent**	**Agent**	**Agent**
Name of agent (genus/species and common name if applicable)				
Type of Agent	Bacterium If other, list:	Bacterium If other, list:	Bacterium If other, list:	Bacterium If other, list:
Risk Group	RG1	RG1	RG1	RG1
From where will the agent be obtained?				
Pathogenic to:	Humans	Humans	Humans	Humans
Infectious Dose				
Natural Modes of Infection				
Primary Laboratory Hazards (e.g. accidental inoculation, aerosols, etc)				
Clinical Symptoms				
Effective Treatments (e.g. antibiotics, immunization)				
Environmental Stability of Agent (e.g. survival time outside host in an infectious form)				
How will you inactivate the agent upon completion of work?				

Section 6 – Research Description and Risk Assessment

6.1 Briefly describe the proposed work in lay terms. Your narrative must include:

1) a brief introduction,
2) the specific goal(s) of your experiment(s),
3) the experimental methods to be used and,
4) the endpoints to be measured

*The Biosafety Office/IBC does not review the scientific merit of the work but rather evaluates projects to ensure that they incorporate steps to minimize potential biohazard exposures and that biohazardous materials are disposed of in an appropriate manner. Provide sufficient information to ensure that the hazards and potential risks are easily identified. Avoid using excess technical jargon and **do not** simply attach grant proposals, abstracts, manuscripts, or IACUC/lab protocols as a substitute.*

6.2 Discuss the hazards/risks associated with this experiment (e.g. potential exposure risks such as needlesticks, handling of the agent, any aerosolization that may occur, release to the environment). If biological agents will be used in animals, be sure to specify additional risks related to animal handling and husbandry (e.g. agent shedding in urine/feces, transmission via bite/scratch).

6.3 Describe the relevant safety and containment procedures that will be used to protect personnel and/or the environment from potential exposure. Consider the necessary safety equipment, work practices, and PPE that will be required for various tasks (e.g. culturing agent, animal inoculation).

Section 7 - Work Practices/Procedures

7.1 Will you use any of the following devices that have the potential to aerosolize biological agents? *Check all that apply.*

☐ Centrifuge If using a centrifuge does it have: ☐ Sealed rotors ☐ Sealed centrifuge cups
☐ Tissue grinders ☐ Sonicators ☐ Vortexers
☐ Blenders ☐ Shakers ☐ Autopsy/necropsy saws
☐ Intranasal/intratracheal inoculation of animals ☐ Pressurized vessels (besides autoclaves)
☐ Other (list):

7.2 Will you work with biological agents in a biosafety cabinet? Yes ☐ No ☐
Manufacturer/model:
Certification date:
Building/room:

7.3 Will you work with large volumes (>10 L) of infectious material? Yes ☐ No ☐

7.4 Are MSDS sheets for these agents available in the lab? Yes ☐ No ☐

7.5 Where are standard operating procedures (SOPs) for work with these agents kept?

7.6 Is a biological spill kit prepared for use in the lab? Yes ☐ No ☐

7.7 Is a there a hand washing sink in the lab? Yes ☐ No ☐

7.8 What personal protective equipment (PPE) will be used to minimize exposure? *Check all that apply.*

☐ Safety glasses ☐ Goggles ☐ Faceshield ☐ Surgical mask
☐ N95 ☐ PAPR ☐ Gloves ☐ Lab coat
☐ Shoe covers ☐ Head cover ☐ Other:

Section 8 - Decontamination and Disposal

8.1 Which types of biological waste will be generated in your lab? *Check all that apply.*

☐ Sharps
☐ Recombinant DNA
☐ Human pathogens
☐ Animal pathogens
☐ Plant pathogens
☐ Human/primate blood, blood products, tissues, cultures, cells, or OPIM
☐ Animal carcasses/tissues
☐ Human remains/tissues
☐ Mixed biological/chemical waste
☐ Mixed biological/radioactive waste

8.2 Do you have access to an autoclave? Yes ☐ No ☐
Building/room:
Proper function & testing monitored by (name):
Test method:
Test frequency:

8.3 Do you have a copy of the biological waste disposal guidelines posted in the lab? Yes ☐ No ☐
(see http://www.ehs.ufl.edu/Bio/biowaste.htm#Policy and http://www.ehs.ufl.edu/Bio/BMW-waste-disposal.pdf)

8.4 Have all personnel been trained regarding proper biological waste disposal? Yes ☐ No ☐

8.5 How will work surfaces be decontaminated?

8.6 How will solid waste be decontaminated and disposed of?

8.7 How will liquid waste be decontaminated and disposed of?

Section 9 - Occupational Health and Training Information

Name and Title	Human/Non-human primate samples used	Vaccinations/Tests received	Training Courses Taken	Years experience working at:		
				BSL-1	BSL-2	BSL-3
	☐ Blood ☐ Tissues ☐ Primary cell cultures ☐ OPIM: ☐ None	☐ Hepatitis B ☐ Vaccinia ☐ TB screening ☐ Serum banking ☐ Respirator fit testing ☐ Other:	☐ BBP ☐ BMW ☐ Shipping & Transport ☐ Biosafety	None	None	None
	☐ Blood ☐ Tissues ☐ Primary cell cultures ☐ OPIM: ☐ None	☐ Hepatitis B ☐ Vaccinia ☐ TB screening ☐ Serum Banking ☐ Respirator fit testing ☐ Other:	☐ BBP ☐ BMW ☐ Shipping & Transport ☐ Biosafety	None	None	None
	☐ Blood ☐ Tissues ☐ Primary cell cultures ☐ OPIM: ☐ None	☐ Hepatitis B ☐ Vaccinia ☐ TB screening ☐ Serum Banking ☐ Respirator fit testing ☐ Other:	☐ BBP ☐ BMW ☐ Shipping & Transport ☐ Biosafety	None	None	None
	☐ Blood ☐ Tissues ☐ Primary cell cultures ☐ OPIM: ☐ None	☐ Hepatitis B ☐ Vaccinia ☐ TB screening ☐ Serum Banking ☐ Respirator fit testing ☐ Other:	☐ BBP ☐ BMW ☐ Shipping & Transport ☐ Biosafety	None	None	None
	☐ Blood ☐ Tissues ☐ Primary cell cultures ☐ OPIM: ☐ None	☐ Hepatitis B ☐ Vaccinia ☐ TB screening ☐ Serum Banking ☐ Respirator fit testing ☐ Other:	☐ BBP ☐ BMW ☐ Shipping & Transport ☐ Biosafety	None	None	None
	☐ Blood ☐ Tissues ☐ Primary cell cultures ☐ OPIM: ☐ None	☐ Hepatitis B ☐ Vaccinia ☐ TB screening ☐ Serum Banking ☐ Respirator fit testing ☐ Other:	☐ BBP ☐ BMW ☐ Shipping & Transport ☐ Biosafety	None	None	None

OPIM = Other potentially infectious material
BBP = Bloodborne Pathogen
BMW = Biomedical Waste

Section 10 – Project Personnel and PI Assurance

The undersigned individual(s) will be involved in the experimentation described above. They are familiar with and agree to abide by the current University of Florida guidelines as outlined in the Biological Safety Manual (http://www.ehs.ufl.edu/programs/bio/bioman/). **ALL PARTICIPANT SIGNATURES REQUIRED.**

UF ID	Name (type or print)	Signature	Date

I attest to the fact that these individuals have received all required training and have also received training specific to the agents that they will be handling.
I agree to comply with UF requirements pertaining to handling, shipment, transfer, & disposal of biological agents.
I am familiar with and agree to abide by the provisions of the current biosafety manual and other specific biosafety office/IBC instructions pertaining to the proposed project.
I understand that I must have EH&S or IBC approval before beginning this work.
I understand that changes to the project described above must be reported to EH&S Biosafety Office in advance.
I understand that associated IACUC or IRB approvals may be held pending EH&S or IBC approval of this work.
The information above is accurate and complete to the best of my knowledge.

Principal Investigator Date

E-mail, fax, or mail form to the Biosafety Office at: **bso@ehs.ufl.edu**, fax: (352) 392-3647, mail: PO Box 112190