



What is a Biological Hygiene Plan And Why do I need it?

University of Miami
Environmental Health & Safety
Biosafety

Biosafety Office



- Shane Gillooly
 - Biosafety Officer



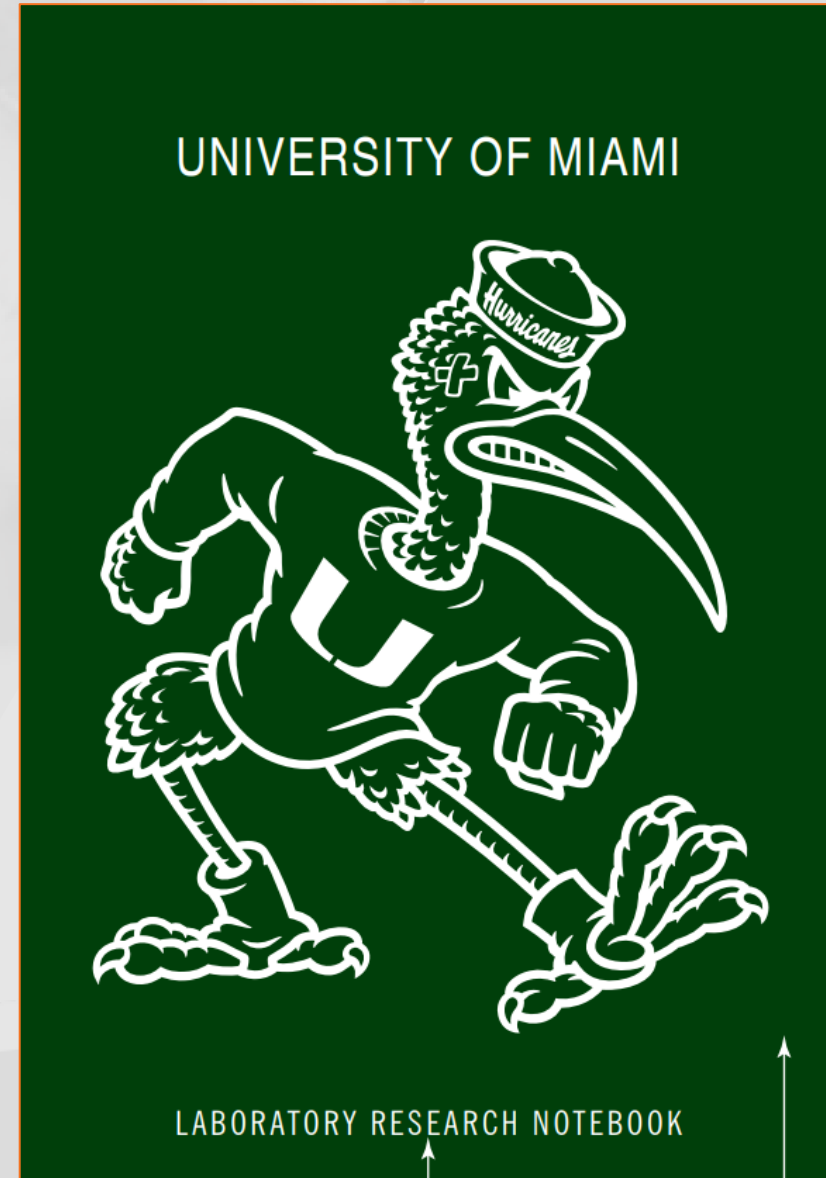
- Melanie Peapell
 - Biosafety Specialist
 - Laser Safety Officer



- Daniel Nunez
 - Biosafety Specialist

Prize Winner

- Branded Laboratory Research Notebook
 - Hardcover
 - Sebastian
 - 232 pages
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- Yesterday's Winner:
 - Joshi Mahesh





What is the Biological Hygiene Plan?

Biological Hygiene Plan

Biological Hygiene Plan

PI Last Name Lab

- This form is both a review tool to assess/develop the safety practices of the lab, as well as a biological hygiene plan outlining some of the safety standards and procedures associated with the lab for lab staff review.
- Please upload a copy into the biological registration documents section at the bottom of your Biological Registration submission.

Section 1: Administration

Principle Investigator:		PI Phone:	
PI Email:			
Lab/Safety Manager:		Manager Phone:	
Manager Email:			
Biosafety Cabinets in Use	<input type="checkbox"/>	BSC Type:	N/A
BSC Room Location(s)		Certification Date	
		Expiration Date	

Section 2: Training Requirements for Lab

Check each box that is applicable	Required Training for Lab
<input type="checkbox"/> 1. Infectious or otherwise risk group 2 agents	Biosafety
<input type="checkbox"/> 2. Human source materials	Bloodborne Pathogens
<input type="checkbox"/> 3. Genetically modified organisms or synthetic nucleic acid molecules	Recombinant DNA
<input type="checkbox"/> 4. Biological materials/specimens shipped to another facility.	Shipping of Dangerous Goods
• Specify designated shipper(s):	Shipping of Biological Materials

Section 3: Hazard Communication

Type of Material Used/Stored by Lab	Specify Genus Species or Disease within Specimen
Provide an overview of the lab and how these biological materials function to serve the aims of the research.	

Section 4: Risk Assessment

What are the possible transmission/exposure routes of the materials used in the lab? (ie. Inhalation, bloodborne, etc.)
List the signs and symptoms of exposure to these materials:
Assess the exposure risks associated with the procedures employed in this lab. How are these risks mitigated?
How would exposures to these hazards be handled/treated?
What disinfectants are used for agent inactivation? If applicable, what disinfectants are used in the BSC?
If applicable, specify how materials are being transported between facilities and/or shipped to other facilities:
List the PPE requirements for researchers in this lab:
<input checked="" type="checkbox"/> Gloves <input checked="" type="checkbox"/> Safety Glasses <input checked="" type="checkbox"/> Lab Coat <input type="checkbox"/> Face Shield <input type="checkbox"/> Disposable Gown <input type="checkbox"/> N95 Respirator
<input type="checkbox"/> Other(s): List...

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Section 5: Hygiene Plan

Below and check/modify as appropriate for adoption by your lab.
A: Engineering Controls
requiring a key or card access to gain entry.
The room will be limited to only that which is unavoidable.
while active work on this project is ongoing.
Materials will always be performed in the biosafety cabinet(s) listed.
to minimize the creation of aerosols, and that which is unavoidable must be limited to work involved in the manipulation of the biohazardous material.
Materials must be visually labeled so as to prevent work in them.
Materials carrying viable pathogens is allowed under any circumstances only out in the biosafety cabinet.
Materials must be cleaned with disinfectant before and after use.
B: Work Practice Controls
Immediately after contact with potentially infectious materials, hands must be washed before exiting the lab.
No eating, drinking, smoking; application of cosmetics; handling of contact lenses.
Materials must be decontaminated (e.g., pipettes, filter units, culture vessels) before decontamination off-site.
1:10 dilution of bleach and poured down the drain.
Waste must be cleaned up once per day, and after any spill of viable material.
Waste must be properly labeled, leak-proof, and closeable.
Sharps must be disposed of and other sharps directly into a labeled, puncture-proof sharps container. Any effort made to recap by hand, destroy or remove needles.
Individuals who are immunocompromised should avoid working with potentially infectious materials.
Leak-proof, meaning a leak-proof, sealed, inner container, a leak-proof, outer container, and a sturdy outer container such as a cooler. The container must be labeled and set up to its delivery location, the site of manipulation, in the PI's name. If a dual for co-delivery, it will not be left in any location except at the destination.
Materials must be sealed, or materials that have a chance of having been exposed to and must be stored in a sealable container and the outside surface decontaminated with disinfectant before the container can be removed and disposed of in a biological waste bin. Any such hazards must have any openings covered and/or sealed prior to their disposal in a biohazardous bin.
Personal Protective Equipment
Individuals exposed to infectious agents, protective clothing and devices must be used.
Individuals present in the lab must wear protective clothing and devices.
Individuals must have the potential for direct or indirect contact with blood or other body fluids during handling of closed vessels containing tissue, blood, or other body fluids or blood. Gloves will also be worn during all cleaning and maintenance of biomedical waste.
Equipment must be cleaned or professionally cleaned.

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Bloodborne Pathogens

as defined in 29 CFR 1910.103 in terms of practices, safety equipment, and procedures, which assumes that all blood, body fluids, and other potentially infectious materials are potentially infectious.
potentially infectious materials have been regulated (Blood-Borne Disease Standard, 29 CFR 1910.103).
Materials must be present in human blood, or blood components, but are not limited to, hepatitis B virus (HBV) and other bloodborne occupational infection hazard to healthcare workers. The risk of occupational infection with HIV is very low. Bloodborne diseases that pose sporadic but significant health risks include malaria, babesiosis, brucellosis, relapsing fever, hepatitis, and arboviruses.
Individuals must not be infected with HBV, HCV, HIV, herpes, or other bloodborne pathogens.
Emergency
Emergency eyewash/safety shower located in room [] for 15 minutes.
Individuals must be reported to the Employee Health Office, the PI, and the PI, who will arrange for the necessary medical care. Incidents will result in suspension of protocols.
Emergency contact: 9-4684
Individuals must prepare an emergency response plan.
Individuals must be appropriately trained individuals. The EHS Biosafety Officer must be immediately to determine whether it can be cleaned.
Individuals must report on to mitigate aerosol creation.
Spill Response Procedures
Individuals in this lab: Explain why and when it's needed and the steps to be taken to minimize needle-stick risks.
Individuals must be notified if necessary, when and where they're working, and when enrollment.

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Select Agents Assessment

Individuals must be determined to have the potential to pose a severe threat to both human health and the environment. An attenuated strain of a select agent or an agent that is not a select agent but meets the requirements of the Select Agent Regulations. Here is a list of select agents:
Select Agents that apply
ERLAP SELECT AGENTS AND TOXINS
Bacillus anthracis
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei
Burkholderia pseudomallei
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus
PPQ SELECT AGENTS AND TOXINS
African horse sickness virus
African swine fever virus
Avian influenza virus
Classical swine fever virus
Foot-and-mouth disease virus
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum
Mycoplasma mycoides
Newcastle disease virus
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
PPQ PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS
Coniothyrium glycinis (formerly Phoma glycinicola and Phoma glycinis)
Peronosclerospora philippinensis
Peronosclerospora sacchari
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae
None

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Select Agents Assessment

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Haz Com & Risk Assessment

Biological Hygiene Plan

PI Last Name Lab

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Principle Investigator:		PI Phone:	
PI Email:			
Lab/Safety Manager:		Manager Phone:	
Manager Email:			
Biosafety Cabinets in Use	<input type="checkbox"/>	BSC Type:	N/A
	<input type="checkbox"/>	Certification Date	
BSC Room Location(s)		Expiration Date	

Section 2: Training Requirements for Lab

Check each box that is applicable	Required Training for Lab
<input type="checkbox"/> 1. Infectious or otherwise risk group 2 agents	Biosafety
<input type="checkbox"/> 2. Human source materials	Bloodborne Pathogens
<input type="checkbox"/> 3. Genetically modified organisms or synthetic nucleic acid molecules	Recombinant DNA
<input type="checkbox"/> 4. Biological materials/specimens shipped to another facility.	Shipping of Dangerous Goods
<ul style="list-style-type: none"> Specify designated shipper(s): 	Shipping of Biological Materials

Section 3: Hazard Communication

Type of Material Used/Stored by Lab	Specify Genus Species or Disease within Specimen
Provide an overview of the lab and how these biological materials function to serve the aims of the research.	

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If applicable, specify how materials are being transported between facilities and/or shipped to other facilities:
List the PPE requirements for researchers in this lab:
<input checked="" type="checkbox"/> Gloves <input checked="" type="checkbox"/> Safety Glasses <input checked="" type="checkbox"/> Lab Coat <input type="checkbox"/> Face Shield <input type="checkbox"/> Disposable Gown <input type="checkbox"/> N95 Respirator
Other(s): List...

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Review and check/modify as appropriate for adoption by your lab.
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the room will be limited to only that which is unavoidable.
while active work on this project is ongoing.
materials will always be performed in the biosafety cabinet(s) listed.
minimize the creation of aerosols, and that which is unavoidable must be limited to work involved in the manipulation of the biohazardous material.
visually labeled so as to prevent work in them.
materials carrying viable pathogens is allowed under any circumstances.
cleaned with disinfectant before and after use.
B: Work Practice Controls
immediately after contact with potentially infectious materials, and before exiting the lab.
drinking; smoking; application of cosmetics; handling of contact sharps.
potentially infectious materials (e.g., pipettes, filter units, culture vessels) for decontamination off-site.
10 dilution of bleach and poured down the drain.
once per day, and after any spill of viable material.
biohazardous waste will be labeled, leak-proof, and closeable.
and other sharps directly into a labeled, puncture-proof sharps container. If any effort made to recap by hand, destroy or remove needles.
immunocompromised) should avoid working with potentially infectious materials.
leak-proof, sealed, inner container, a leak-proof, outer container, and a sturdy outer container such as a cooler. The container must be labeled with the agent, the site of manipulation, in the PI's dual for co-delivery, it will not be left in any location except at the lab.
used, or materials that have a chance of having been exposed to and must be stored in a leak-proof, sealed, inner container and the outside surface decontaminated with bleach before the container can be removed and disposed of in a biological waste bin. Any such hazards must have any openings covered and/or sealed prior to their disposal in a biohazardous bin.
Personal Protective Equipment
exposure to infectious agents, protective clothing and devices must be worn.
individuals present in the lab must wear protective clothing and footwear.
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decontaminated or professionally cleaned.

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Bloodborne Pathogens

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present in human blood, or blood components, but are not limited to, hepatitis B virus (HBV) and other bloodborne occupational infection hazard to healthcare workers. The risk of occupational infection with HIV is very low. Bloodborne diseases that pose sporadic but significant health risks include malaria, babesiosis, brucellosis, relapsing fever, and arboviruses.
not to be infected with HBV, HCV, HIV, herpes, or other bloodborne pathogens.
Emergency
biohazardous safety shower located in room [] for 15 minutes.
reported to the Employee Health Office, the PI (PI's name), and the PI, who will arrange for the incident to be reported to OSHA. The PI's name will be included in the incident report. 9-4684
biohazardous materials or agents must prepare an incident report.
appropriately trained individuals. The EHS Biosafety Officer will be notified immediately to determine whether it can be cleaned.
effort on to mitigate aerosol creation.
Spill Response Procedures
in this lab: Explain why and when it's needed and the steps to be taken to minimize the risk of a spill.
spill is necessary, when and where they're working.
enrollment.

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Select Agents Assessment

permitted to have the potential to pose a severe threat to both human health and the environment. An attenuated strain of a select agent or an agent that is not a select agent but meets the requirements of the Select Agent Regulations. Here is a list of select agents:
Check all that apply)
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Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae
None

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Select Agents Assessment

purposes can be utilized for both human health and the environment.
research that, based on current practices, technologies that could be used to public health and safety, agricultural and other purposes.
Department of Life Sciences Dual Use Research was released to establish the Department. On September 24, 2014, the US Government was released to establish the Department. The US Government considers these two categories of select agents:
projects at the University of Miami, and the categories of experiments deemed potential DURC.
15 listed agents.
enza virus
<i>Clostridium botulinum</i>
can be reasonably anticipated to be used in the laboratory.
the agent or toxin without clinical data.
useful prophylactic or therapeutic purposes. The PI will follow these procedures to ensure its ability to be disseminated.
listed in Question 6.2 of this form.
Other
practices, containment equipment, personal protective equipment, and other safety level applicable to this project. I will follow these procedures and will follow these

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Admin Information

Biological Hygiene Plan

PI Last Name Lab

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PI Email:			
Lab/Safety Manager:		Manager Phone:	
Manager Email:			
Biosafety Cabinets in Use	<input type="checkbox"/>	BSC Type: N/A	Certification Date
BSC Room Location(s)		Expiration Date	

Section 2: Training Requirements for Lab	
Check each box that is applicable	Required Training for Lab
<input type="checkbox"/> 1. Infectious or otherwise risk group 2 agents	Biosafety
<input type="checkbox"/> 2. Human source materials	Bloodborne Pathogens
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Section 3: Hazard Communication	
Type of Material Used/Stored by Lab	Specify Genus Species or Disease within Specimen
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Other(s): List...

- Section 1 – Administration

Training Required for Lab

Biological Hygiene Plan

PI Last Name Lab

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Other(s): List...

- Section 1 – Administration
- Section 2 – Training Requirements

Training Subjects

[Open All Tabs](#)

Biosafety Training



Recombinant DNA Training



Bloodborne Pathogens Training



Shipping Training



Lab Safety Training



Biohazardous Agents Used

Biological Hygiene Plan

PI Last Name Lab

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Other(s): List...

- Section 1 – Administration
- Section 2 – Training Requirements
- Section 3 – Hazard Communication

Weighing the Risks

Biological Hygiene Plan

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Other(s): List...

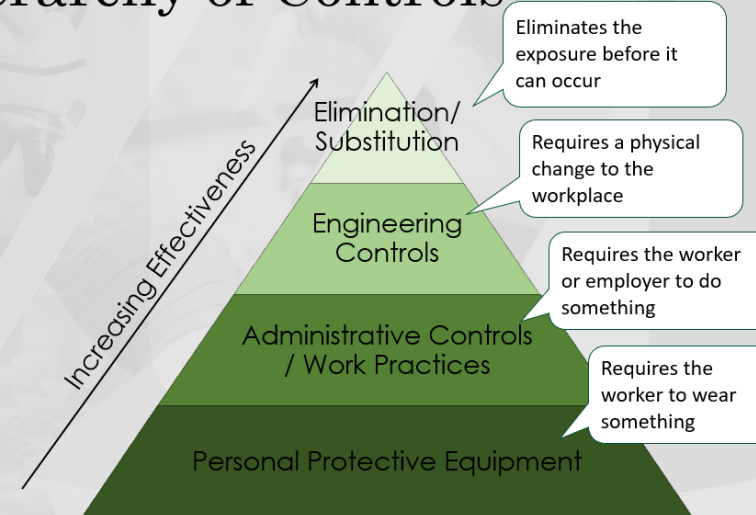
- Section 1 – Administration
- Section 2 – Training Requirements
- Section 3 – Hazard Communication
- Section 4 – Risk Assessment

Lab Specific Safety SOPs

- Section 1 – Administration
- Section 2 – Training Requirements
- Section 3 – Hazard Communication
- Section 4 – Risk Assessment
- Section 5 – Hygiene Plan

Section 5: Hygiene Plan	
Please review the standard operating procedures below and check/modify as appropriate for adoption by your lab.	
Part A: Engineering Controls	
<input type="checkbox"/>	Access to this laboratory is always restricted, requiring a key or card access to gain entry.
<input type="checkbox"/>	When manipulating specimens, traffic into the room will be limited to only that which is unavoidable.
<input type="checkbox"/>	No other research may be allowed in the room while active work on this project is ongoing.
<input type="checkbox"/>	All manipulations of potentially pathogenic materials will always be performed in the biosafety cabinet(s) listed.
<input type="checkbox"/>	All procedures are performed carefully to minimize the creation of aerosols, and that which is unavoidable must be performed in the biosafety cabinet, as is all work involved in the manipulation of the biohazardous material.
<input type="checkbox"/>	Biosafety cabinets will be certified annually, or visually labeled so as to prevent work in them.
<input type="checkbox"/>	No open-bench work with infected samples or materials carrying viable pathogens is allowed under any circumstances, all such work must be carried out in the biosafety cabinet.
<input type="checkbox"/>	The surface of the biological safety cabinet is cleaned with disinfectant before and after use.
Part B: Work Practice Controls	
<input type="checkbox"/>	Employees will wash their hands with soap immediately after contact with potentially infectious materials, following the removal of protective gloves, and before exiting the lab.
<input type="checkbox"/>	The following activities are prohibited: eating; drinking; smoking; application of cosmetics; handling of contact lenses; storage or preparation of food or drink.
<input type="checkbox"/>	All supplies that come into contact with potentially infectious materials (e.g., pipettes, filter units, culture dishes) are disposed of in biohazardous waste for decontamination off-site.
<input type="checkbox"/>	Liquid waste will be decontaminated with a 1:10 dilution of bleach and poured down the drain.
<input type="checkbox"/>	Work surfaces are decontaminated at least once per day, and after any spill of viable material.
<input type="checkbox"/>	Containers for potentially infectious laboratory waste will be labeled, leak-proof, and closeable.
<input type="checkbox"/>	Long hair must be pulled back and contained.
<input type="checkbox"/>	Employees will place used needles, scalpels, and other sharps directly into a labeled, puncture-proof sharps container immediately following use, without any effort made to recap by hand, destroy or remove needles from the syringes.
<input type="checkbox"/>	Employees with increased risk (broken skin, immunocompromised) should avoid working with potentially infectious materials.
<input type="checkbox"/>	During transport, samples will be triple packed, meaning a leak-proof, sealed, inner container, a leak-proof, sealed secondary container such as a Ziploc bag, and a sturdy outer container such as a cooler. The container shall be delivered directly from the point of pick-up to its delivery location, the site of manipulation, in the PI's lab. It will not be handed off to another individual for co-delivery, it will not be left in any location except at the lab and handed to the PI's lab directly.
<input type="checkbox"/>	Any human specimen samples remaining unused, or materials that have a chance of having been exposed to and carrying viable pathogens, must be placed in a sealable container and the outside surface decontaminated with 70% ethanol inside of the biosafety cabinet before the container can be removed and disposed of in a biological waste container. Any sharps bins containing any such hazards must have any openings covered and/or sealed prior to removal from the biosafety cabinet, prior to their disposal in a biohazardous bin.
Part C: Personal Protective Equipment	
<input type="checkbox"/>	When there is a potential for occupational exposure to infectious agents, protective clothing and devices must be used.
<input type="checkbox"/>	When there is ongoing work in the lab, all individuals present in the lab must wear protective clothing and devices, such as safety glasses.
<input type="checkbox"/>	In general, gloves will be worn when employees have the potential for direct or indirect contact with blood or other potentially infectious materials. This includes during handling of closed vessels containing tissue, blood, or culture medium that is contaminated with tissue or blood. Gloves will also be worn during all cleaning and decontamination procedures, and during handling of biomedical waste.
<input type="checkbox"/>	Lab coats must be decontaminated before laundering or professionally cleaned.

Hierarchy of Controls



Lab Containment SOPs

- Section 5 – Hygiene Plan
 - Part A – Engineering Controls

Section 5: Hygiene Plan	
Please review the standard operating procedures below and check/modify as appropriate for adoption by your lab.	
Part A: Engineering Controls	
<input type="checkbox"/>	Access to this laboratory is always restricted, requiring a key or card access to gain entry.
<input type="checkbox"/>	When manipulating specimens, traffic into the room will be limited to only that which is unavoidable.
<input type="checkbox"/>	No other research may be allowed in the room while active work on this project is ongoing.
<input type="checkbox"/>	All manipulations of potentially pathogenic materials will always be performed in the biosafety cabinet(s) listed.
<input type="checkbox"/>	All procedures are performed carefully to minimize the creation of aerosols, and that which is unavoidable must be performed in the biosafety cabinet, as is all work involved in the manipulation of the biohazardous material.
<input type="checkbox"/>	Biosafety cabinets will be certified annually, or visually labeled so as to prevent work in them.
<input type="checkbox"/>	No open-bench work with infected samples or materials carrying viable pathogens is allowed under any circumstances, all such work must be carried out in the biosafety cabinet.
<input type="checkbox"/>	The surface of the biological safety cabinet is cleaned with disinfectant before and after use.
Part B: Work Practice Controls	
<input type="checkbox"/>	Employees will wash their hands with soap immediately after contact with potentially infectious materials, following the removal of protective gloves, and before exiting the lab.
<input type="checkbox"/>	The following activities are prohibited: eating; drinking; smoking; application of cosmetics; handling of contact lenses; storage or preparation of food or drink.
<input type="checkbox"/>	All supplies that come into contact with potentially infectious materials (e.g., pipettes, filter units, culture dishes) are disposed of in biohazardous waste for decontamination off-site.
<input type="checkbox"/>	Liquid waste will be decontaminated with a 1:10 dilution of bleach and poured down the drain.
<input type="checkbox"/>	Work surfaces are decontaminated at least once per day, and after any spill of viable material.
<input type="checkbox"/>	Containers for potentially infectious laboratory waste will be labeled, leak-proof, and closeable.
<input type="checkbox"/>	Long hair must be pulled back and contained.
<input type="checkbox"/>	Employees will place used needles, scalpels, and other sharps directly into a labeled, puncture-proof sharps container immediately following use, without any effort made to recap by hand, destroy or remove needles from the syringes.
<input type="checkbox"/>	Employees with increased risk (broken skin, immunocompromised) should avoid working with potentially infectious materials.
<input type="checkbox"/>	During transport, samples will be triple packed, meaning a leak-proof, sealed, inner container, a leak-proof, sealed secondary container such as a Ziploc bag, and a sturdy outer container such as a cooler. The container shall be delivered directly from the point of pick-up to its delivery location, the site of manipulation, in the PI's lab. It will not be handed off to another individual for co-delivery, it will not be left in any location except at the lab and handed to the PI's lab directly.
<input type="checkbox"/>	Any human specimen samples remaining unused, or materials that have a chance of having been exposed to and carrying viable pathogens, must be placed in a sealable container and the outside surface decontaminated with 70% ethanol inside of the biosafety cabinet before the container can be removed and disposed of in a biological waste container. Any sharps bins containing any such hazards must have any openings covered and/or sealed prior to removal from the biosafety cabinet, prior to their disposal in a biohazardous bin.
Part C: Personal Protective Equipment	
<input type="checkbox"/>	When there is a potential for occupational exposure to infectious agents, protective clothing and devices must be used.
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<input type="checkbox"/>	In general, gloves will be worn when employees have the potential for direct or indirect contact with blood or other potentially infectious materials. This includes during handling of closed vessels containing tissue, blood, or culture medium that is contaminated with tissue or blood. Gloves will also be worn during all cleaning and decontamination procedures, and during handling of biomedical waste.
<input type="checkbox"/>	Lab coats must be decontaminated before laundering or professionally cleaned.

Lab Work Practice SOPs

- Section 5 – Hygiene Plan
 - Part A – Engineering Controls
 - Part B – Work Practice Controls

Section 5: Hygiene Plan	
Please review the standard operating procedures below and check/modify as appropriate for adoption by your lab.	
Part A: Engineering Controls	
<input type="checkbox"/>	Access to this laboratory is always restricted, requiring a key or card access to gain entry.
<input type="checkbox"/>	When manipulating specimens, traffic into the room will be limited to only that which is unavoidable.
<input type="checkbox"/>	No other research may be allowed in the room while active work on this project is ongoing.
<input type="checkbox"/>	All manipulations of potentially pathogenic materials will always be performed in the biosafety cabinet(s) listed.
<input type="checkbox"/>	All procedures are performed carefully to minimize the creation of aerosols, and that which is unavoidable must be performed in the biosafety cabinet, as is all work involved in the manipulation of the biohazardous material.
<input type="checkbox"/>	Biosafety cabinets will be certified annually, or visually labeled so as to prevent work in them.
<input type="checkbox"/>	No open-bench work with infected samples or materials carrying viable pathogens is allowed under any circumstances, all such work must be carried out in the biosafety cabinet.
The surface of the biological safety cabinet is cleaned with disinfectant before and after use.	
Part B: Work Practice Controls	
<input type="checkbox"/>	Employees will wash their hands with soap immediately after contact with potentially infectious materials, following the removal of protective gloves, and before exiting the lab.
<input type="checkbox"/>	The following activities are prohibited: eating; drinking; smoking; application of cosmetics; handling of contact lenses; storage or preparation of food or drink.
<input type="checkbox"/>	All supplies that come into contact with potentially infectious materials (e.g., pipettes, filter units, culture dishes) are disposed of in biohazardous waste for decontamination off-site.
<input type="checkbox"/>	Liquid waste will be decontaminated with a 1:10 dilution of bleach and poured down the drain.
<input type="checkbox"/>	Work surfaces are decontaminated at least once per day, and after any spill of viable material.
<input type="checkbox"/>	Containers for potentially infectious laboratory waste will be labeled, leak-proof, and closeable.
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<input type="checkbox"/>	When there is ongoing work in the lab, all individuals present in the lab must wear protective clothing and devices, such as safety glasses.
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<input type="checkbox"/>	Lab coats must be decontaminated before laundering or professionally cleaned.

Lab PPE SOPs

- Section 5 – Hygiene Plan
 - Part A – Engineering Controls
 - Part B – Work Practice Controls
 - Part C – Personal Protective Equipment

Section 5: Hygiene Plan	
Please review the standard operating procedures below and check/modify as appropriate for adoption by your lab.	
Part A: Engineering Controls	
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<input type="checkbox"/>	The surface of the biological safety cabinet is cleaned with disinfectant before and after use.
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<input type="checkbox"/>	Lab coats must be decontaminated before laundering or professionally cleaned.

Lab BBP SOPs

Part D: Human Materials and Bloodborne Pathogens	
<input type="checkbox"/>	We will apply the criteria recommended for biosafety level 2 (BSL-2) in terms of practices, safety equipment, and facilities, and we will adopt the concept of "universal precautions", which assumes that all blood, body fluids, tissues, secretions, and excretions from all persons are potentially infectious.
<input type="checkbox"/>	Standard practices for occupational exposure to blood or other potentially infectious materials have been defined by the University of Miami in accordance with Federal Regulations (Blood-Borne Disease Standard, 29 Code of Federal Regulations 1910.1030).
<input type="checkbox"/>	Bloodborne pathogens are pathogenic microorganisms that are present in human blood, or blood components, which can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). HBV constitutes the primary occupational infection hazard to healthcare workers, wherein approximately 18,000 cases occur annually. The risk of occupational infection with HIV is very low, although the consequences are much more severe. Other bloodborne diseases that pose sporadic but infrequent occupational infection risks include: hepatitis C, syphilis, malaria, babesiosis, brucellosis, relapsing fever, human T-lymphotropic viruses, viral hemorrhagic fever agents, and arboviruses.
<input type="checkbox"/>	Specimens will come from <i>otherwise</i> healthy patients, not known to be infected with HBV, HCV, HIV, herpes, or any other highly contagious pathogen.
Part E: Exposure, Spill, and Emergency	
<input type="checkbox"/>	In the event of an exposure, research staff will use sink/eyewash/safety shower located in room [] for 15 minutes.
<input type="checkbox"/>	Spills and accidents that result in exposure are immediately reported to the Employee Health Office, the Biosafety Office, the IBC (if material is used on a recombinant DNA project), and the PI, who will arrange for the appropriate medical evaluation and follow-up. <i>Failure to report incidents will result in suspension of protocols.</i> <ul style="list-style-type: none">EHS Office: 305-243-3267; after business hours: 305-299-4684
<input type="checkbox"/>	Employees who experience exposures to potentially infectious materials or agents must prepare an Injury/Exposure Intake Form and submit it to Employee Health.
<input type="checkbox"/>	All spills shall be immediately contained and cleaned up by appropriately trained individuals. The EHS Biosafety Office and IBC (when applicable) will be notified of the spill immediately to determine whether it can be cleaned by lab staff or if professional services are needed. <ul style="list-style-type: none">EHS Biosafety Office: 305-243-3400
<input type="checkbox"/>	In the event of a spill in the biosafety cabinet, the BSC will be left on to mitigate aerosol creation.
Part F: Special Use Standard Operating Procedures	
<input type="checkbox"/>	Recapping of needles is sometimes needed for procedures in this lab: Explain why and when it's needed and the techniques and/or engineering controls used to mitigate recapping needle-stick risks.
<input type="checkbox"/>	Use of N95 respirators are required for this lab: Explain why an N95 is necessary, when and where they're required, and the need for annual respiratory protection program enrollment.
<input type="checkbox"/>	Additional special procedures: Detail...

• Section 5 – Hygiene Plan

- Part A – Engineering Controls
- Part B – Work Practice Controls
- Part C – Personal Protective Equipment
- Part D – Human Materials (BBPs)

Lab Emergency Response SOPs

Part D: Human Materials and Bloodborne Pathogens	
<input type="checkbox"/>	We will apply the criteria recommended for biosafety level 2 (BSL-2) in terms of practices, safety equipment, and facilities, and we will adopt the concept of "universal precautions", which assumes that all blood, body fluids, tissues, secretions, and excretions from all persons are potentially infectious.
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<input type="checkbox"/>	Employees who experience exposures to potentially infectious materials or agents must prepare an Injury/Exposure Intake Form and submit it to Employee Health.
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<input type="checkbox"/>	In the event of a spill in the biosafety cabinet, the BSC will be left on to mitigate aerosol creation.
Part F: Special Use Standard Operating Procedures	
<input type="checkbox"/>	Recapping of needles is sometimes needed for procedures in this lab: Explain why and when it's needed and the techniques and/or engineering controls used to mitigate recapping needle-stick risks.
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<input type="checkbox"/>	Additional special procedures: Detail...

- Section 5 – Hygiene Plan
 - Part A – Engineering Controls
 - Part B – Work Practice Controls
 - Part C – Personal Protective Equipment
 - Part D – Human Materials (BBPs)
 - Part E – Exposure, Spill, & Emergency

Other Critical SOPs

Part D: Human Materials and Bloodborne Pathogens	
<input type="checkbox"/>	We will apply the criteria recommended for biosafety level 2 (BSL-2) in terms of practices, safety equipment, and facilities, and we will adopt the concept of "universal precautions", which assumes that all blood, body fluids, tissues, secretions, and excretions from all persons are potentially infectious.
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Part E: Exposure, Spill, and Emergency	
<input type="checkbox"/>	In the event of an exposure, research staff will use sink/eyewash/safety shower located in room <input type="text"/> for 15 minutes.
<input type="checkbox"/>	Spills and accidents that result in exposure are immediately reported to the Employee Health Office, the Biosafety Office, the IBC (if material is used on a recombinant DNA project), and the PI, who will arrange for the appropriate medical evaluation and follow-up. <i>Failure to report incidents will result in suspension of protocols.</i> <ul style="list-style-type: none">EHS Office: 305-243-3267; after business hours: 305-299-4684
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Part F: Special Use Standard Operating Procedures	
<input type="checkbox"/>	Recapping of needles is sometimes needed for procedures in this lab: Explain why and when it's needed and the techniques and/or engineering controls used to mitigate recapping needle-stick risks.
<input type="checkbox"/>	Use of N95 respirators are required for this lab: Explain why an N95 is necessary, when and where they're required, and the need for annual respiratory protection program enrollment.
<input type="checkbox"/>	Additional special procedures: Detail...

• Section 5 – Hygiene Plan

- Part A – Engineering Controls
 - Part B – Work Practice Controls
 - Part C – Personal Protective Equipment
 - Part D – Human Materials (BBPs)
 - Part E – Exposure, Spill, & Emergency
 - Part F – Special Use SOPs
- Additional boxes (if needed)

Screening & Acknowledgement

Biological Hygiene Plan

PI Last Name Lab

- This form is both a review tool to assess/develop the safety practices of the lab, as well as a biological hygiene plan outlining some of the safety standards and procedures associated with the lab for lab staff review.
- Please upload a copy into the biological registration documents section at the bottom of your Biological Registration submission.

Section 1: Administration

Principle Investigator:	PI Phone:	
PI Email:		
Lab/Safety Manager:	Manager Phone:	
Manager Email:		
Biosafety Cabinets in Use	BSC Type: N/A	Certification Date
BSC Room Location(s)	Expiration Date	

Section 2: Training Requirements for Lab

Check each box that is applicable	Required Training for Lab
<input type="checkbox"/> 1. Infectious or otherwise risk group 2 agents	Biosafety
<input type="checkbox"/> 2. Human source materials	Bloodborne Pathogens
<input type="checkbox"/> 3. Genetically modified organisms or synthetic nucleic acid molecules	Recombinant DNA
<input type="checkbox"/> 4. Biological materials/specimens shipped to another facility.	Shipping of Dangerous Goods
<ul style="list-style-type: none"> Specify designated shipper(s): 	Shipping of Biological Materials

Section 3: Hazard Communication

Type of Material Used/Stored by Lab	Specify Genus Species or Disease within Specimen
Provide an overview of the lab and how these biological materials function to serve the aims of the research.	

Section 4: Risk Assessment

What are the possible transmission/exposure routes of the materials used in the lab? (ie. Inhalation, bloodborne, etc.)

List the signs and symptoms of exposure to these materials:

Assess the exposure risks associated with the procedures employed in this lab. How are these risks mitigated?

How would exposures to these hazards be handled/treated?

What disinfectants are used for agent inactivation? If applicable, what disinfectants are used in the BSC?

If applicable, specify how materials are being transported between facilities and/or shipped to other facilities:

List the PPE requirements for researchers in this lab:

Gloves Safety Glasses Lab Coat Face Shield Disposable Gown N95 Respirator

Other(s): List...

Revision Date: 07-12-21

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Section 5: Hygiene Plan

below and check/modify as appropriate for adoption by your lab.

A: Engineering Controls

requiring a key or card access to gain entry.
The room will be limited to only that which is unavoidable.
While active work on this project is ongoing.
Materials will always be performed in the biosafety cabinet(s) listed.
Minimize the creation of aerosols, and that which is unavoidable must be minimized.
Work involved in the manipulation of the biohazardous material.
Materials must be visually labeled so as to prevent work in them.
Materials carrying viable pathogens is allowed under any circumstances only out in the biosafety cabinet.

cleaned with disinfectant before and after use.

B: Work Practice Controls

Immediately after contact with potentially infectious materials, wash hands and face before exiting the lab.
No eating, drinking, smoking; application of cosmetics; handling of contact lenses.

Do not use potentially infectious materials (e.g., pipettes, filter units, culture vessels) for decontamination off-site.

Use a 10% dilution of bleach and poured down the drain.

Wash hands once per day, and after any spill of viable material.

Sharps waste will be labeled, leak-proof, and closeable.

Do not discard other sharps directly into a labeled, puncture-proof sharps container. Make every effort made to recap by hand, destroy or remove needles.

Individuals immunocompromised should avoid working with potentially infectious materials.

Leak-proof, sealed, inner container, a leak-proof, outer container, bag, and a sturdy outer container such as a cooler. The container must be labeled up to its delivery location, the site of manipulation, in the PI's name and address. If dual for co-delivery, it will not be left in any location except at the destination.

Materials used, or materials that have a chance of having been exposed to and are not in a leak-proof, sealed, inner container and the outside surface decontaminated with bleach before the container can be removed and disposed of in a biological waste container. Any such hazards must have any openings covered and/or sealed prior to their disposal in a biohazardous bin.

Personal Protective Equipment

Individuals exposed to infectious agents, protective clothing and devices must be worn.

Individuals present in the lab must wear protective clothing and footwear.

Individuals have the potential for direct or indirect contact with blood or other body fluids during handling of closed vessels containing tissue, blood, or other fluids or blood. Gloves will also be worn during all cleaning and disinfection of biomedical waste. The lab must be thoroughly cleaned and disinfected after handling or professionally cleaned.

Revision Date: 07-12-21

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SECTION 6: SELECT AGENTS ASSESSMENT

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. Here is a list of excluded agents and toxins.

2.1 Agent or Toxin Actively Used By Or Stored In Lab (check all that apply)

HHS SELECT AGENTS AND TOXINS	OVERLAP SELECT AGENTS AND TOXINS
<input type="checkbox"/> Abrin	<input type="checkbox"/> Bacillus anthracis
<input type="checkbox"/> Bacillus cereus Biovar anthracis	<input type="checkbox"/> Bacillus anthracis Pasteur strain
<input type="checkbox"/> Botulinum neurotoxins	<input type="checkbox"/> Brucella abortus
<input type="checkbox"/> Botulinum neurotoxin producing species of Clostridium	<input type="checkbox"/> Brucella melitensis
<input type="checkbox"/> Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)	<input type="checkbox"/> Brucella suis
<input type="checkbox"/> Coxiella burnetii	<input type="checkbox"/> Burkholderia mallei
<input type="checkbox"/> Crimean-Congo haemorrhagic fever virus	<input type="checkbox"/> Burkholderia pseudomallei
<input type="checkbox"/> Diacetoxyscirpenol	<input type="checkbox"/> Hendra virus
<input type="checkbox"/> Eastern Equine Encephalitis virus	<input type="checkbox"/> Nipah virus
<input type="checkbox"/> Ebola virus	<input type="checkbox"/> Rift Valley fever virus
<input type="checkbox"/> Francisella tularensis	<input type="checkbox"/> Venezuelan equine encephalitis virus
<input type="checkbox"/> Lassa fever virus	
<input type="checkbox"/> Lujo virus	
<input type="checkbox"/> Marburg virus	
<input type="checkbox"/> Monkeypox virus	
<input type="checkbox"/> Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)	
<input type="checkbox"/> Ricin	
<input type="checkbox"/> Rickettsia prowazekii	
<input type="checkbox"/> SARS-associated coronavirus (SARS-CoV)	
<input type="checkbox"/> Saxitoxin	
<input type="checkbox"/> South American Haemorrhagic Fever virus:	
<input type="checkbox"/> Chapare	
<input type="checkbox"/> Guanarito	
<input type="checkbox"/> Junin	
<input type="checkbox"/> Machupo	
<input type="checkbox"/> Sabia	
<input type="checkbox"/> Staphylococcal enterotoxins (subtypes A, B, C, D, E)	
<input type="checkbox"/> T-2 toxin	
<input type="checkbox"/> Tetradotoxin	
<input type="checkbox"/> Tick-borne encephalitis complex (flavivirus):	
<input type="checkbox"/> Far Eastern subtype	
<input type="checkbox"/> Siberian subtype	
<input type="checkbox"/> Kyasanur Forest disease virus	
<input type="checkbox"/> Omsk hemorrhagic fever virus	
<input type="checkbox"/> Variola major virus (Smallpox virus)	
<input type="checkbox"/> Variola minor virus (Alastrim)	
<input type="checkbox"/> Yersinia pestis	

USDA SELECT AGENTS AND TOXINS

<input type="checkbox"/> African horse sickness virus
<input type="checkbox"/> African swine fever virus
<input type="checkbox"/> Avian influenza virus
<input type="checkbox"/> Classical swine fever virus
<input type="checkbox"/> Foot-and-mouth disease virus
<input type="checkbox"/> Goat pox virus
<input type="checkbox"/> Lumpy skin disease virus
<input type="checkbox"/> Mycoplasma capricolum
<input type="checkbox"/> Mycoplasma mycoides
<input type="checkbox"/> Newcastle disease virus
<input type="checkbox"/> Peste des petits ruminants virus
<input type="checkbox"/> Rinderpest virus
<input type="checkbox"/> Sheep pox virus
<input type="checkbox"/> Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

<input type="checkbox"/> Coniothyrium glycinis (formerly Phoma glycinicola and Pyrenochaeta glycinis)
<input type="checkbox"/> Peronosclerospora philippinensis (Peronosclerospora sacchari)
<input type="checkbox"/> Ralstonia solanacearum
<input type="checkbox"/> Rathayibacter toxicus
<input type="checkbox"/> Sclerophthora rayssiae
<input type="checkbox"/> Synchytrium endobioticum
<input type="checkbox"/> Xanthomonas oryzae

NONE

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ASSESSMENT

Purposes can be utilized for both human and animal health, to plant health, or to animal and plant products.

Research that, based on current products, or technologies that could be used to protect public health and safety, agricultural and forest resources.

On September 24, 2014, the US Department of Agriculture released the [USDA Select Agent Concern](#) to establish the Select Agent Regulations. The US Government considers these two categories of agents to be Select Agents.

Projects at the University of Miami, including those involving Select Agents and toxins and categories of experiments deemed potential DURC.

Listed agents:

Enza virus

Clostridium botulinum

Agents that can be reasonably anticipated to be used in the lab.

Agents that can be reasonably anticipated to be used in the lab.

Agents that can be reasonably anticipated to be used in the lab.

Agents that can be reasonably anticipated to be used in the lab.

Agents that can be reasonably anticipated to be used in the lab.

Agents that can be reasonably anticipated to be used in the lab.

Page 5 | 5

Screening: Select Agents

SECTION 6: SELECT AGENTS ASSESSMENT

- The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. Here is a list of [excluded agents and toxins](#).

2.1 Agent or Toxin Actively Used By Or Stored In Lab (check all that apply)

HHS SELECT AGENTS AND TOXINS	OVERLAP SELECT AGENTS AND TOXINS	USDA SELECT AGENTS AND TOXINS	USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS
<input type="checkbox"/> Abrin	<input type="checkbox"/> Bacillus anthracis	<input type="checkbox"/> African horse sickness virus	<input type="checkbox"/> Coniothyrium glycinis (formerly Phoma glycinicola and Pyrenochaeta glycinis)
<input type="checkbox"/> Bacillus cereus Biovar anthracis	<input type="checkbox"/> Bacillus anthracis Pasteur strain	<input type="checkbox"/> African swine fever virus	<input type="checkbox"/> Peronosclerospora philippinensis (Peronosclerospora sacchari)
<input type="checkbox"/> Botulinum neurotoxins	<input type="checkbox"/> Brucella abortus	<input type="checkbox"/> Avian influenza virus	<input type="checkbox"/> Ralstonia solanacearum
<input type="checkbox"/> Botulinum neurotoxin producing species of Clostridium	<input type="checkbox"/> Brucella melitensis	<input type="checkbox"/> Classical swine fever virus	<input type="checkbox"/> Rathayibacter toxicus
<input type="checkbox"/> Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)	<input type="checkbox"/> Brucella suis	<input type="checkbox"/> Foot-and-mouth disease virus	<input type="checkbox"/> Sclerophthora rayssiae
<input type="checkbox"/> Coxiella burnetii	<input type="checkbox"/> Burkholderia mallei	<input type="checkbox"/> Goat pox virus	<input type="checkbox"/> Synchytrium endobioticum
<input type="checkbox"/> Crimean-Congo haemorrhagic fever virus	<input type="checkbox"/> Burkholderia pseudomallei	<input type="checkbox"/> Lumpy skin disease virus	<input type="checkbox"/> Xanthomonas oryzae
<input type="checkbox"/> Diacetoxyscirpenol	<input type="checkbox"/> Hendra virus	<input type="checkbox"/> Mycoplasma capricolum	
<input type="checkbox"/> Eastern Equine Encephalitis virus	<input type="checkbox"/> Nipah virus	<input type="checkbox"/> Mycoplasma mycoides	
<input type="checkbox"/> Ebola virus	<input type="checkbox"/> Rift Valley fever virus	<input type="checkbox"/> Newcastle disease virus	
<input type="checkbox"/> Francisella tularensis	<input type="checkbox"/> Venezuelan equine encephalitis virus	<input type="checkbox"/> Peste des petits ruminants virus	
<input type="checkbox"/> Lassa fever virus		<input type="checkbox"/> Rinderpest virus	
<input type="checkbox"/> Lujo virus		<input type="checkbox"/> Sheep pox virus	
<input type="checkbox"/> Marburg virus		<input type="checkbox"/> Swine vesicular disease virus	
<input type="checkbox"/> Monkeypox virus			
<input type="checkbox"/> Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)			
<input type="checkbox"/> Ricin			
<input type="checkbox"/> Rickettsia prowazekii			
<input type="checkbox"/> SARS-associated coronavirus (SARS-CoV)			
<input type="checkbox"/> Saxitoxin			
<input type="checkbox"/> South American Haemorrhagic Fever viruses:			
<input type="checkbox"/> Chapare			
<input type="checkbox"/> Guanarito			
<input type="checkbox"/> Junin			
<input type="checkbox"/> Machupo			
<input type="checkbox"/> Sabia			
<input type="checkbox"/> Staphylococcal enterotoxins (subtypes A,B,C,D,E)			
<input type="checkbox"/> T-2 toxin			
<input type="checkbox"/> Tetrodotoxin			
<input type="checkbox"/> Tick-borne encephalitis complex (flavi) viruses:			
<input type="checkbox"/> Far Eastern subtype			
<input type="checkbox"/> Siberian subtype			
<input type="checkbox"/> Kyasanur Forest disease virus			
<input type="checkbox"/> Omsk hemorrhagic fever virus			
<input type="checkbox"/> Variola major virus (Smallpox virus)			
<input type="checkbox"/> Variola minor virus (Alastrim)			
<input type="checkbox"/> Yersinia pestis			

NONE

- Section 1 – Administration
- Section 2 – Training Requirements
- Section 3 – Hazard Communication
- Section 4 – Risk Assessment
- Section 5 – Hygiene Plan
- Section 6 – Select Agents Assessment

Screening: Dual Use Research

SECTION 7: DUAL USE RESEARCH OF CONCERN (DURC) ASSESSMENT

- Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called Dual Use Research (DUR).
- Dual Use Research of Concern (DURC) is a subset of DUR and is defined as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”
- On March 29, 2012, the US Government released the [US Government Policy for Oversight of Life Sciences Dual Use Research of Concern](#) to establish the requirements for the oversight of DURC by the US Government. On September 24, 2014, the [US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#) was released to establish the requirements for institutional (i.e., non-US Government) oversight of DURC. The US Government considers these two policies to be complementary.
- These definitions could potentially encompass a number of life sciences research projects at the University of Miami, however, the current scope of the policy has been limited to the following agents and toxins and categories of experiments. Research must involve both a listed agent/toxin and category of experiment to be deemed potential DURC.

1.1 Agent or Toxin Actively Used By Or Stored In Lab (check all that apply)

Verify if this project directly involves non-attenuated forms of 1 or more of the 15 listed agents.

- | | |
|--|--|
| <input type="checkbox"/> Avian Influenza (highly pathogenic) | <input type="checkbox"/> Marburg virus |
| <input type="checkbox"/> Bacillus anthracis | <input type="checkbox"/> Reconstructed 1918 influenza virus |
| <input type="checkbox"/> Botulinum neurotoxin (any quantity) | <input type="checkbox"/> Rinderpest virus |
| <input type="checkbox"/> Burkholderia mallei | <input type="checkbox"/> Toxin producing strains of <i>Clostridium botulinum</i> |
| <input type="checkbox"/> Burkholderia pseudomallei | <input type="checkbox"/> Variola major virus |
| <input type="checkbox"/> Ebola virus | <input type="checkbox"/> Variola minor virus |
| <input type="checkbox"/> Foot-and-mouth disease virus | <input type="checkbox"/> <i>Yersinia pestis</i> |
| <input type="checkbox"/> Francisella tularensis | <input type="checkbox"/> NONE |

2.2 Experimental Effects (check all that apply)

Indicate whether the research project indicated above produces, aims or can be reasonably anticipated to produce any of the following experimental effects.

- Enhances the harmful consequences of the agent or toxin.
- Disrupts the immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.
- Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against the agent or toxin or facilitates its ability to evade detection methodologies.
- Alters properties of the agent or toxin in a manner that would enhance its ability to be disseminated.
- Alters the host range or tropism of the agent or toxin.
- Enhances the susceptibility of a host population to the agent or toxin.
- Generates or reconstitutes an eradicated or extinct agent or toxin listed in Question 6.2 of this form.
- NONE

If you checked any of the above experimental effects, please explain:

Section 8: Acknowledgement and E-Signature

I have read and am familiar with the standard and special microbiological practices, containment equipment, personal protective equipment, and laboratory facilities recommended for the biosafety level applicable to this project. I will ensure that all faculty, staff, and students working on this project will review this document and will follow these recommendations as a condition of approval of this project.

Type Your Full Name Date Completed

- Section 1 – Administration
- Section 2 – Training Requirements
- Section 3 – Hazard Communication
- Section 4 – Risk Assessment
- Section 5 – Hygiene Plan
- Section 6 – Select Agents Assessment
- Section 7 – DURC Assessment

Confirm Lab Policy

SECTION 7: DUAL USE RESEARCH OF CONCERN (DURC) ASSESSMENT

- Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called Dual Use Research (DUR).
- Dual Use Research of Concern (DURC) is a subset of DUR and is defined as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”
- On March 29, 2012, the US Government released the [US Government Policy for Oversight of Life Sciences Dual Use Research of Concern](#) to establish the requirements for the oversight of DURC by the US Government. On September 24, 2014, the [US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#) was released to establish the requirements for institutional (i.e., non-US Government) oversight of DURC. The US Government considers these two policies to be complementary.
- These definitions could potentially encompass a number of life sciences research projects at the University of Miami, however, the current scope of the policy has been limited to the following agents and toxins and categories of experiments. Research must involve both a listed agent/toxin and category of experiment to be deemed potential DURC.

1.1 **Agent or Toxin Actively Used By Or Stored In Lab (check all that apply)**
Verify if this project directly involves non-attenuated forms of 1 or more of the 15 listed agents.

<input type="checkbox"/> Avian Influenza (highly pathogenic)	<input type="checkbox"/> Marburg virus
<input type="checkbox"/> Bacillus anthracis	<input type="checkbox"/> Reconstructed 1918 influenza virus
<input type="checkbox"/> Botulinum neurotoxin (any quantity)	<input type="checkbox"/> Rinderpest virus
<input type="checkbox"/> Burkholderia mallei	<input type="checkbox"/> Toxin producing strains of <i>Clostridium botulinum</i>
<input type="checkbox"/> Burkholderia pseudomallei	<input type="checkbox"/> Variola major virus
<input type="checkbox"/> Ebola virus	<input type="checkbox"/> Variola minor virus
<input type="checkbox"/> Foot-and-mouth disease virus	<input type="checkbox"/> <i>Yersinia pestis</i>
<input type="checkbox"/> Francisella tularensis	<input type="checkbox"/> NONE

2.2 **Experimental Effects (check all that apply)**
Indicate whether the research project indicated above produces, aims or can be reasonably anticipated to produce any of the following experimental effects.

- Enhances the harmful consequences of the agent or toxin.
- Disrupts the immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.
- Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against the agent or toxin or facilitates its ability to evade detection methodologies.
- Alters properties of the agent or toxin in a manner that would enhance its ability to be disseminated.
- Alters the host range or tropism of the agent or toxin.
- Enhances the susceptibility of a host population to the agent or toxin.
- Generates or reconstitutes an eradicated or extinct agent or toxin listed in Question 6.2 of this form.
- NONE

If you checked any of the above experimental effects, please explain:

Section 8: Acknowledgement and E-Signature

I have read and am familiar with the standard and special microbiological practices, containment equipment, personal protective equipment, and laboratory facilities recommended for the biosafety level applicable to this project. I will ensure that all faculty, staff, and students working on this project will review this document and will follow these recommendations as a condition of approval of this project.

Type Your Full Name Date Completed

- Section 1 – Administration
- Section 2 – Training Requirements
- Section 3 – Hazard Communication
- Section 4 – Risk Assessment
- Section 5 – Hygiene Plan
- Section 6 – Select Agents Assessment
- Section 7 – DURC Assessment
- Section 8 – Acknowledgement / Sign

The Small Fine Print

Biological Hygiene Plan

PI Last Name Lab

- This form is both a review tool to assess/develop the safety practices of the lab, as well as a biological hygiene plan outlining some of the safety standards and procedures associated with the lab for lab staff review.
- Please upload a copy into the biological registration documents section at the bottom of your Biological Registration submission.

Section 1: Administration			
Principle Investigator:		PI Phone:	
PI Email:			
Lab/Safety Manager:		Manager Phone:	
Manager Email:			
Biosafety Cabinets in Use	<input type="checkbox"/>	BSC Type: N/A	Certification Date
BSC Room Location(s)		Expiration Date	

Section 2: Training Requirements for Lab	
Check each box that is applicable	Required Training for Lab
<input type="checkbox"/> 1. Infectious or otherwise risk group 2 agents	Biosafety
<input type="checkbox"/> 2. Human source materials	Bloodborne Pathogens
<input type="checkbox"/> 3. Genetically modified organisms or synthetic nucleic acid molecules	Recombinant DNA
<input type="checkbox"/> 4. Biological materials/specimens shipped to another facility. • Specify designated shipper(s):	Shipping of Dangerous Goods Shipping of Biological Materials

Section 3: Hazard Communication	
Type of Material Used/Stored by Lab	Specify Genus Species or Disease within Specimen
Provide an overview of the lab and how these biological materials function to serve the aims of the research.	

Section 4: Risk Assessment
What are the possible transmission/exposure routes of the materials used in the lab? (ie. Inhalation, bloodborne, etc.)
List the signs and symptoms of exposure to these materials:
Assess the exposure risks associated with the procedures employed in this lab. How are these risks mitigated?
How would exposures to these hazards be handled/treated?
What disinfectants are used for agent inactivation? If applicable, what disinfectants are used in the BSC?
If applicable, specify how materials are being transported between facilities and/or shipped to other facilities:
List the PPE requirements for researchers in this lab:
<input checked="" type="checkbox"/> Gloves <input checked="" type="checkbox"/> Safety Glasses <input checked="" type="checkbox"/> Lab Coat <input type="checkbox"/> Face Shield <input type="checkbox"/> Disposable Gown <input type="checkbox"/> N95 Respirator
Other(s): List...

Revision Date: 07-12-21

Page 1 | 5

- Revision Date: 07-12-2021
- Updates coming this summer
- Feedback/suggestions welcome

Parking Completed Forms

- Submit *Biological Hygiene Plan* under the *Biological Registration* on BioRAFT (SciShield)
 - Or send to biosafety@miami.edu

- Biological Registrations
 - Required for all labs working with bios
 - Ie, BHP req'd for all bio labs
 - Provides overview of lab work
 - rDNA must go to IBC for review

- Umbrella vs Protocol/Agent Specific

The screenshot displays the BioRAFT (SciShield) web interface. At the top, there are navigation tabs: View, Edit, Dashboard, Members, and Bio. Below this, there are links for Biological Summary, Projects, Cell Lines, Tissues, Plants, Microbes, Biological Toxins, and rDNA. The main content area is titled "IBC Support Testing Lab Biologicals" and contains a warning message: "There are changes to the biological usage summary that have not been certified. Please notify the PI when all changes are ready to be submitted for review. View changes since 09/24/2020". Below this, there is a link to view all changes to the biological usage summary since last approval.

A pop-up window titled "Biological Registration Documents" is overlaid on the page. It contains a table with the following columns: File Name, File Type, Description, Date uploaded, and Submitted By. Below the table, it states: "There are currently no files attached to this Laboratory --" and "These files are uploaded materials. For accessibility concerns, please contact EHS". There is a button labeled "Attach a New Document".

Below the pop-up, the main interface shows the "Assigned Biosafety Level: Review Frequency: 3 Years" and "Dual Use Research of Concern: No Ships Biomaterials: Yes". A table shows the number of items for various categories:

	Number
Projects	3
Viral Vector Forms	2
Pathogen Forms	1
Cell Lines	1
Tissues	1
Plants	0
Microbes	0
Biological Toxins	0
rDNA	4

Below the table, there is a link to "View or Update Biological Usage Summary". To the right, there is a list of materials: Non-Human Primate Source Materials, Non-Human Primates, Non-Primate Materials (Amphibians, Arthropods, Bloodborne Pathogens, Fish, Lab Animal Cell Lines (Non-Primate), Lab Animal Source Materials (Non-Primate), Lab Animal Tissues (Non-Primate), Lab Animals (Non-Primate), Non-Pathogenic Microorganisms, Pathogenic Microorganisms, Plants), and Other Biological Source Materials (Biological Toxins, Infectious Proteins, Mutagenic Agents, Recombinant or Synthetic Nucleotides, Select Agent Biological Toxins, Viral Vectors).

At the bottom, there is a "Registration Summary" section with a dropdown menu for "Submission: Current" and a link to "Amended Awaiting Review (change status)". It lists registration dates: Registration Started: 09/10/2020, PI Last Certified: 09/24/2020, Registration Approved: 09/22/2020, Research Last Confirmed: 09/24/2020, Next Review Date: 09/15/2023. There is a link to "Download PDF | View". Below this is a link to "View Registration History and Download PDFs".

On the right, there is a "Submission Requests" section with links for "Request Clarification/Modification", "Submission Request/Reminder", "Delegate to a Lab Member", and "Request PI Certification". It also shows "Last Request Sent: 09/22/2020" and a link to "View All Past Requests".



Yeah... But **why** the
Biological Hygiene Plan?

Let's Recap – What's Captured

- Section 1 – Lab Admin & Emergency Contacts
- Section 2 – Training Required of Lab Staff
- Section 3 – Agent Specific Hazard Communication
- Section 4 – Agent Specific Risk Assessment
- Section 5 – Lab Specific Hygiene Plan
- Sections 6 & 7 – Highly Regulated Materials Screening
- Section 8 – Acknowledgement & Sign

Why We Should Do It

1. Ensures we know who the emergency contacts are and how to get ahold of them 24/7
2. Ensures all lab personnel know what training is req'd of them
3. Serves as agent specific training to lab personnel
4. Ensures lab personnel understand the risks in the lab and how to mitigate them
5. Meets universal standard for hygiene plans
6. Screens for materials that could require additional oversight and be a risk to the University
7. Confirms lab understands and has planned accordingly for hazardous work
8. Gives EHS Biosafety quick opportunity to provide safety guidance
9. Best practice, always prepared for regulatory inspections

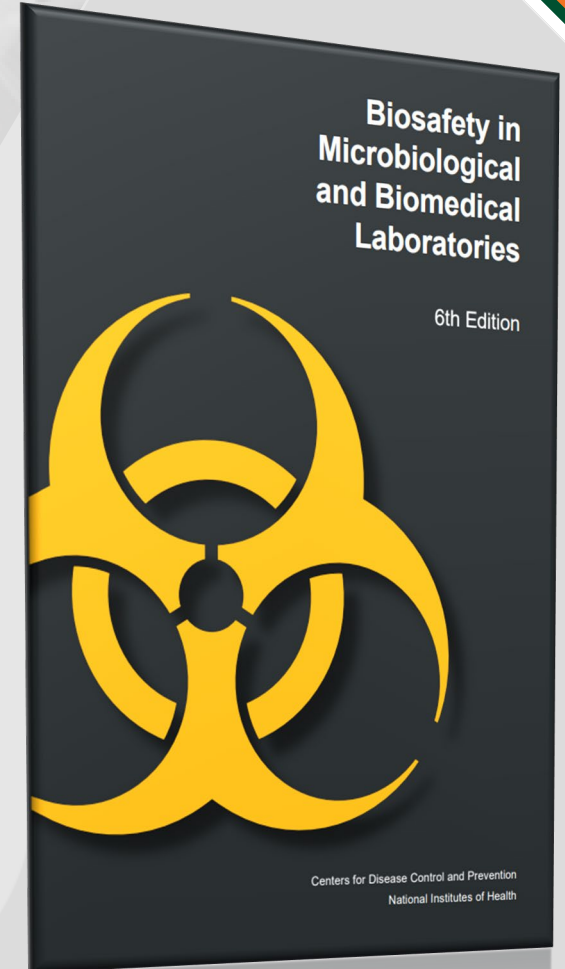
Yeah But Hit Me With a Citation

- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
 - For BSL-1 – BSL-4

A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated, as necessary.

- a. The safety manual contains sufficient information to describe the biosafety and containment procedures for the organisms and biological materials in use, appropriate agent-specific decontamination methods, and the work performed.
- b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.

- <https://www.cdc.gov/labs/bmbbl/index.html>





Wrap Up

Biosafety Website

Biological Safety

Biological Safety

Default Folder

Biohazardous Emergencies

Training

Biological Protocol Review

Shipping of Dangerous Goods

Laboratory Inspections

Equipment

Frequently Asked Questions

Resources

Training

Fire Safety

Hazardous Materials

Industrial Hygiene and Air Quality

Laboratory Safety

Laser Safety

Safety Data Sheets

Radiation Control

Biological Safety

Default Folder

Biohazardous Emergencies

General Office Contact

biosafety@miami.edu

305-243-3269

Biosafety Manager

[Shane Gillcoy](#)

786-797-0387

Biosafety Specialist

[Melanie Peepell](#)

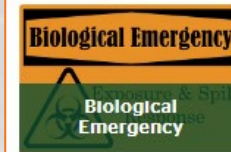
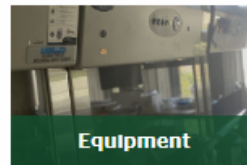
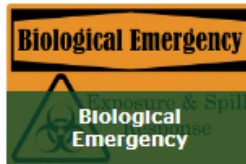
305-389-9931

Biosafety Specialist

[Daniel Nunez](#)

305-901-6327

We offer a variety of services to our campus researchers and clinicians as outlined in the links below. Please reach out to us if there is anything further we can do for your lab!



ehs.miami.edu/biosafety

Bio Hygiene Plan Form Online

The screenshot shows the website header for the University of Miami's Environmental Health and Safety department. The navigation menu includes Services, Resources, Contact Us, and About Us. The main content area is titled 'Resources' and features a left-hand sidebar with categories like Default Folder, Biohazardous Emergencies, Training, Biological Protocol Review, Shipping of Dangerous Goods, Laboratory Inspections, Equipment, Frequently Asked Questions, Resources, and Training. The main content is divided into three sections: 'Manuals & Guidance' with links to Biosafety Manual, Lab Safety Manual, Hurricane Lab Preparation Checklist, Employee Workday Injury/Illness Reporting Instructions, Spill Clean-Up Procedure SOPs, and BioRAFT Biological Registration Guidance; 'Documents & Templates' with links to Biological Hygiene Plan, Biological Ancillary Review Assessment (BARA) Form, Lab Inspection Checklist, Exposure Injury Intake Form, Researcher Incident Report Form, Chemical Inventory Template, and Nature of Shipment Document; and 'Postings' with links to Laboratory Emergency Procedures & SOPs, BSL-2 Biohazard Door Sign, Lab Safety Information & Emergency Contact Card, Stop Wash Call Poster, No Gloves on Doors Signs, Biological Spill Response, Biosafety Cabinets Tips & Spills, Sharps Safety, Gloves Dos and Donts, and Lab Waste Disposal Guide. An 'Additional Resources' section at the bottom lists a Biosafety Month 2023 Presentation. An orange arrow points from the 'Biological Hygiene Plan' link in the 'Documents & Templates' section to the right.

Biological Hygiene Plan

October is Biosafety Month

ABSA
INTERNATIONAL
OCTOBER 2020
Biosafety Month

*Promoting a Culture of
Biosafety & Responsibility*

6 Easy Ways to Promote Safety Culture at the University of Miami

1

Adhere to
Pandemic
Guidelines
in the Lab

Report
Exposures,
Injuries &
Near Misses

2

3

Review
Biosafety
Protocols
& SOPs

Post New
Biosafety
Signage

4

5

Take
Biosafety
Training

Get to
Know Your
Biosafety
Team!

6

ehs.miami.edu

- Biosafety Focus All Month
- Lunch & Learns
- Free Food
- Prizes
- Lab of the Year Awards

Questions

- Shane Gillooly
 - 786-797-0387
 - sxg1519@med.miami.edu
- Contact the Biosafety Office:
 - 305-243-3269
 - biosafety@miami.edu
- Website
 - <http://ehs.miami.edu>

