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

University of Miami

Environmental Health & Safety

Biosafety

Biosafety Office

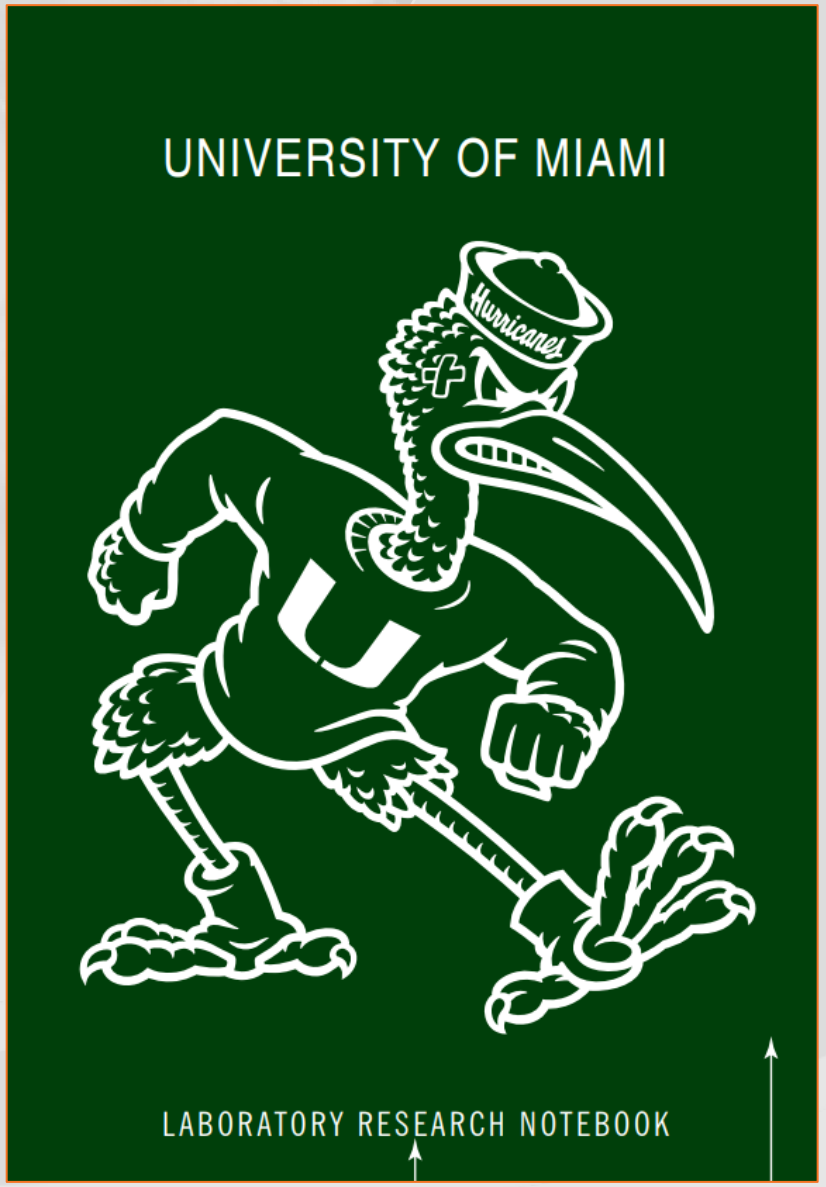
- Shane Gillooly
  - Biosafety Officer

- Melanie Peapell
  - Biosafety Specialist
  - Laser Safety Officer

- Daniel Nunez
  - Biosafety Specialist

Prize Winner

- Branded Laboratory Research Notebook
  - Hardcover
  - Sebastian
  - 232 pages
- Brought to you by:
  - Office of Environmental Health & Safety
  - Office of the Vice Provost for Research & Scholarship
- Yesterday's Winner:
  - Joshi Mahesh



What is the Biological Hygiene Plan?

Biological Hygiene Plan

Biological Hygiene Plan

PI Last Name Lab

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- *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
☐ 1. Infectious or otherwise risk group 2 agents	Biosafety
☐ 2. Human source materials	Bloodborne Pathogens
☐ 3. Genetically modified organisms or synthetic nucleic acid molecules	Recombinant DNA
☐ 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.	

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ion 5: Hygiene Plan
below and check/modify as appropriate for adoption by your lab.
t A: Engineering Controls
requiring a key or card access to gain entry.
e room will be limited to only that which is unavoidable.
n while active work on this project is ongoing.
aterials will always be performed in the biosafety cabinet(s) listed.
imize the creation of aerosols, and that which is unavoidable must
l work involved in the manipulation of the biohazardous material.
r visually labeled so as to prevent work in them.
r materials carrying viable pathogens is allowed under any
out in the biosafety cabinet.
cleaned with disinfectant before and after use.
B: Work Practice Controls
mediately after contact with potentially infectious materials,
d before exiting the lab.
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any such hazards must have any openings covered and/or sealed
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odborne Pathogens
SL-2) in terms of practices, safety equipment, and
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potentially infectious materials have been
Regulations (Blood-Borne Disease Standard, 29
present in human blood, or blood components,
but are not limited to, hepatitis B virus (HBV) and
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The risk of occupational infection with HIV is very
bloodborne diseases that pose sporadic but
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9-4684
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N95 is necessary, when and where they're
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CT AGENTS ASSESSMENT
ermined to have the potential to pose a severe threat to both
nd plant products. An attenuated strain of a select agent or an
requirements of the Select Agent Regulations. Here is a list of
eck all 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
DA 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
DA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS D TOXINS
Coniothyrium glycines (formerly Phoma glycinicola and enochaeta glycines)
Peronosclerospora philippinensis
ronosclerospora sacchari)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae
NONE

ASSESSMENT
urposes can be utilized for both
).
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products, or technologies that could be
to public health and safety, agricultural
versight of Life Sciences Dual Use Research
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projects at the University of Miami,
and toxins and categories of experiments.
deemed potential DURC.
15 listed agents.
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f Clostridium botulinum
r can be reasonably anticipated to
nst the agent or toxin without clinical
useful prophylactic or therapeutic
de detection methodologies.
nce its ability to be disseminated.
n.
sted in Question 6.2 of this form.
ture
tices, containment equipment, personal
level applicable to this project. I will
his document and will follow these

Haz Com & Risk Assessment

Biological Hygiene Plan

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Brucella melitensis
Brucella suis
Burkholderia mallei
Burkholderia pseudomallei
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus

DA 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

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Coniothyrium glycines (formerly Phoma glycinicola and enochaeta glycines)
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ronosclerospora sacchari)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

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ASSESSMENT

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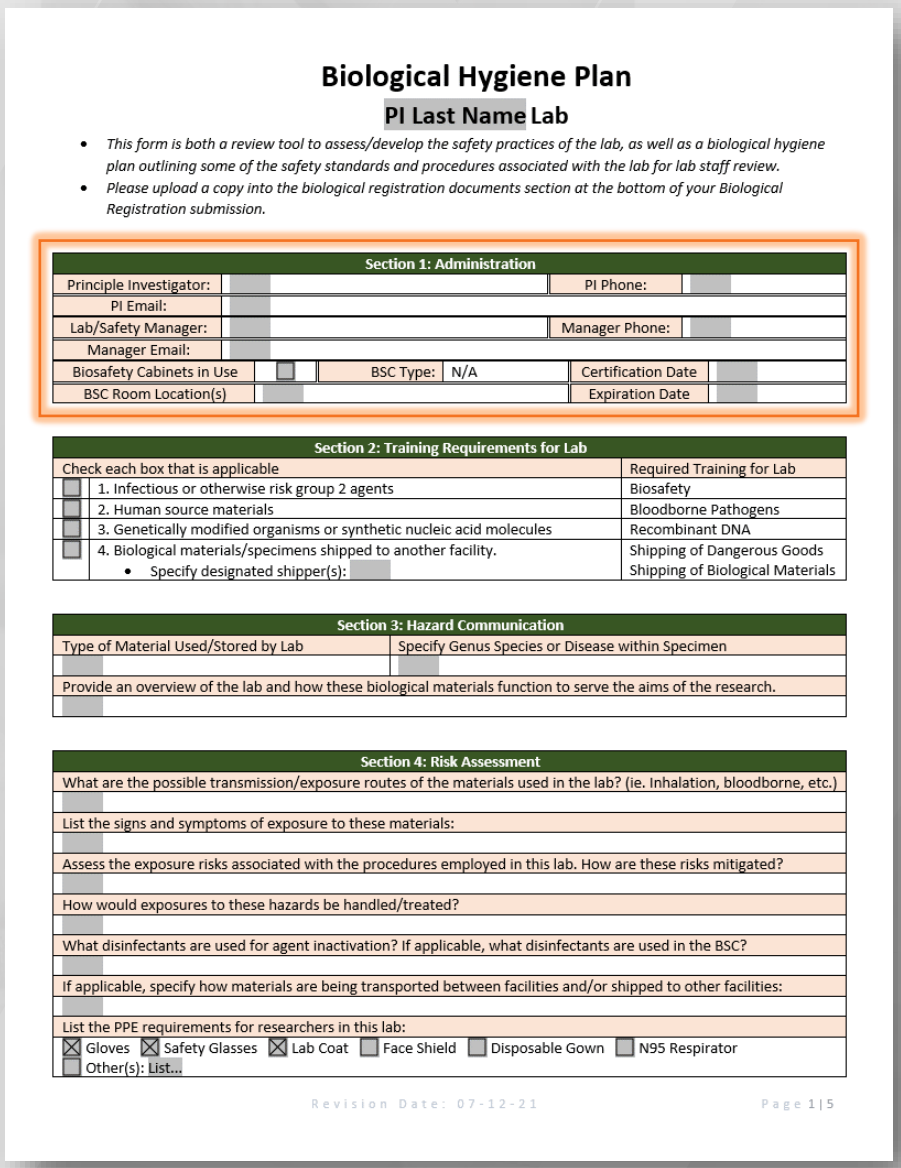

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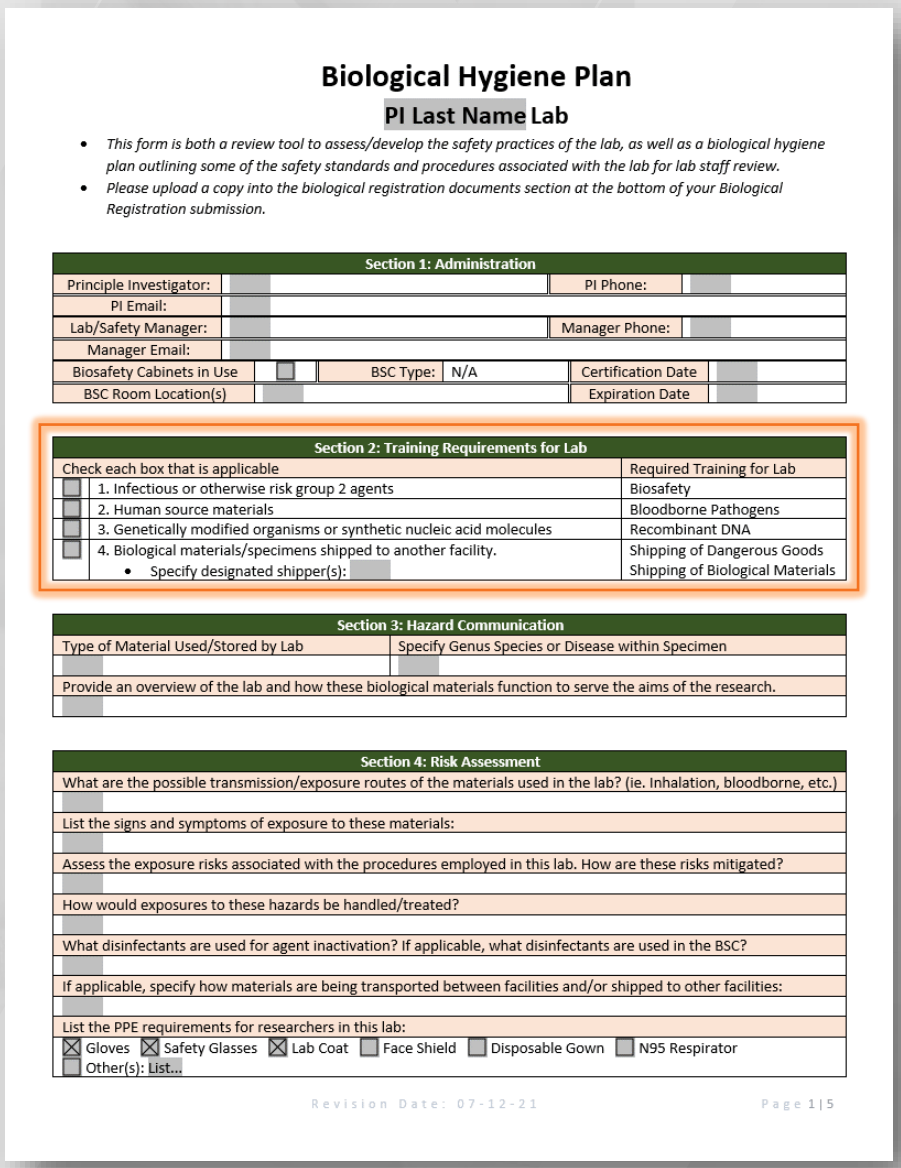
- Section 1 – Administration

Training Required for Lab



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Revision Date: 07-12-21 Page 1|5

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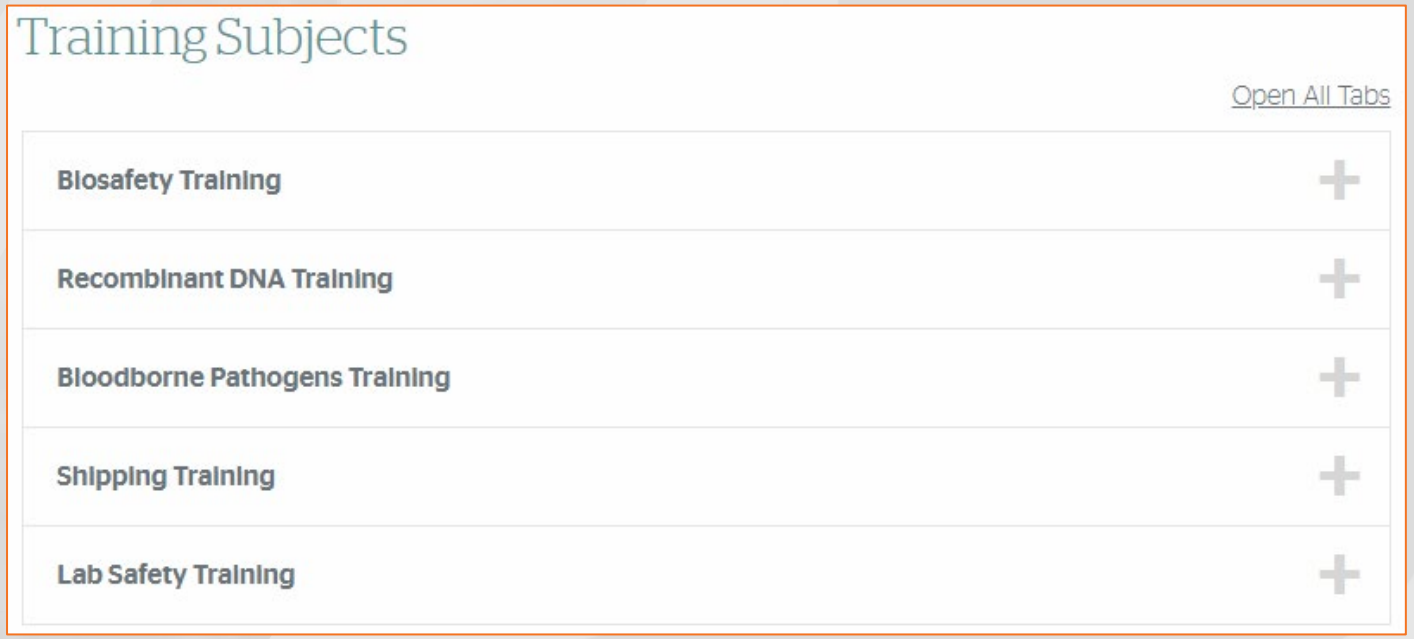
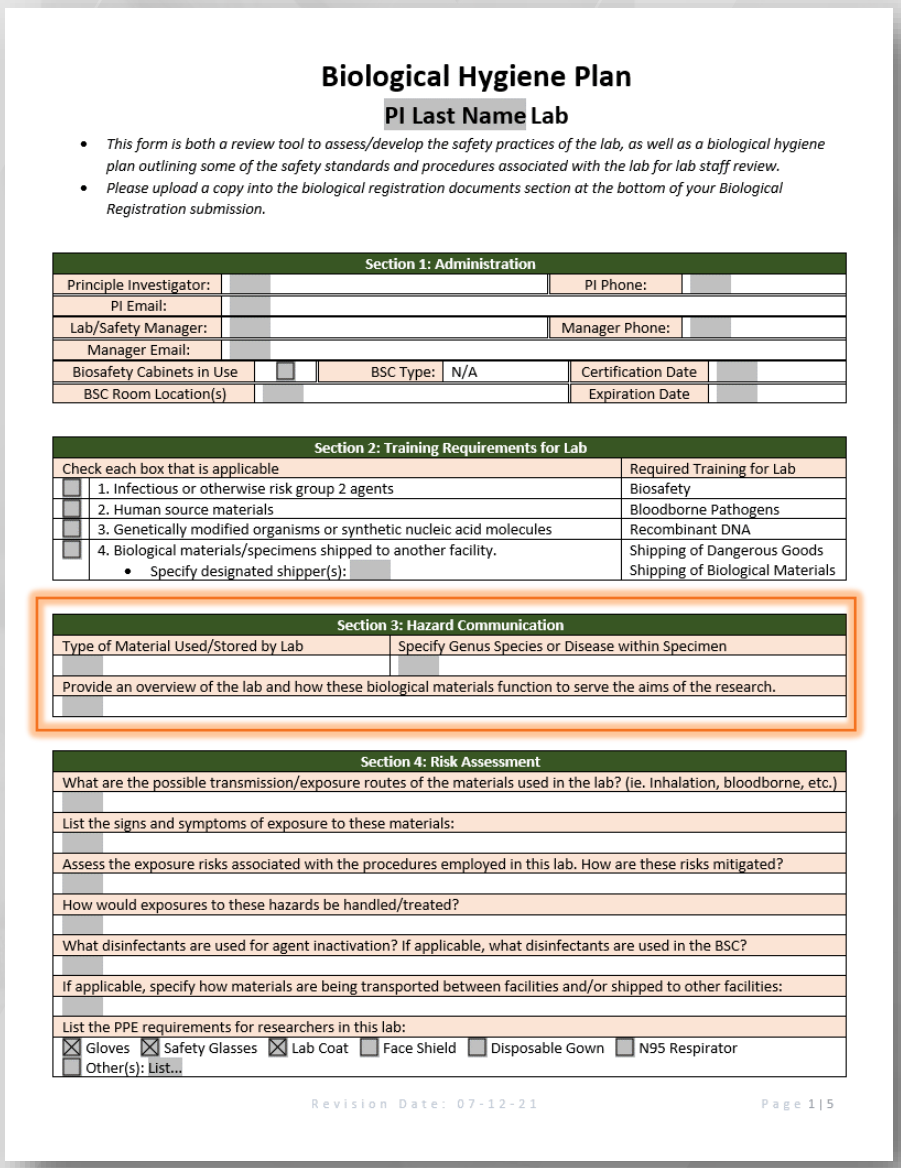


Training Subjects

Open All Tabs

- Biosafety Training
- Recombinant DNA Training
- Bloodborne Pathogens Training
- Shipping Training
- Lab Safety Training

Biohazardous Agents Used



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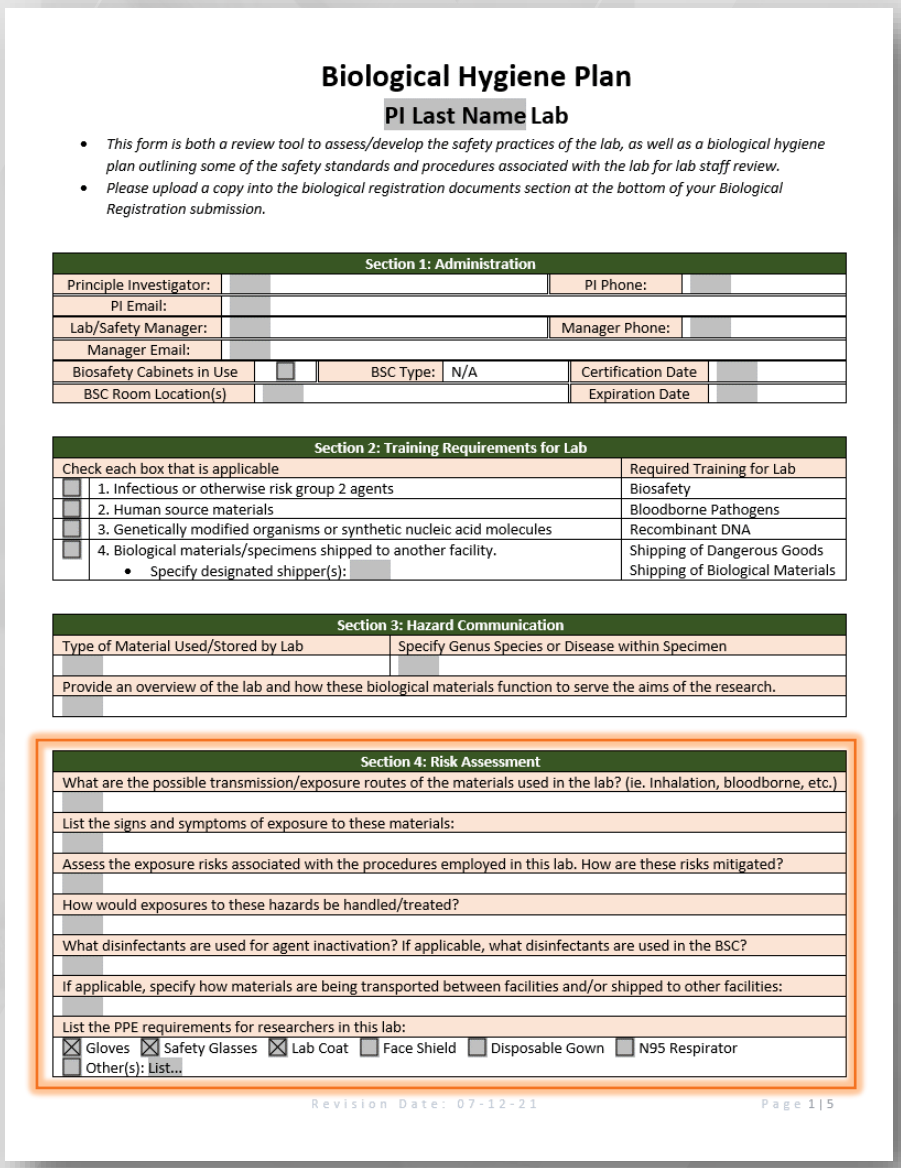

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Section 5: Hygiene Plan	
Please review the standard operating procedures below and check/modify as appropriate for adoption by your lab.	
	Part A: Engineering Controls
☐	Access to this laboratory is always restricted, requiring a key or card access to gain entry.
☐	When manipulating specimens, traffic into the room will be limited to only that which is unavoidable.
☐	No other research may be allowed in the room while active work on this project is ongoing.
☐	All manipulations of potentially pathogenic materials will always be performed in the biosafety cabinet(s) listed.
☐	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.
☐	Biosafety cabinets will be certified annually, or visually labeled so as to prevent work in them.
☐	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
☐	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.
☐	The following activities are prohibited: eating; drinking; smoking; application of cosmetics; handling of contact lenses; storage or preparation of food or drink.
☐	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.
☐	Liquid waste will be decontaminated with a 1:10 dilution of bleach and poured down the drain.
☐	Work surfaces are decontaminated at least once per day, and after any spill of viable material.
☐	Containers for potentially infectious laboratory waste will be labeled, leak-proof, and closeable.
☐	Long hair must be pulled back and contained.
☐	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.
☐	Employees with increased risk (broken skin, immunocompromised) should avoid working with potentially infectious materials.
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	Part C: Personal Protective Equipment
☐	When there is a potential for occupational exposure to infectious agents, protective clothing and devices must be used.
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odborne Pathogens

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gents, and arboviruses.
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f Emergency

n/safety shower located in room ____ for 15

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NA project), and the PI, who will arrange for the
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9-4684

naterials or agents must prepare an

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erating Procedures

is lab: Explain why and when it's needed and the
ing needle-stick risks.
N95 is necessary, when and where they're
m enrollment.

T AGENTS ASSESSMENT

ermined to have the potential to pose a severe threat to both
nd plant products. An attenuated strain of a select agent or an
requirements of the Select Agent Regulations. Here is a list of

eck all 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

DA 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

DA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS D TOXINS
Coniothyrium glycines (formerly Phoma glycinicola and enochaeta glycines)
Peronosclerospora philippinensis
ronosclerospora sacchari)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

NONE

ASSESSMENT

urposes can be utilized for both
).

ences research that, based on current
products, or technologies that could be
to public health and safety, agricultural

versight of Life Sciences Dual Use Research
ernment. On September 24, 2014, the US
f Concern was released to establish the
S Government considers these two

projects at the University of Miami,
and toxins and categories of experiments.
deemed potential DURC.

15 listed agents.

enza virus

f Clostridium botulinum

r can be reasonably anticipated to

nst the agent or toxin without clinical

useful prophylactic or therapeutic
de detection methodologies.
nce its ability to be disseminated.

n.
sted in Question 6.2 of this form.

ture

tices, containment equipment, personal
level applicable to this project. I will
his document and will follow these

Lab Specific Safety SOPs

Section 5: Hygiene Plan	
Please review the standard operating procedures below and check/modify as appropriate for adoption by your lab.	
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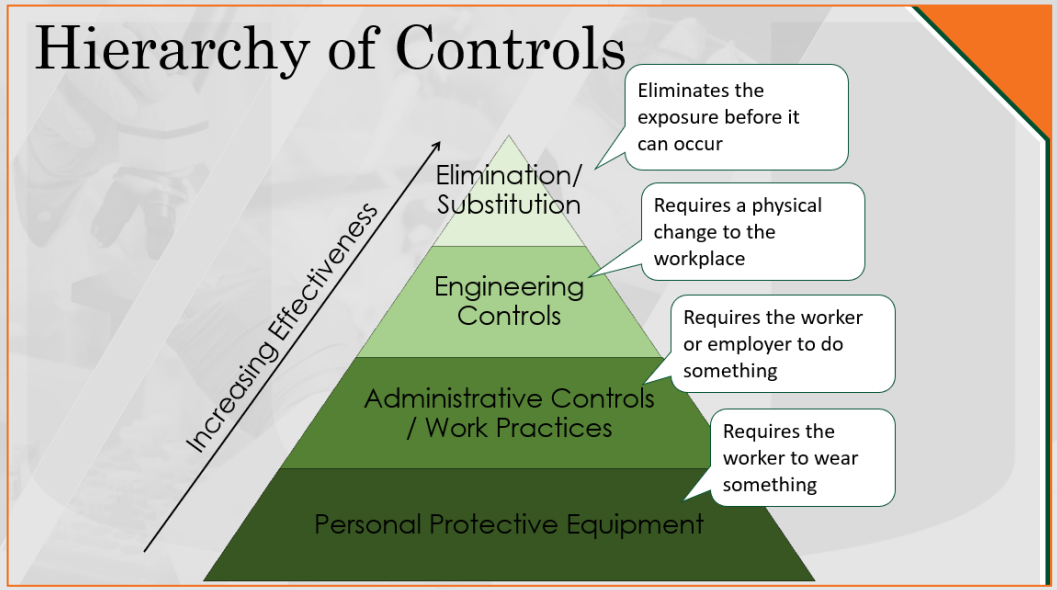
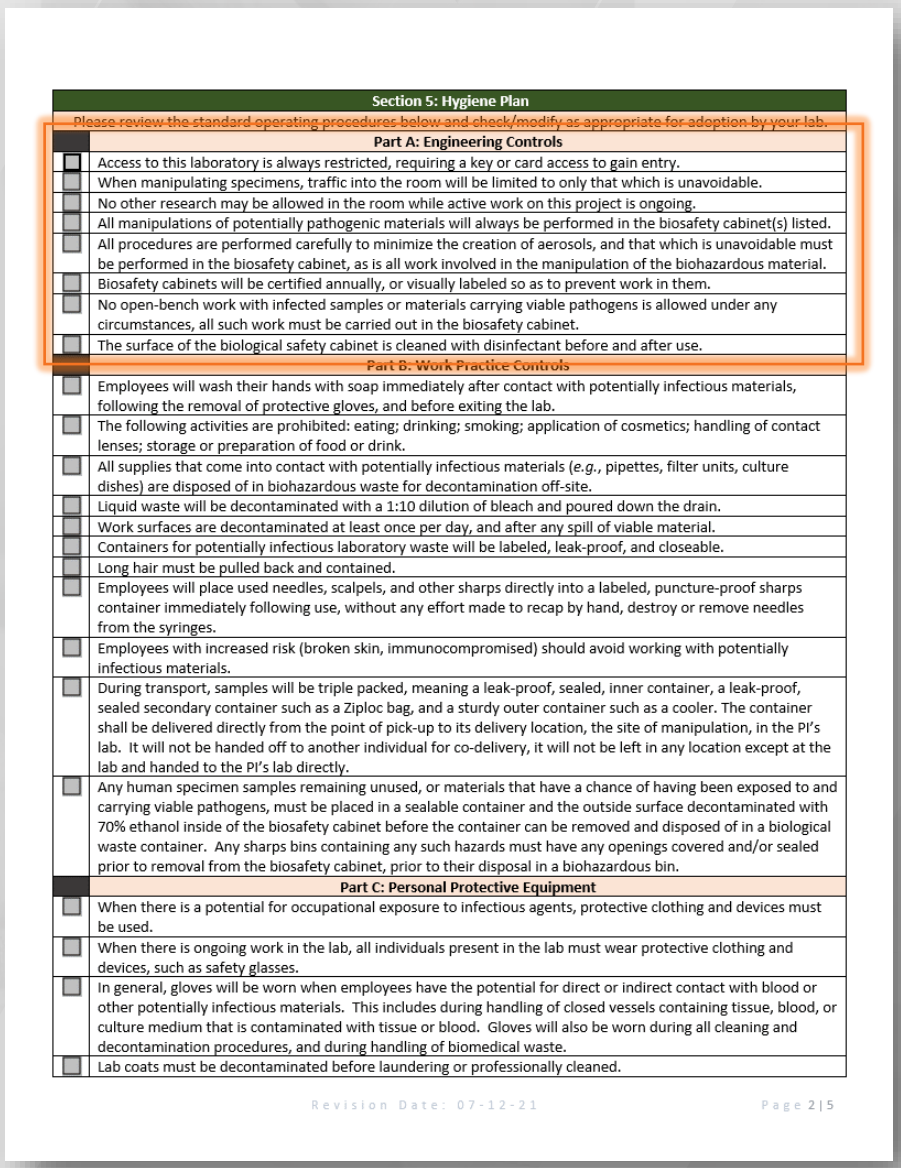
- Section 1 – Administration
- Section 2 – Training Requirements
- Section 3 – Hazard Communication
- Section 4 – Risk Assessment
- Section 5 – Hygiene Plan



Lab Containment SOPs



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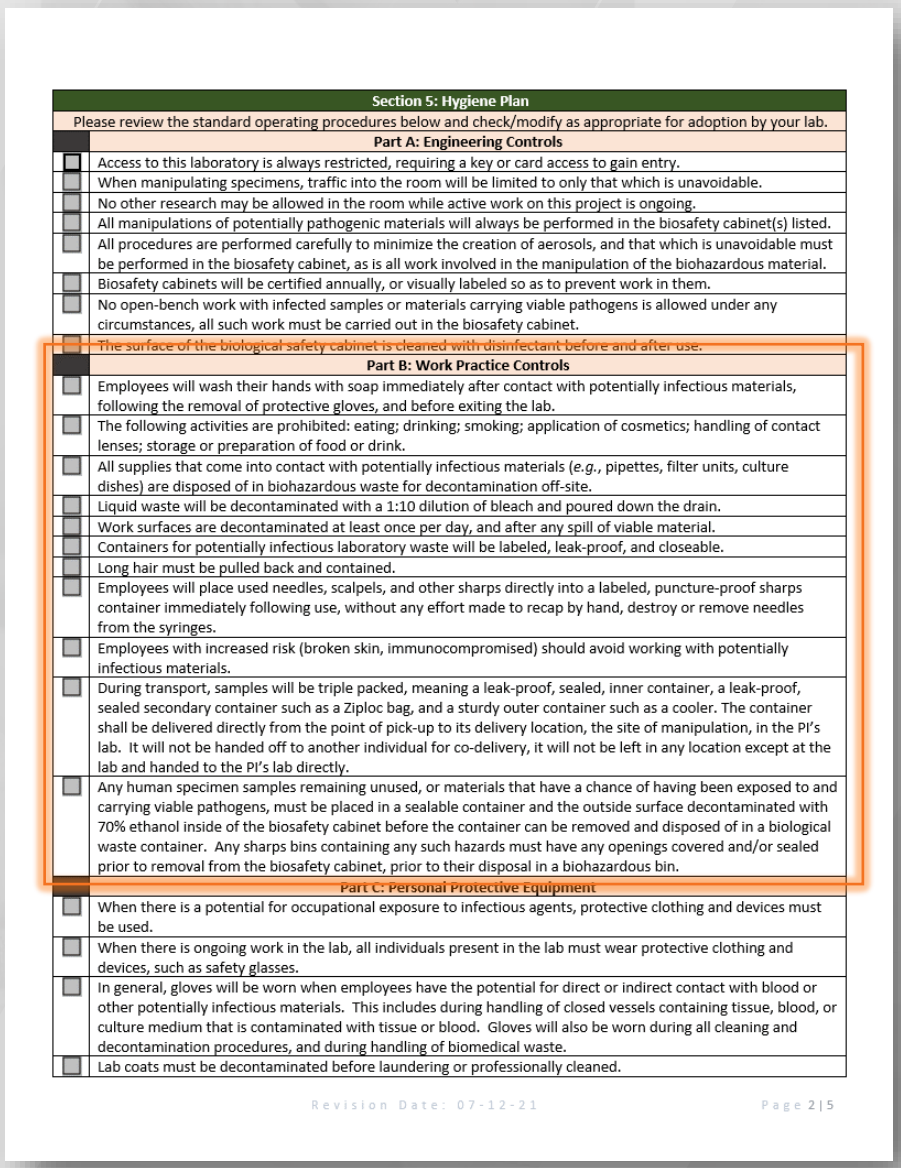
- Section 5 – Hygiene Plan
  - Part A – Engineering Controls

Lab Work Practice SOPs



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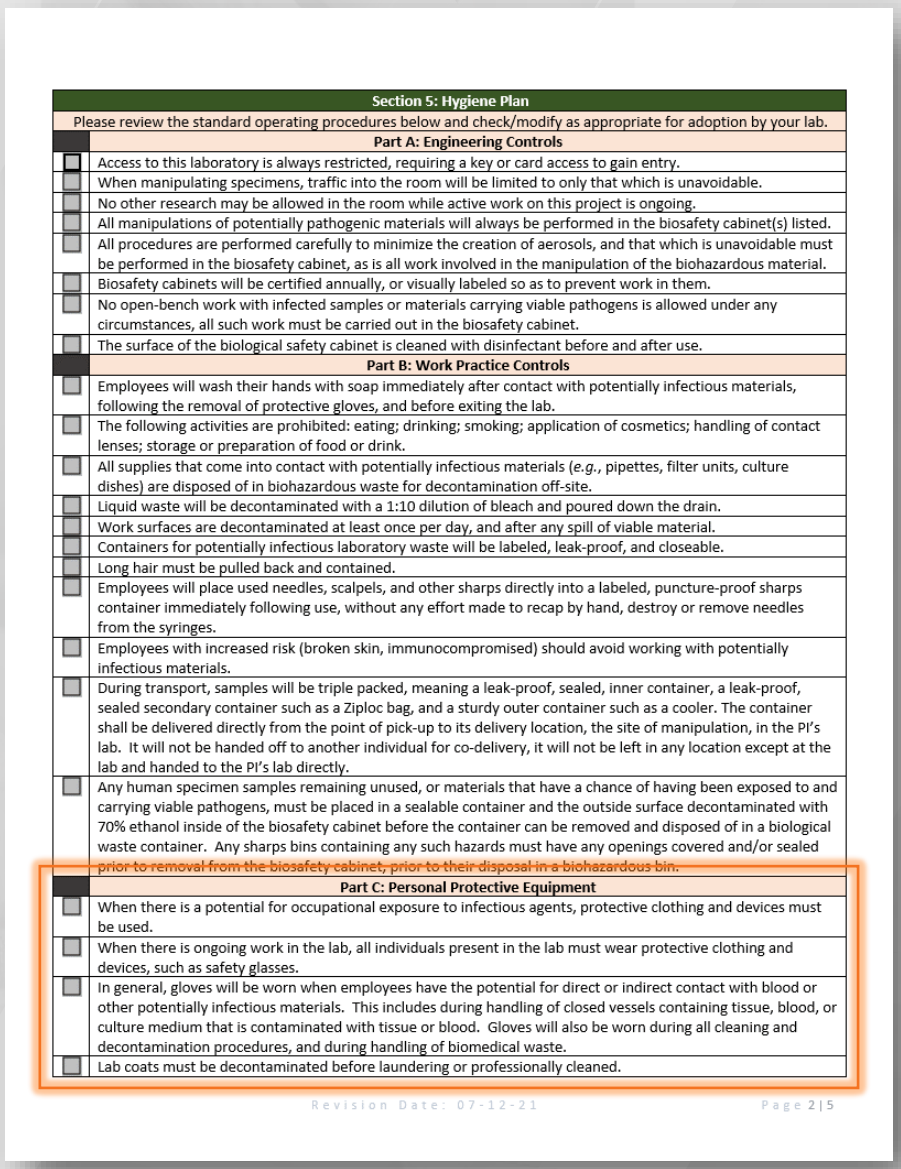
Revision Date: 07-12-21 Page 2 | 5

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

Lab PPE SOPs



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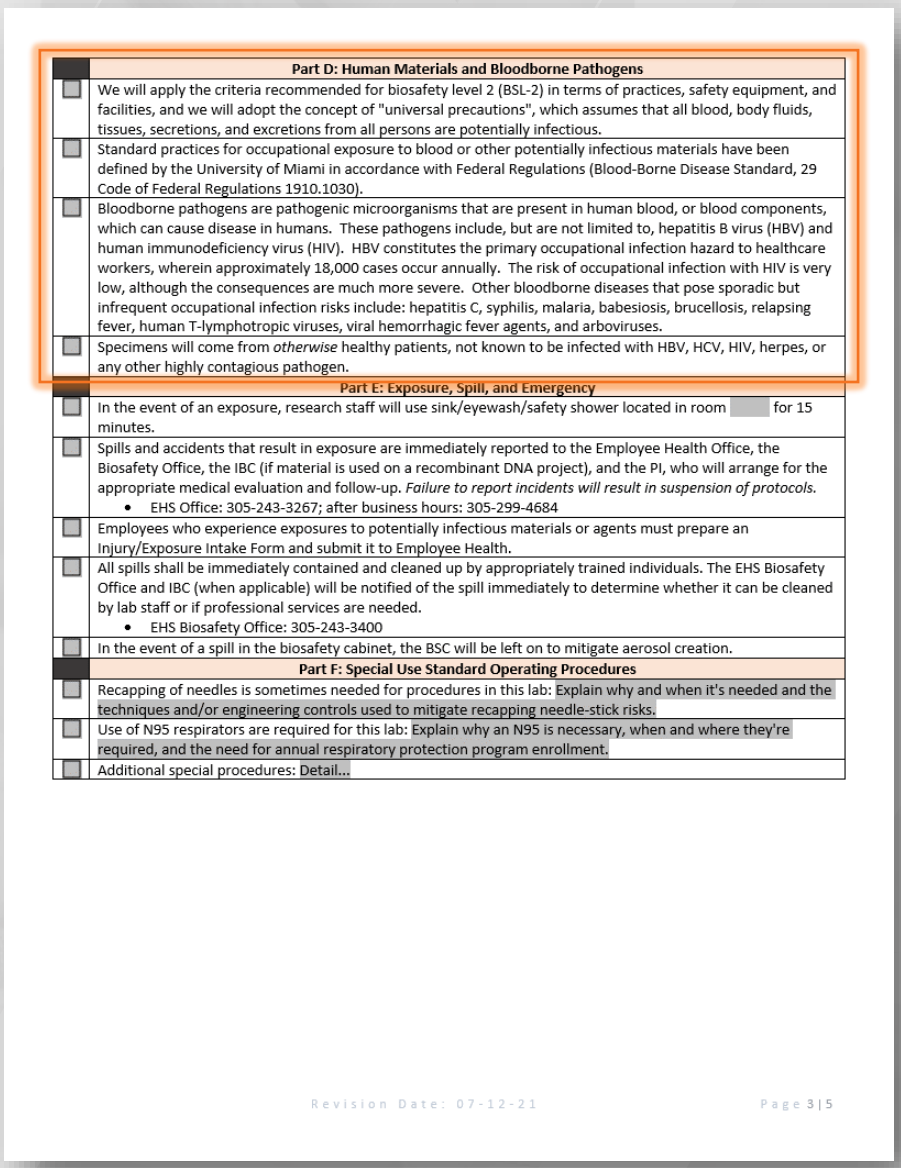
- Section 5 – Hygiene Plan
  - Part A – Engineering Controls
  - Part B – Work Practice Controls
  - Part C – Personal Protective Equipment

Lab BBP SOPs



	Part D: Human Materials and Bloodborne Pathogens
☐	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.
☐	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).
☐	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.
☐	Specimens will come from *otherwise* healthy patients, not known to be infected with HBV, HCV, HIV, herpes, or any other highly contagious pathogen.
	Part E: Exposure, Spill, and Emergency
☐	In the event of an exposure, research staff will use sink/eyewash/safety shower located in room ____ for 15 minutes.
☐	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. *Failure to report incidents will result in suspension of protocols.* • EHS Office: 305-243-3267; after business hours: 305-299-4684
☐	Employees who experience exposures to potentially infectious materials or agents must prepare an Injury/Exposure Intake Form and submit it to Employee Health.
☐	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. • EHS Biosafety Office: 305-243-3400
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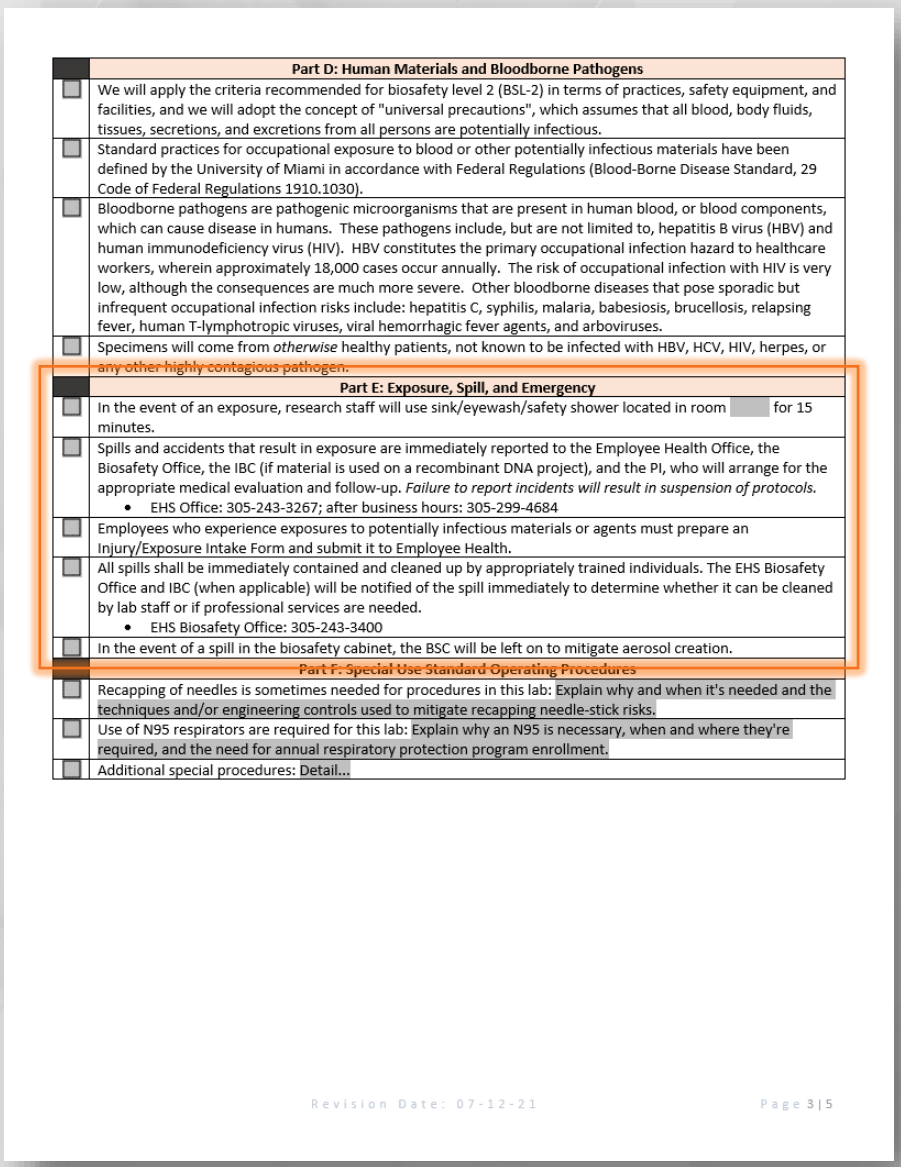
	Part F: Special Use Standard Operating Procedures
☐	Recapping of needles is sometimes needed for procedures in this lab: Explain why and when it's needed and the techniques and/or engineering controls used to mitigate recapping needle-stick risks.
☐	Use of N95 respirators are required for this lab: Explain why an N95 is necessary, when and where they're required, and the need for annual respiratory protection program enrollment.
☐	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



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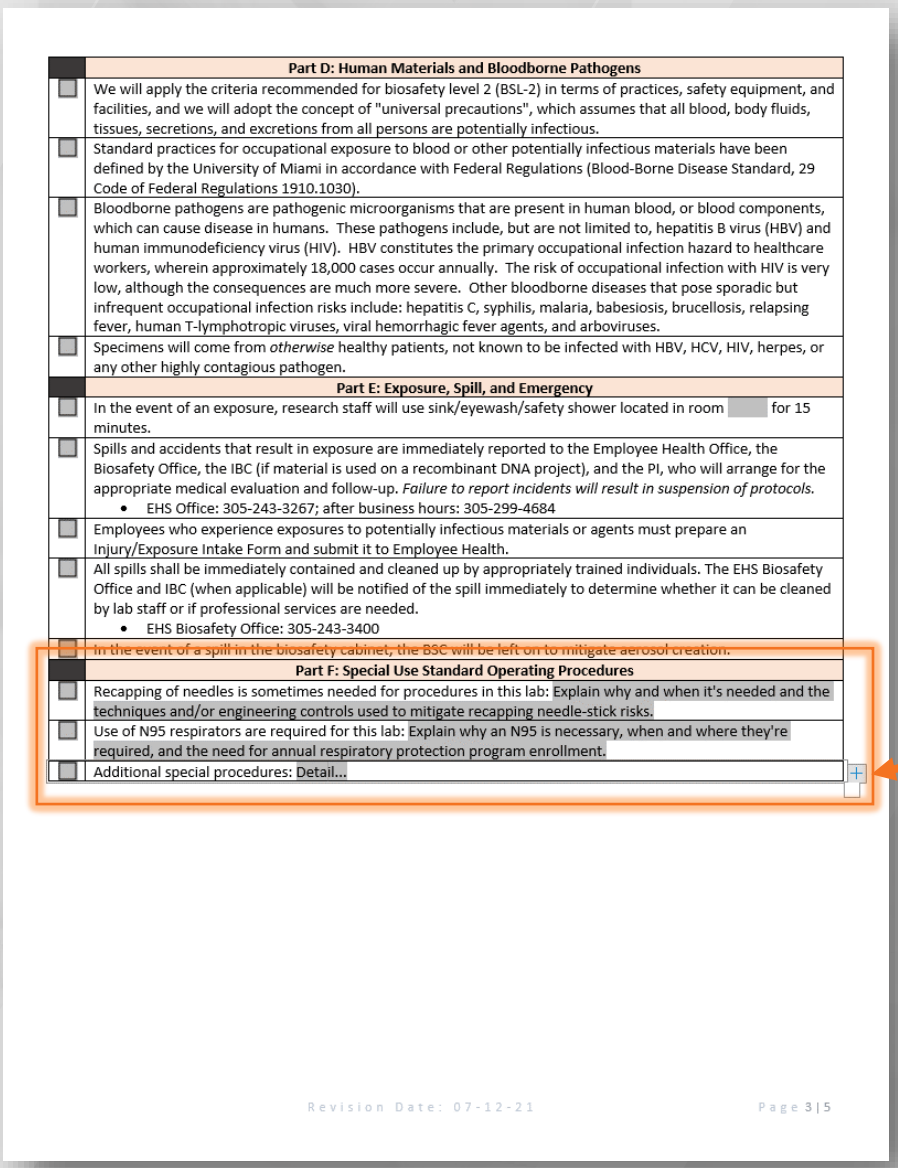
Other Critical SOPs



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	Part E: Exposure, Spill, and Emergency
☐	In the event of an exposure, research staff will use sink/eyewash/safety shower located in room ____ for 15 minutes.
☐	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. *Failure to report incidents will result in suspension of protocols.* • EHS Office: 305-243-3267; after business hours: 305-299-4684
☐	Employees who experience exposures to potentially infectious materials or agents must prepare an Injury/Exposure Intake Form and submit it to Employee Health.
☐	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. • EHS Biosafety Office: 305-243-3400
☐	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
☐	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.
☐	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.
☐	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
☐	1. Infectious or otherwise risk group 2 agents	Biosafety
☐	2. Human source materials	Bloodborne Pathogens
☐	3. Genetically modified organisms or synthetic nucleic acid molecules	Recombinant DNA
☐	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:
☒ Gloves ☒ Safety Glasses ☒ Lab Coat ☐ Face Shield ☐ Disposable Gown ☐ N95 Respirator ☐ Other(s): List...

ion 5: Hygiene Plan

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

t A: Engineering Controls

requiring a key or card access to gain entry.
e room will be limited to only that which is unavoidable.
n while active work on this project is ongoing.
aterials will always be performed in the biosafety cabinet(s) listed.
imize the creation of aerosols, and that which is unavoidable must
l work involved in the manipulation of the biohazardous material.
r visually labeled so as to prevent work in them.
r materials carrying viable pathogens is allowed under any
ut in the biosafety cabinet.
cleaned with disinfectant before and after use.

B: Work Practice Controls

mediately after contact with potentially infectious materials,
d before exiting the lab.
; drinking; smoking; application of cosmetics; handling of contact
k.
tially infectious materials (*e.g.*, pipettes, filter units, culture
for decontamination off-site.
:10 dilution of bleach and poured down the drain.
ce per day, and after any spill of viable material.
y waste will be labeled, leak-proof, and closeable.

nd other sharps directly into a labeled, puncture-proof sharps
any effort made to recap by hand, destroy or remove needles

mmunocompromised) should avoid working with potentially

d, meaning a leak-proof, sealed, inner container, a leak-proof,
ag, and a sturdy outer container such as a cooler. The container
ck-up to its delivery location, the site of manipulation, in the PI's
idual for co-delivery, it will not be left in any location except at the

sed, or materials that have a chance of having been exposed to and
a sealable container and the outside surface decontaminated with
efore the container can be removed and disposed of in a biological
any such hazards must have any openings covered and/or sealed
rior to their disposal in a biohazardous bin.

ersonal Protective Equipment

posure to infectious agents, protective clothing and devices must

viduals present in the lab must wear protective clothing and

es have the potential for direct or indirect contact with blood or
cludes during handling of closed vessels containing tissue, blood, or
sue or blood. Gloves will also be worn during all cleaning and
dling of biomedical waste.
ndering or professionally cleaned.

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

- ☐ Abrin
- ☐ Bacillus cereus Biovar anthracis
- ☐ Botulinum neurotoxins
- ☐ Botulinum neurotoxin producing species of Clostridium
- ☐ Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)
- ☐ Coxiella burnetii
- ☐ Crimean-Congo haemorrhagic fever virus
- ☐ Diacetoxyscirpenol
- ☐ Eastern Equine Encephalitis virus
- ☐ Ebola virus
- ☐ Francisella tularensis
- ☐ Lassa fever virus
- ☐ Lujo virus
- ☐ Marburg virus
- ☐ Monkeypox virus
- ☐ 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)
- ☐ Ricin
- ☐ Rickettsia prowazekii
- ☐ SARS-associated coronavirus (SARS-CoV)
- ☐ Saxitoxin
- ☐ South American Haemorrhagic Fever viruses:
  - ☐ Chapare
  - ☐ Guanarito
  - ☐ Junin
  - ☐ Machupo
  - ☐ Sabia
- ☐ Staphylococcal enterotoxins (subtypes A,B,C,D,E)
- ☐ T-2 toxin
- ☐ Tetrodotoxin
- ☐ Tick-borne encephalitis complex (flavi) viruses:
  - ☐ Far Eastern subtype
  - ☐ Siberian subtype
- ☐ Kyasanur Forest disease virus
- ☐ Omsk hemorrhagic fever virus
- ☐ Variola major virus (Smallpox virus)
- ☐ Variola minor virus (Alastrim)
- ☐ Yersinia pestis

OVERLAP 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

USDA 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

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

- ☐ Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines)
- ☐ Peronosclerospora philippinensis (Peronosclerospora sacchari)
- ☐ Ralstonia solanacearum
- ☐ Rathayibacter toxicus
- ☐ Sclerophthora rayssiae
- ☐ Synchytrium endobioticum
- ☐ Xanthomonas oryzae

☐ **NONE**

ASSESSMENT

urposes can be utilized for both
).

nces research that, based on current
products, or technologies that could be
to public health and safety, agricultural

ersight of Life Sciences Dual Use Research
ernment. On September 24, 2014, the US
Concern was released to establish the
S Government considers these two

rojects at the University of Miami,
and toxins and categories of experiments.
deemed potential DURC.

15 listed agents.

enza virus

Clostridium botulinum

can be reasonably anticipated to

st the agent or toxin without clinical

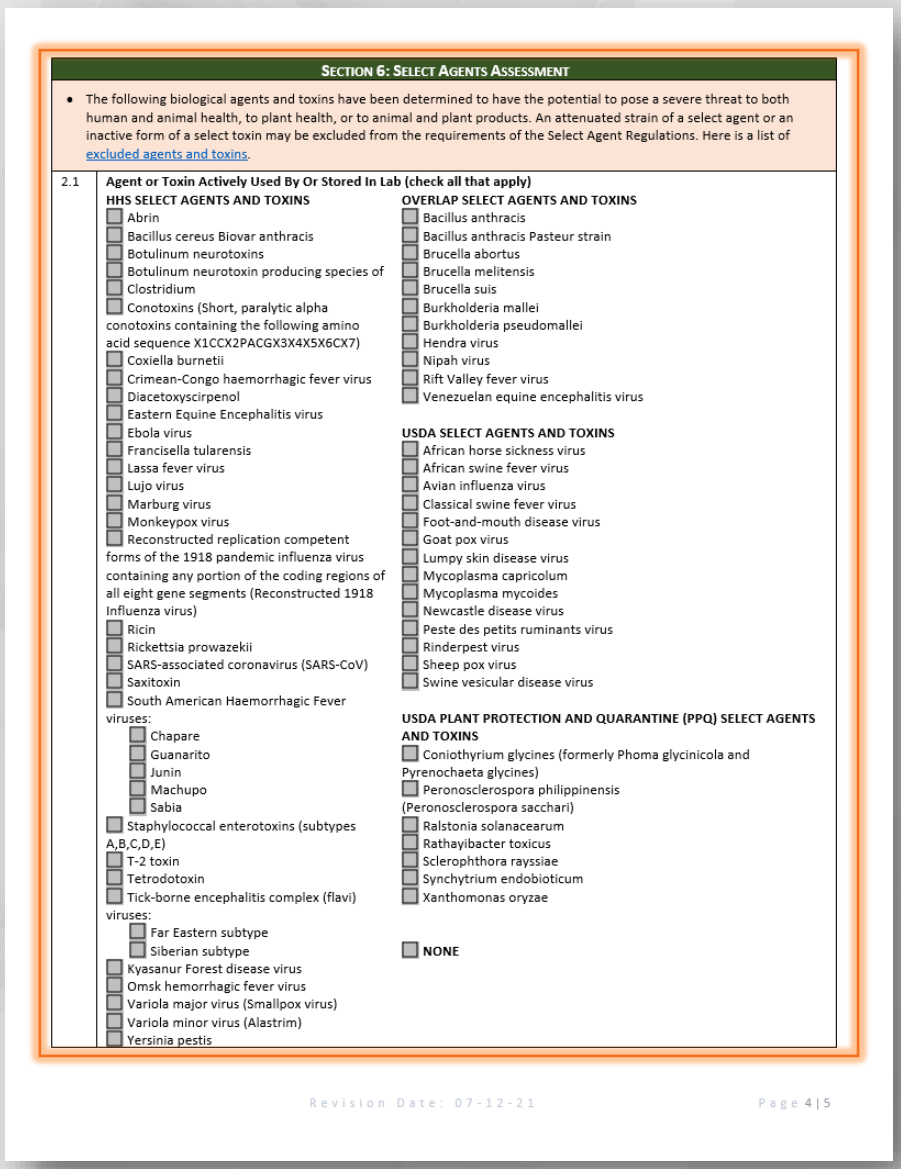
useful prophylactic or therapeutic
de detection methodologies.
ce its ability to be disseminated.

ted in Question 6.2 of this form.

ture

ices, containment equipment, personal
level applicable to this project. I will
is document and will follow these

Screening: Select Agents



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- ☐ Synchytrium endobioticum
- ☐ Xanthomonas oryzae

☐ **NONE**

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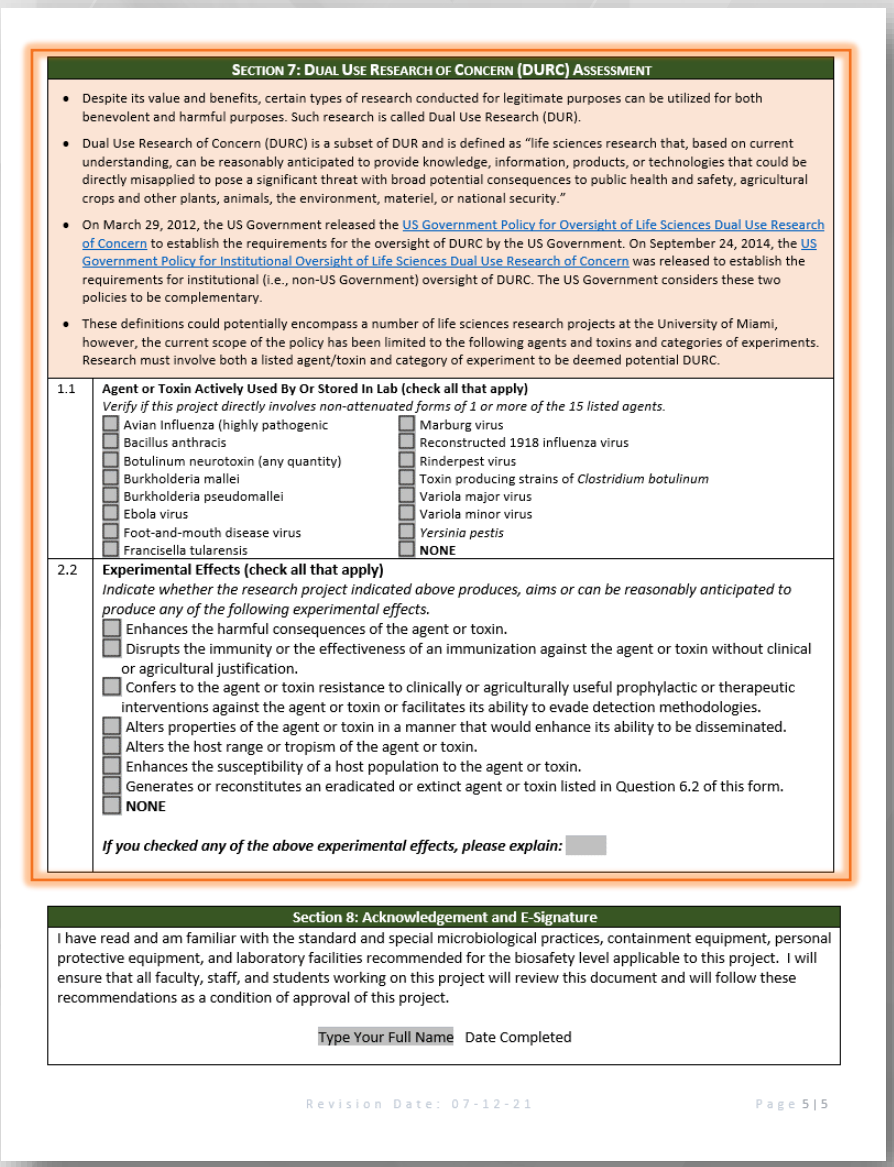
- Section 1 – Administration
- Section 2 – Training Requirements
- Section 3 – Hazard Communication
- Section 4 – Risk Assessment
- Section 5 – Hygiene Plan
- Section 6 – Select Agents Assessment

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.

- ☐ Avian Influenza (highly pathogenic)
- ☐ Bacillus anthracis
- ☐ Botulinum neurotoxin (any quantity)
- ☐ Burkholderia mallei
- ☐ Burkholderia pseudomallei
- ☐ Ebola virus
- ☐ Foot-and-mouth disease virus
- ☐ Francisella tularensis
- ☐ Marburg virus
- ☐ Reconstructed 1918 influenza virus
- ☐ Rinderpest virus
- ☐ Toxin producing strains of *Clostridium botulinum*
- ☐ Variola major virus
- ☐ Variola minor virus
- ☐ *Yersinia pestis*
- ☐ **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

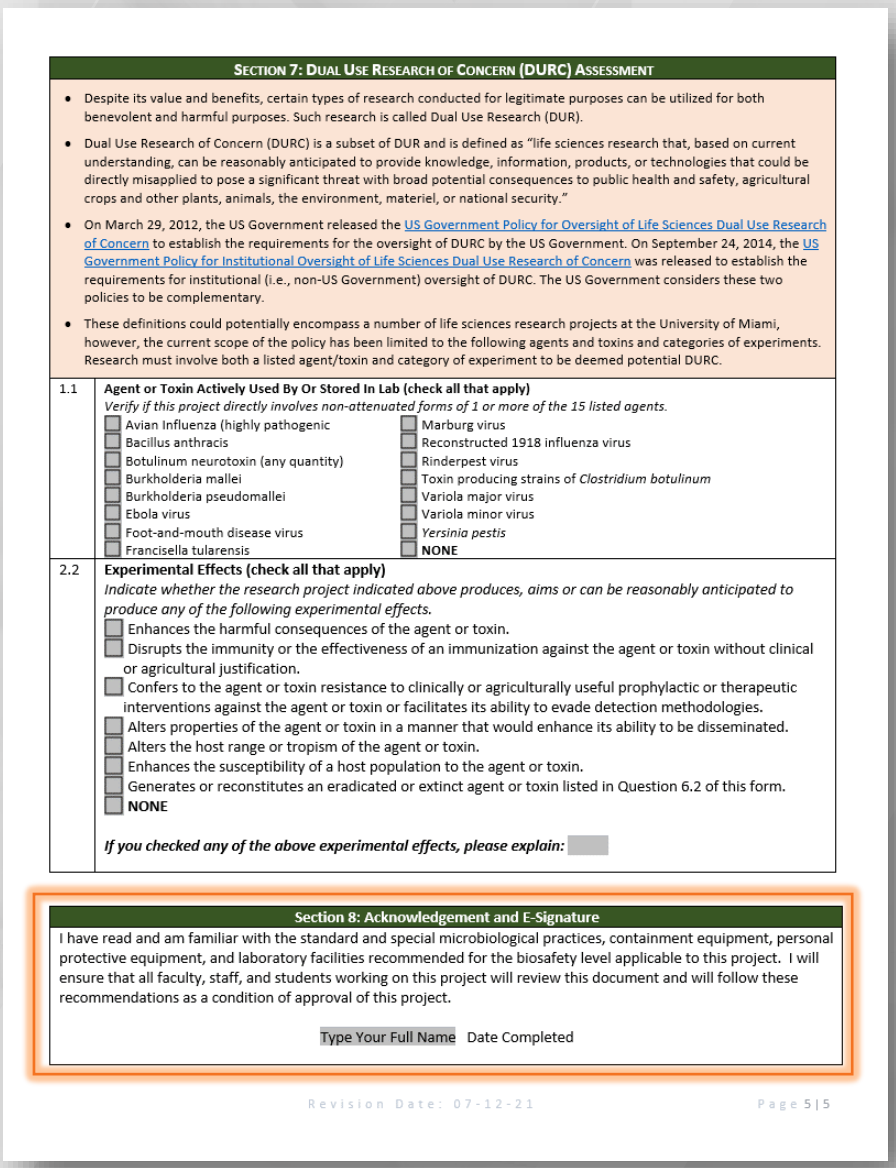
I have read and am familiar with the standard and special microbiological practices, containment equipment, personal protective equipment, and laboratory facilities recommended for the biosafety level applicable to this project. I will ensure that all faculty, staff, and students working on this project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

Type Your Full Name Date Completed

Revision Date: 07-12-21 Page 5|5

- 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



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Revision Date: 07-12-21 Page 5|5

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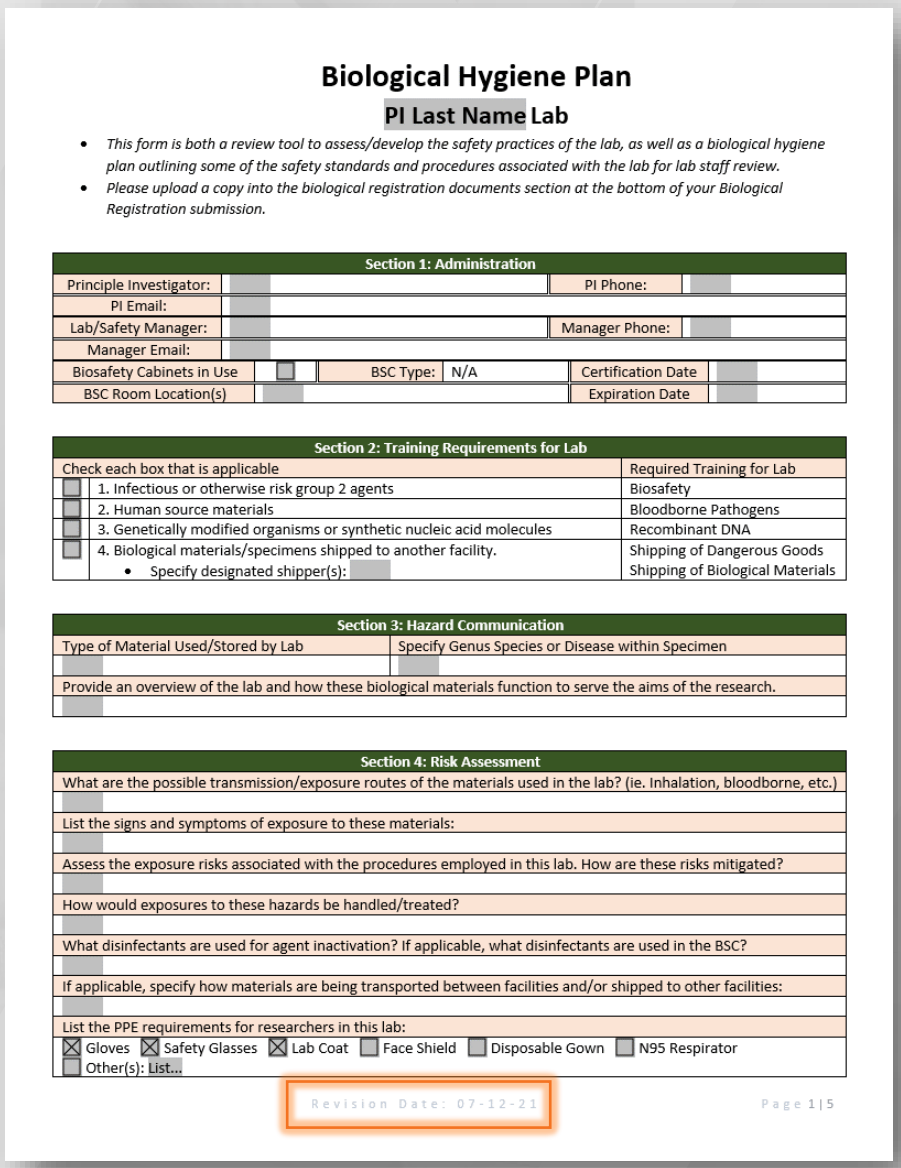
- Section 7 – DURC Assessment
- Section 8 – Acknowledgement / Sign

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	☐ 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
☐	1. Infectious or otherwise risk group 2 agents	Biosafety
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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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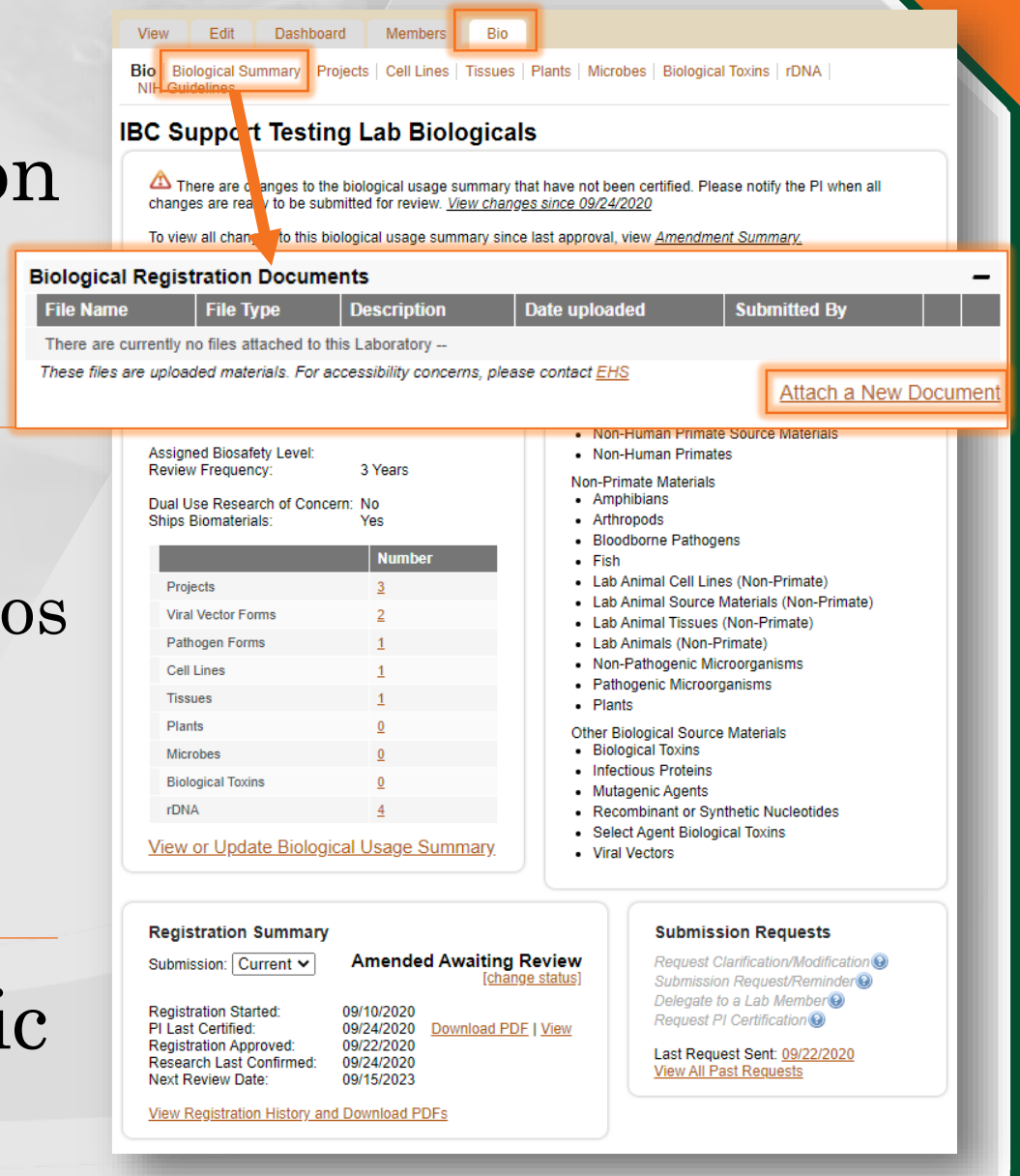
- Revision Date: 07-12-2021
- Updates coming this summer
- Feedback/suggestions welcome

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



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

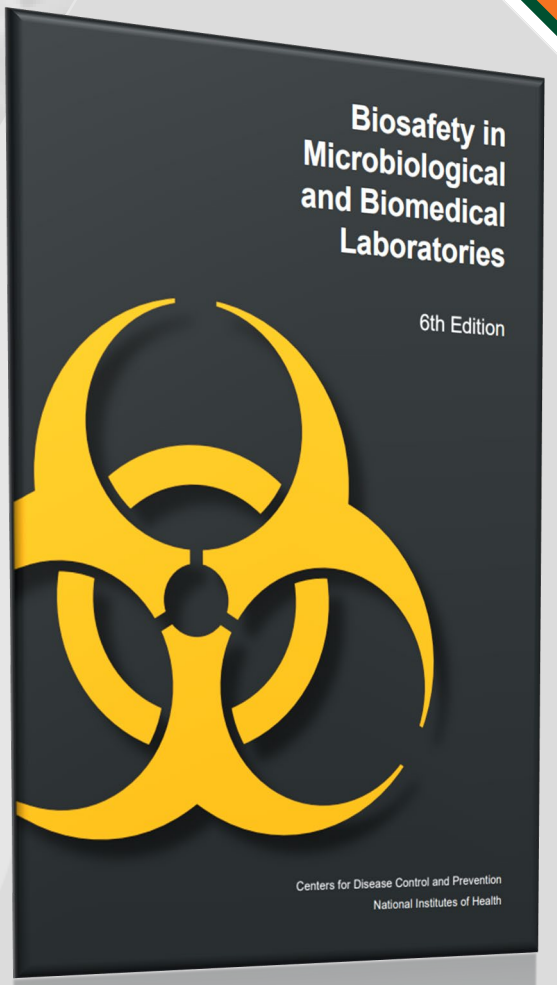
Yeah But Hit Me With a Citation

- 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.

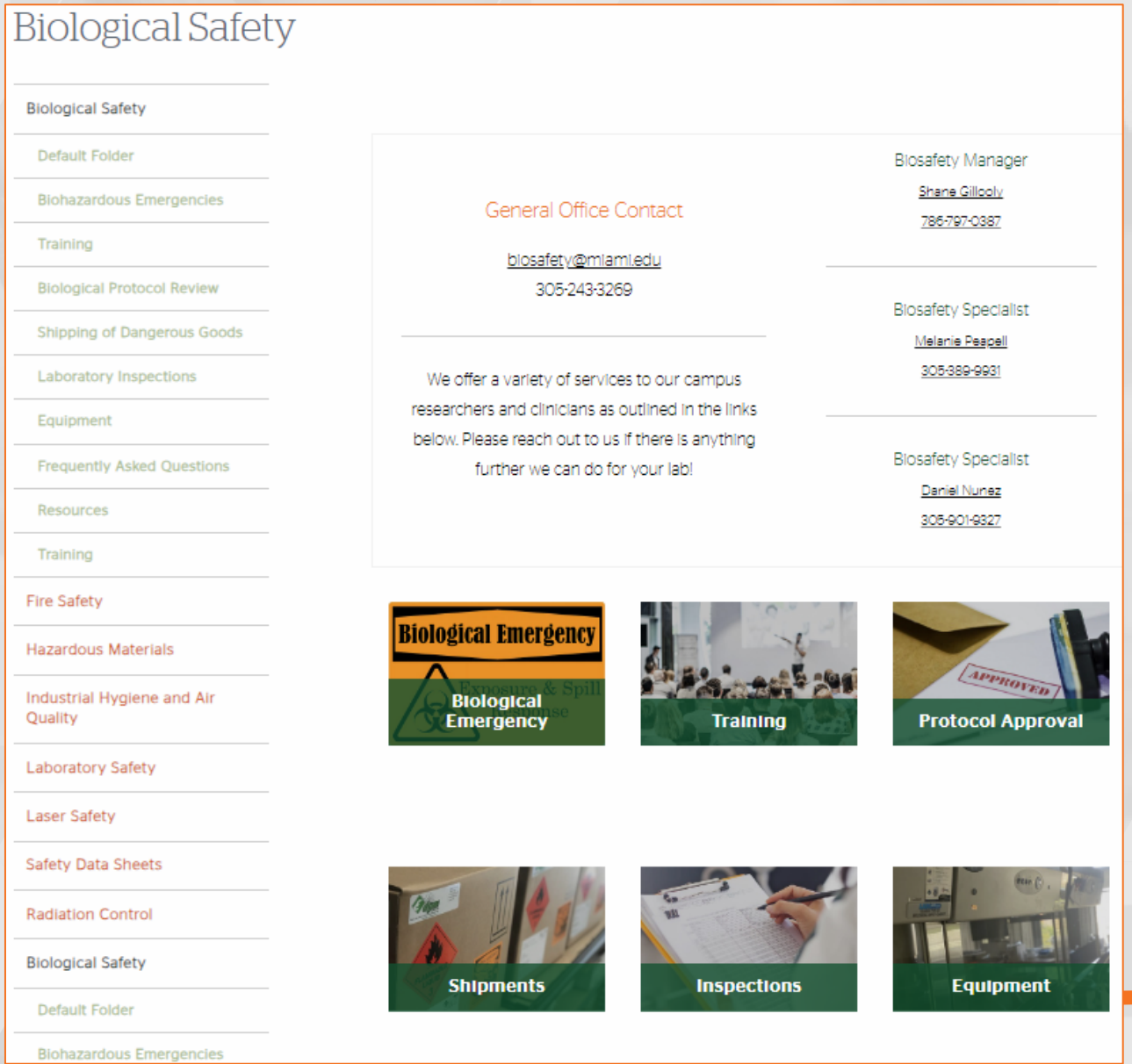
b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.

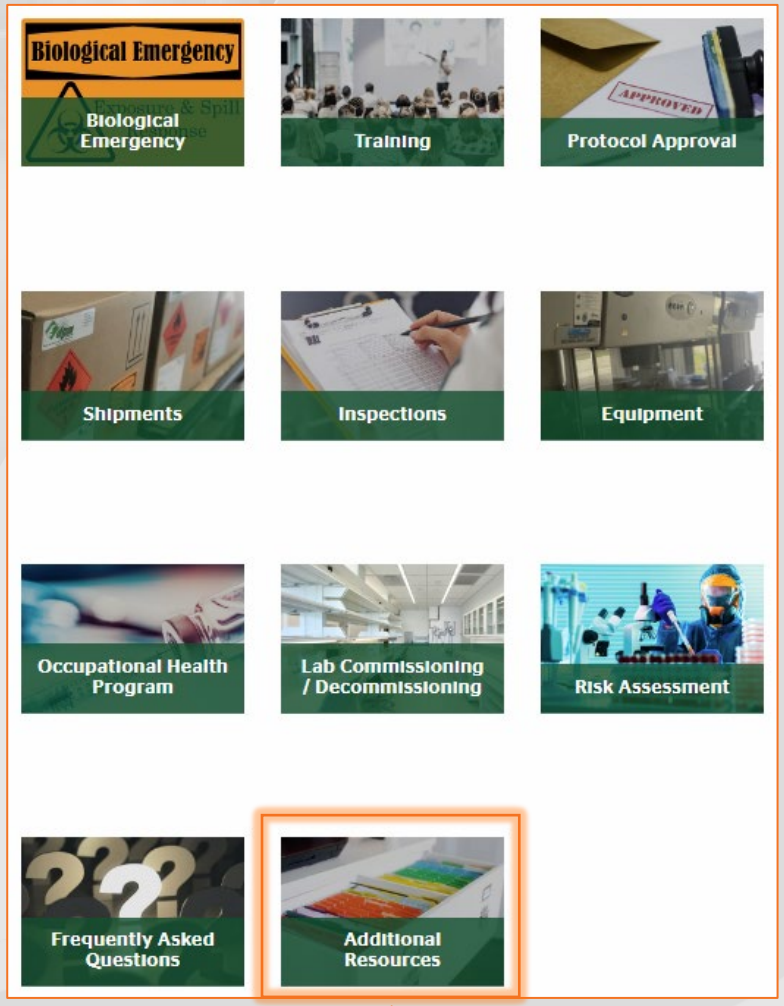


- https://www.cdc.gov/labs/bmbl/index.html

Wrap Up

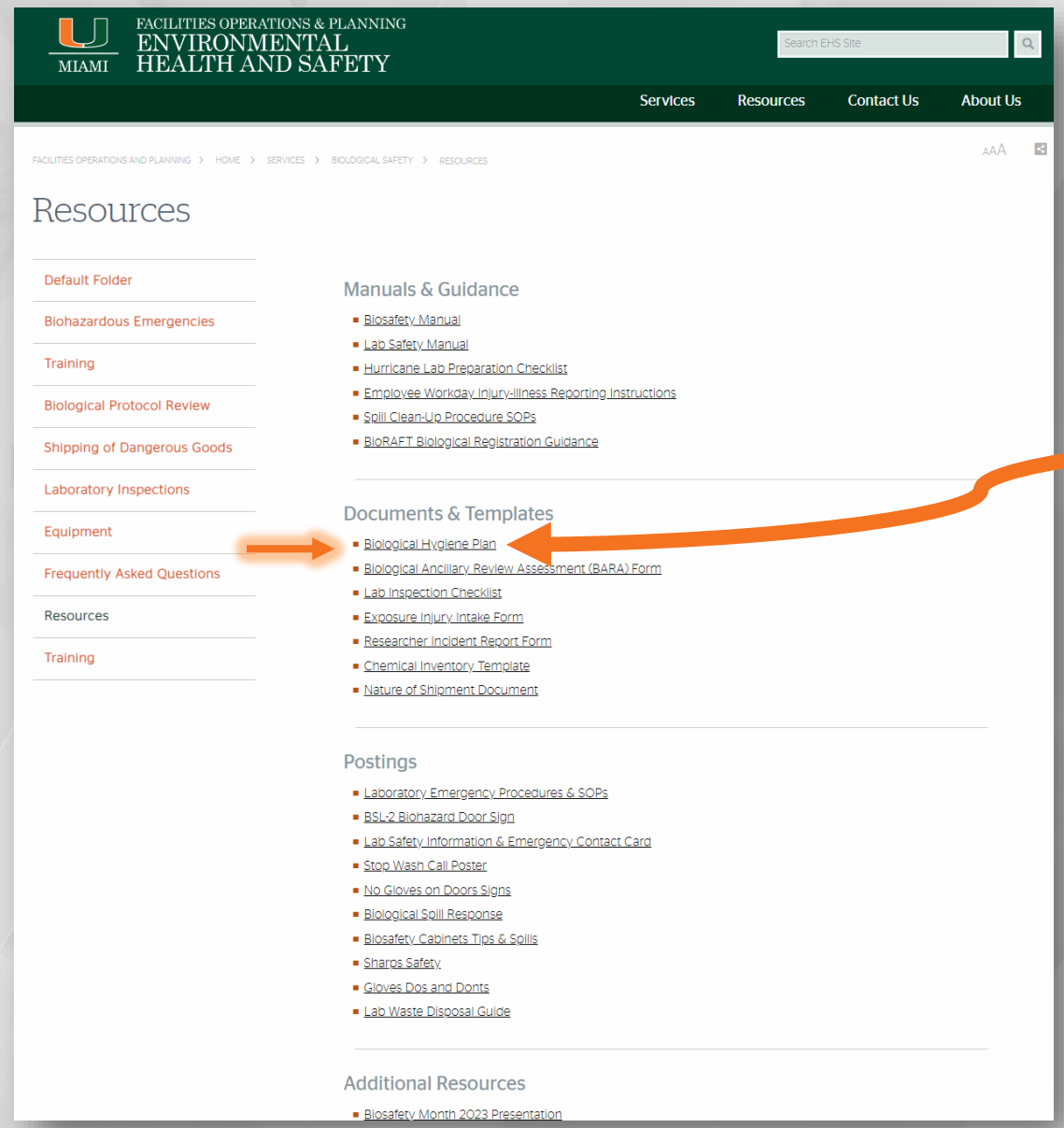
Biosafety Website





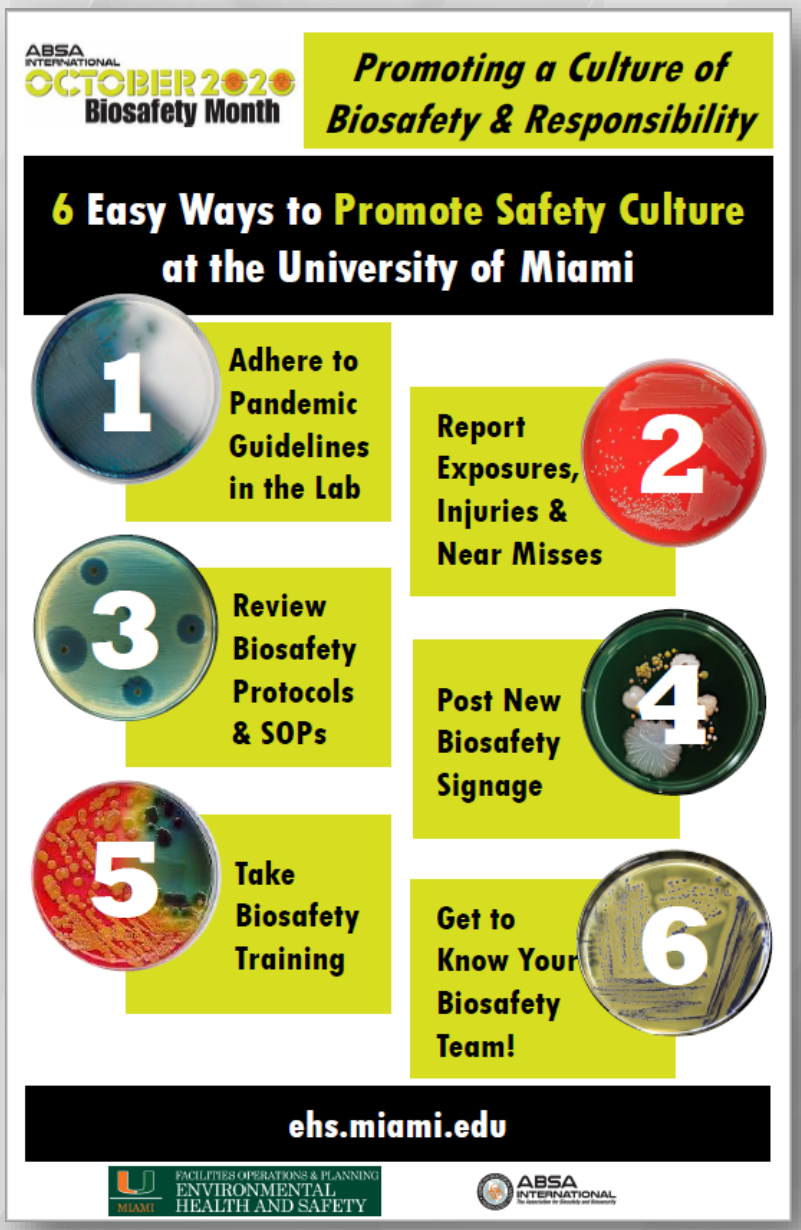
ehs.miami.edu/biosafety

Bio Hygiene Plan Form Online



Biological Hygiene Plan

October is Biosafety Month



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

Questions

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