State of our Union: Updates & Best Practices

- Identify the recent policy updates
- Examine operating system requirements
- Explore best practices to stay compliant

Speakers: ORA, IITSU, RIC, EHS

All presenters have indicated that they have no relevant financial relationships with ineligible companies.

State of our Union: Updates & Best Practices

Topic	Presenter
Office of Research Administration - Updates and Best Practices	D. Stewart MacIntyre, III, Esq. Executive Director, Interim, ORA
Clinical Trial Management and Participant Enrollment and Tracking Policy - Use of the University of Miami Clinical Trial Management System (CTMS), Velos eResearch	Nicole S. McCullough Director, Regulatory Support, IITSU
Huron Updates for 2026	Kanchan Sakhrani Supervisor, Business Systems Analyst Research Intelligence & Capacity (RIC) (OVPRS)
EHS Review Process	Jennifer Laine, DrPH, CSP, CPH, CHMM, CFI Executive Director, Environmental Health and Safety

IRB Grand Rounds 2026 - Virtual Series

Time	Topic	SPEAKER
January 15, 2026, 10-11 am	State of our Union: Updates & Best Practices	ORA, RIC, EHS, IITSU, HSRO
February 19, 2026, 10-11 am	**Guardians of the Data in the Digital Age**	**Data Brokers, AI, HSRO**
March 19, 2026, 10-11 am	Key Ingredients to Running a Successful Clinical Trial (UM & JHS)	IITSU, JHS, CTD
April 16, 2026, 10-11 am	Balancing Act: Biobanking, Big Data & Data Privacy	RI, OTT
May 21, 2026, 10-11 am	Beyond the Approval: Building a Culture of Compliance	RQA, DSAM, EC

Office of Research Administration

Updates and Best Practices

D. Stewart MacIntyre, III, Esq.
Executive Director, Interim, ORA

Relevant Conflicts

I DO NOT have an actual or potential conflict of interest in relation to this program/presentation.

ORA Lifecycle Improvement Overview

ORA Service Level Agreements ☑

Reviewed and established acceptable timeframes for 60 steps across the Grant/Contract lifecycle.

Work is underway to get campus agreement and socialization of SLAs

Projects prioritized for implementation

1. **Create and Distribute Financial Reports for PIs**
2. **Revisit the award set-up process**
3. Incoming Grant Transfers
4. **Dashboard Creation**
5. ServiceNow Implementation
6. Efficient use of Grant funding
7. Expand use of monitoring and exception reports
8. Define ORA Roles and Responsibilities
9. Create and Distribute Department Tools (e.g. checklists)
10. Invoicing Optimization
11. Communication Plan

ORA Submission

(Industry Sponsored)

- **Simultaneous Submission to IRB and ORA is required**. (Effective July 29, 2024)
  - ORA and IRB submissions must be linked using the “Manage Relationships” functionality in either the FP or IRB workspace.
  - Studies submitted after July 29th must submit to IRB within the latter of either
    - two weeks, or
    - when ORA starts to work on the coverage analysis (MCA) and budget.
- **Protocol Modifications**:
  - CTA, Budget and MCA need to align with current version of Protocol approved in IRB.
  - Protocol Amendments may require an amendment to the CTA (modified clinical research protocols, modified ICFs, Change of PI and other changes may warrant revision of MCA).
- **If JHS is involved**:
  - JHS must be included as a Resource in the applicable FP (Funding Proposal) in IBIS
    - JHS CTO Application
    - JHS Calendar

ORA Submission

(Industry Sponsored)

Use ORA Resources!

https://www.ora.miami.edu/about-ora/clinical-research/engaging-clinical-research/index.html

- Has information on some Institutional fees.
- F&A Rate for Industry Clinical Trials (36%)
- Checklists:
  - Clinical Trial Checklist
  - Budget Checklist

Pre-Award Guidance

https://www.ora.miami.edu/about-ora/pre-award/contracts/pre-award-guidance/index.html

TIPS!

- When in doubt. Ask.
- Try to avoid the cart before the horse.
  - i.e. ORA cannot begin review of a CTA before the protocol is finalized.

Pre-Award Guidance

Form	Description	Date Revised
IBIS Submission Guidance-Advance Account	Please follow this guidance document on how to submit an Advance Account to ORA through IBIS.	New
IBIS Submission Guidance-Award Mod Request	Please follow this guidance document when submitting an Award Modification Request (AMR) to ORA through IBIS.	New
IBIS Submission Guidance-CDA	Please follow this guidance document on how to submit a new Confidentiality Agreement to ORA through IBIS.	New
IBIS Guidance-Collaboration Agreement	Please follow this guidance document on how to submit a new Collaboration Agreement to ORA through IBIS.	New
IBIS Submission Guidance-CTA	Please follow this guidance document on how to submit a new Clinical Trial Agreement to ORA through IBIS.	New
IBIS Submission Guidance - DUA	Please follow this guidance document on how to submit a Data Use Agreement to ORA through IBIS.	New
IBIS Submission Guidance-MTA	Please follow this guidance document on how to submit a new Material Transfer Agreement to ORA through IBIS.	New
IBIS Submission Guidance-OS (New)	Please follow this guidance document on how to submit a new Outbound Subcontract to ORA through IBIS.	New

Industry Clinical Negotiation Process

Contract Negotiations:

- Virtually all agreements need review and a fair amount of revision.
- Timely responses by PI/Dept. relating to contractual language are very helpful to avoid delays in negotiations.
- Certain contractual terms and clauses may need different departmental review and approval (i.e., Intellectual Property language is reviewed by OTT-Office of Technology Transfer).

Budget Negotiations:

- MCA development is before Budget development.
- MCA and draft internal budget needs PI/Dept review and approval before submission to Sponsor.
    - Timely responses by PI/Dept. are very helpful to avoid delays in negotiations.
- Protocol Modifications: If you are made aware that the Sponsor is modifying the protocol, inform your ORA Budget Analyst immediately. This directly affects budget negotiations.

Industry Clinical – Best Practice

- Make sure to know who your ORA contact is. https://www.ora.miami.edu/about-ora/contact-us/pre-award-contact-information/index.html

- F&A Rate:
  - 36% for Industry Clinical Trials.
  - 53.5% for Industry Clinical Research.

- Simultaneous submission to ORA and IRB.

- If JHS is involved, JHS must be listed as a resource in FP.
- Provide Sponsor's original budget.
- Provide any needed budgetary justifications.

Industry Clinical - Most common pitfalls:

- Not submitting an Agreement and FP simultaneously.
- No simultaneous submission to ORA and IRB.
- Make sure you submit the correct agreement type.
    - CTA's are often submitted for projects that aren't Clinical Trials. (Not all Clinical Research projects are Clinical Trials).
- Make sure FP is consistent with Agreement:
- Deadlines: Enrollment deadlines soon after submission.
- MSOM or SCCC Feasibility Approval

IBIS Proposal Information

1. * **What is the primary purpose of this project?**
Clinical Trial

Compliance Review

1. * **Human subjects involved in this project:**
Yes No

a. * Is this a clinical trial?
Yes No

b. * IRB protocol has been submitted:
Yes No

Thank You!

Contact Information

D. Stewart MacIntyre, Interim Executive Director
(DMacIntyre@miami.edu)

UNIVERSITY OF MIAMI

Clinical Trial Management and Participant Enrollment and Tracking Policy

Use of the University of Miami Clinical Trial Management System (CTMS), Velos eResearch

V 1.0, Dec2025, Nicole.S. McCullough, Director, Regulatory Support

UNIVERSITY OF MIAMI

Policy Purpose

1. To ensure that institutional reports about the types of clinical research studies, as well as reports on numbers of participants consented and enrolled on clinical trials, conducted at the University of Miami (UM) are accurate and current.

2. To ensure that participants' information and related study activities furnished pursuant to a clinical research study involving billable services are entered in the University of Miami Clinical Trial Management System (CTMS) without delay so that the services are appropriately billed to the correct financial responsible party.

Scope of the policy:

This policy shall apply to all UM investigators and research team members engaged in clinical research study activities performed in any UM hospital, clinic, physician's office, medical office building or ambulatory surgery center and any Jackson Health System (JHS) facility, including satellite locations, as well as research conducted in the community.

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Policy Requirement 1 – Applicable Studies

It is the policy of the University of Miami (UM) that the following types of clinical research studies shall be registered in the University of Miami Clinical Trial Management System ("the CTMS") called Velos:

- **Any interventional study or clinical trial** or
- Any clinical research study that includes billable medical services (clinical procedures), unless noted in policy exceptions.

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Policy Requirement 2 - MCA

The Medicare Coverage Analysis (the "MCA") must be uploaded into the CTMS **before any participants are enrolled in the study**.

Principal Investigators or their designees must follow the instructions provided in Office of Research Administration (ORA) ancillary review for modifications submitted to IRB and related to Protocol's amendments for the studies where Q5 in "Study Scope" section is answered "Yes" and ensure timely provision of matching contractual amendments to ORA Pre-Award if required.

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Policy Requirement 3 – Study Status Updates

The CTMS (Velos) must be updated as follows:

a. Study status should be kept updated for clinical trials as follows:

   i. Change to "**Active/Enrolling**" with the date reflective of the documented date that the site was activated to enrollment by the sponsor or Principal Investigator. For UM investigator-initiated studies, this should be the date when all items needed for activation are in place, e.g. case report forms built, protocol training completed, funding agreement executed, etc.

   ii. Changed to "**Temporary Closed to Accrual**" as applicable during the study if enrollment is temporarily halted or suspended for interim analysis, protocol amendment or other reasons. Please also refer to the UM Investigator Manual for IRB submission timeline requirements for interim or premature suspension of studies.

   iii. Changed to "**Active/ Closed to Enrollment**" once the study has permanently closed to enrollment and with the date reflective of the documented date that the site or study was closed to enrollment by the sponsor or principal investigator.

   iv. **Studies that are terminated or completed should be reported as such to the University of Miami IRB.** Please also refer to the UM Investigator Manual for IRB submission timeline requirements for premature termination of studies. Closure of studies with the UM IRB automatically updates the study status in Velos to "Study completed".

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Policy Requirements – Participant Status

The CTMS (Velos) must be updated as follows:

b. Each individual research participant's status must be updated to "Informed Consent Signed" in the CTMS within 2 business days after informed consent is obtained.

c. "Off Study" status of each research participant must be entered in the CTMS within 2 business days of participant withdrawal or completion of all in-person study visits.

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Policy Requirements - JHS

To comply with Jackson Health System (JHS) policy:

a. Copies of all signed informed consent forms and HIPAA Authorizations signed by JHS patients must be submitted to the JHS Clinical Trials Office (CTO) at ClinicalTrialsOffice@jhsmiami.org within 2 business days of obtaining informed consent;

b. Confirmation of enrolled participants and their study status, i.e., "Off Study" status, is required on a monthly basis by submitting the JHS patient enrollment form to the JHS CTO;

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Additional Policy Requirements

D. Faculty and staff engaged in clinical research studies must be trained on this policy.

E. Each invoice or milestone report that generates an invoice, that will be presented to a study sponsor for payment in connection with a study, must be recorded in the CTMS, even if the study falls within an exception pursuant to section 4 below.

F. Principal Investigators submitting new clinical research protocols for IRB approval shall be accountable for ensuring that all questions in the IRB electronic protocol submission and tracking system (IBIS Research) are correctly answered.

G. While a Principal Investigator may delegate any task set forth in this policy to a study team member, the Principal Investigator retains full responsibility for ensuring such tasks are performed in compliance with this policy and study team members working under their supervision adhere to this Policy.

Policy requirements E, F & G were previously listed under “Duties of Principal Investigator” section

Exceptions to the policy:

The following study types shall be exempt from the provisions of section A (MCA) and B (CTMS updates).a and 1.b of this policy, provided there are no services billable to third party payers performed in conjunction with the study activities:

- Registry studies
- Survey and questionnaire studies
- Retrospective and prospective chart review studies
- Studies ONLY collecting samples for tissue banks, non-invasive exams, or conducting tests (such as pregnancy tests), blood draws, urinalysis and other procedures where the processing services on the sample(s) are performed within a UM or JHS research facility/laboratory and ARE NOT sent to a commercial laboratory.

Responsibilities & Enforcement

Academic Department Chairs, Division Chiefs, and/or Center/Institute/Unit Directors are responsible for enforcing this policy.

Principal Investigators and members of their study teams who fail to adhere to this policy shall be subject to corrective measures, which may include training and disciplinary sanctions, up to and including the loss of the right to conduct any clinical studies as a UM Principal Investigator.

Non-compliance with JHS Participant Enrollment & HIPAA Authorization policy (see policy link: https://storage.googleapis.com/jackson-library/policies/Policy-802-Participant-Enrollment-HIPAA-Authorization-Notification.pdf) shall be subject to corrective measures, as determined by JHS, which may include training and disciplinary sanctions, up to and including the loss of the right to conduct clinical studies at JHS.

Added

Enforcement actions related to non-compliance with MCA part of policy requirements may or will include:

- Immediate enrollment hold
- Transfer of balance to department if not resolved within 30 days of notification

Added

Enforcement actions related to non-compliance with all other policy requirements may or will include:

- 1st offense: warning and complete re-training in 30 days
- 2nd offense and training not completed: $500 fine charged to departments
- 3rd offense: double fine charged to department
- 4th offense: Immediate enrollment holds and prohibition on serving as a Principal Investigator (PI) and submitting new studies to the IRB.

Added

Questions?

Huron Updates for 2026

Timelines

Presented by: Kanchan Sakhrani, Supervisor, Business Systems Analyst, Research Intelligence & Capacity (RIC) (OVPRS)

CURATING CONNECTION

IRB Grand Rounds 2026

Huron Updates for 2026

SF424 Update (Jan 2026)

SF424 version is currently 10.8.0. We will be updating it to **10.9.1** to meet the latest NIH guidelines.

IACUC/AOPS/Facilities Update (Q1 2026)

Bug fixes and enhancements; improved alignment between IACUC and AOPS

Workday Integration (Q1-Q2 2026)

Improved integration between Workday and Grants/Awards to improve New Award Setup process and timeline.

COI/IRB Update (Q2 2026)

Bug fixes and enhancements

Grants/Agreements Update (Q4 2026)

Bug fixes and enhancements; revised process for JIT

Best Practices for Data Integrity

IBISResearch, Velos, REDCap, Complion

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Tips and Best Practices

	IBIS	VELOS	REDCAP	COMPLION
User Access	HR Feed/IBIS Request Form	Velos Access Request/Training	REDCap Login	Complion Access Request/Training
Policies	ORA, COI	Velos Tracking	REDCap Accruals	FDA Study Binders
Billable?	IRB Scope Q5 & Agreements MCA	Velos MCA & CRRC Flag (IRB = billable)	Patient Accrual (IRB = non-billable)	N/A
Key Personnel	IRB Study Team/; Grants/Awards FCOI Investigator; COI Disclosure	Velos/IRB Integration	IRB Approved Study Team	IRB Approved Study Team
NCT	IRB Clinical Trial Activity	Velos/IRB Integration	N/A	N/A
Funding/Acct	SPN/GR	SPN/GR	SPN	SPN

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IRB Grand Rounds 2026

EHS Ancillary Review for IRB 2026

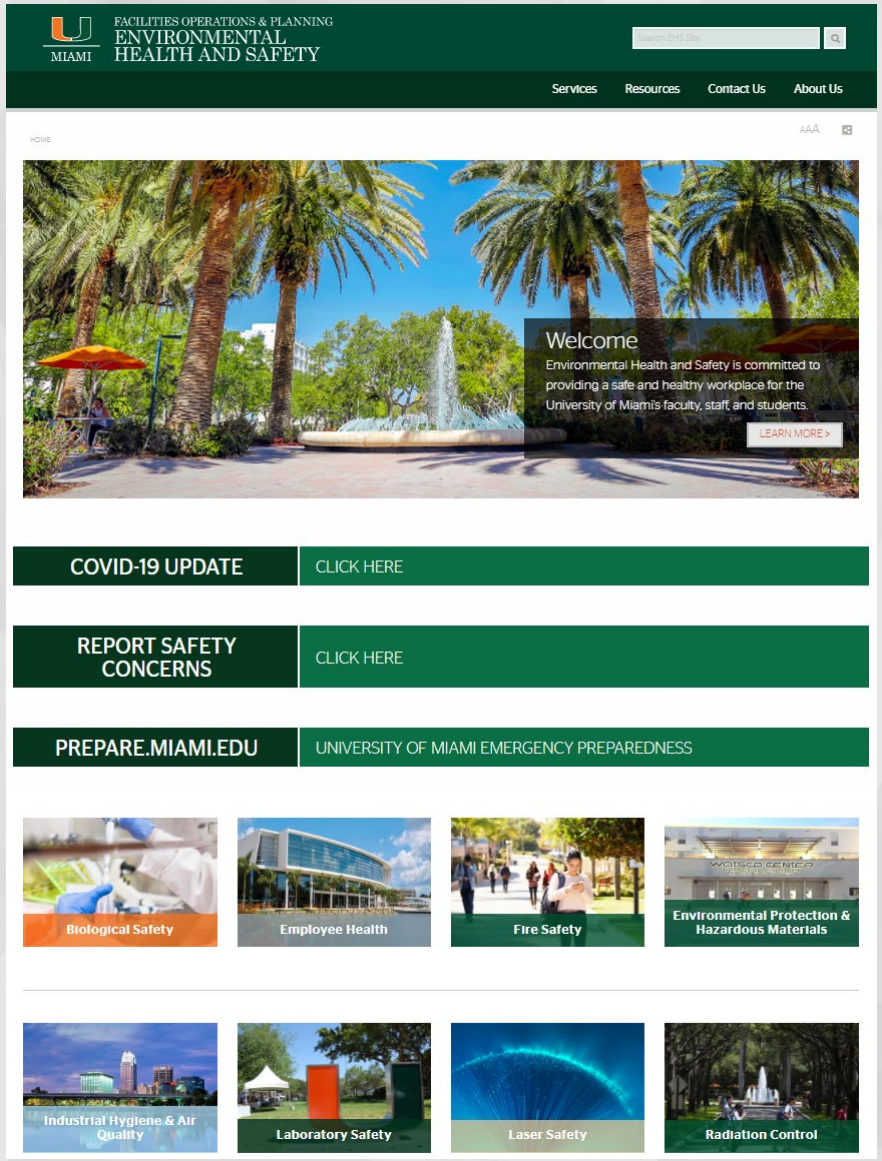
University of Miami
Environmental Health & Safety

Biosafety

Presented by Dr. Jennifer Laine, Executive Director, Environmental Health and Safety

What is EHS?

Environmental Health & Safety



- Biosafety
- Chemical Safety
- Laser Safety
- Hazardous Materials Management
- Industrial Hygiene & Air Quality
- Fire Safety

- Combine to service Lab Safety

Biosafety Office

- Shane Gillooly
  - Biosafety Officer

- Melanie Peapell
  - Biosafety Specialist
  - Laser Safety Officer

- Position Open
  - Biosafety Specialist

What is our focus in reviews?

- A ***biohazard*** is an agent of biological origin that is able to inflict harm on, or to humans, animals or the environment

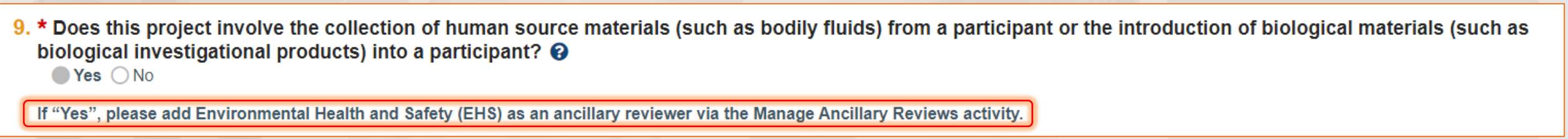
- Common ***biohazardous agents*** in IRB reviews include human source materials such as blood, infectious microorganisms, and the therapeutics derived from biological agents such as recombinant viral vectors.

Human Source Materials Research

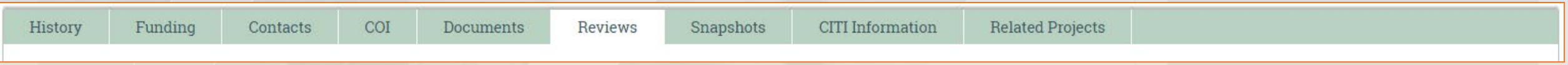
- All human source materials are considered risk group 2 and should be considered hazardous to human health
- BSL-2 lab facilities should be employed when manipulating or processing these materials
- Being pathogen free does not exempt the culture from being worked on in a BSL-2 environment

EHS Review Process

EHS Trigger in Form



- Triggers EHS to review study



- **Must** complete and upload the BARA form under Reviews
  - Without form, there is nothing for EHS to review
  - Forms must be complete, or review will be kicked back

BARA Form Revisions

Biological Ancillary Review Assessment (BARA) Form

PI Last Name Lab

- *Completing this form is required for IRB submissions requiring EHS (Environmental Health & Safety) review.*
- *Please upload a copy under EHS on the "Reviews" tab on the IRB submission page.*
- *Note that EHS is NOT notified of further edits on already submitted studies, please email us for re-reviews.*
- *For questions or if assistance is needed to complete this form, please contact us at BSO_Review@miami.edu.*

Section 1: Administration			
Full Protocol Title:			
Principal Investigator:		IRB Number:	
PI Email:		PI Emergency Phone #:	

Section 2: Study Personnel & Training Verification

List the PI & personnel on the study who will be involved with either collecting, handling, or processing specimens or investigational products. This must include the PI and corresponding training dates, as appropriate.

Name	Biosafety	Bloodborne Pathogens	Lab Safety	Shipping of Dang Goods	Shipping of Bio Materials
PI name / add researchers	mm/dd/yyyy	mm/dd/yyyy	mm/dd/yyyy	mm/dd/yyyy	mm/dd/yyyy

Section 3: Risk Screening Questions

- ☐ 1. This project involves biological investigational product(s).
  - ☐ 1a. The investigational product is infectious to humans.
- ☐ 2. This project involves recombinant or synthetic nucleic acid molecule based investigational product(s).
  - ☐ 2a. The investigational product is a viral vector.
  - ☐ 2b. The investigational product is a product created by a viral vector.
- ☐ 3. Human specimens, such as blood, or other biological materials are being collected.
  - ☐ 2a. Our lab will be manipulating or processing collected samples.
  - ☐ 2b. Our lab will collect specimens, but they are processed/manipulated by another lab.
  - ☐ 2c. Specimens are coming from patients known to be or suspected of carrying a disease.
    - Specify:
- ☐ 4. We will be responsible for shipping materials to another facility.

Section 4: Specimen Processing and Manipulation

- ☐ Collected specimens will be processed, manipulated, or shipped by another lab or core facility at the University.
  - Note that this lab is required to complete the Biological Hygiene Plan and be inspected annually by EHS.

PI Name/Core Lab Facility:	
Contact Email for Lab:	
Contact Phone # for Lab:	

- ☐ Collected specimens will be processed/manipulated by a non-University entity.

Name of Entity:	
Location of Entity:	

- Save a link, **not** the file

Section 5: Hazard Communication

Describe investigational product(s) or specimens collected by lab, their biological nature, & their associated hazards.

Provide an overview of the lab and how these biological materials function to serve the aims of the research.

How are the specimens being handled or collected by your lab?

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, 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...

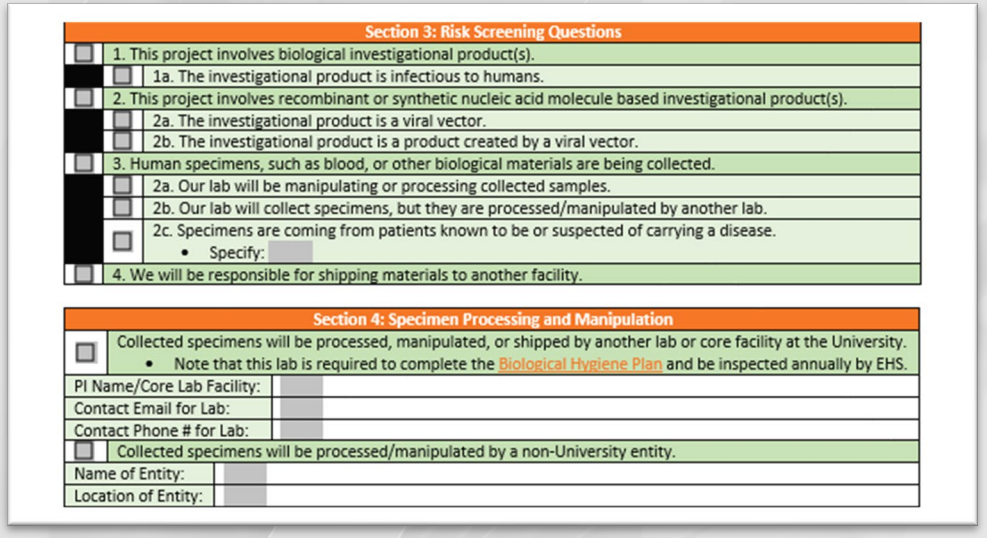
Section 6: Acknowledgement and E-Signature

I have read and am familiar with the standard and special microbiological practices, containment equipment, personal protective equipment, and laboratory facilities 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.

Professional Investigator Full Name Date Completed

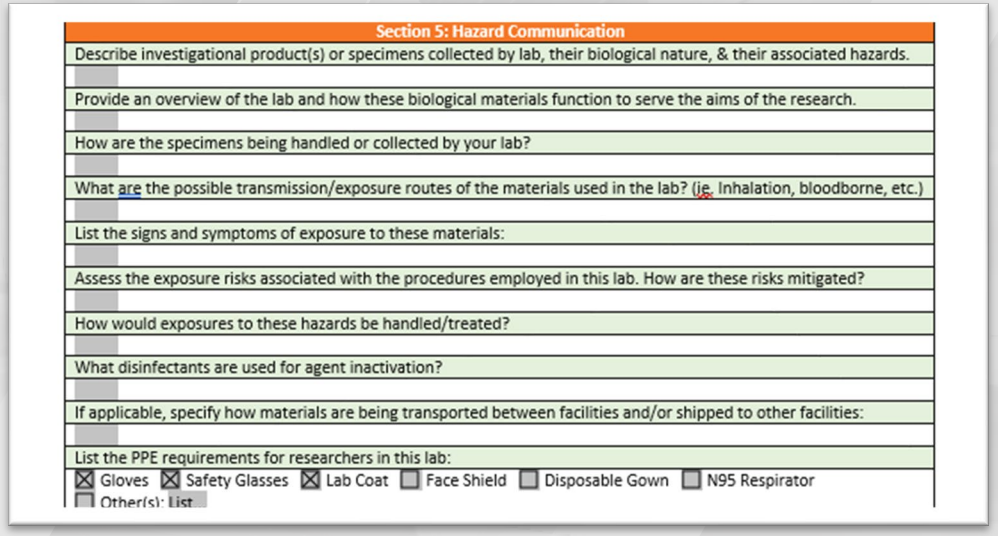
If your lab is processing/manipulating specimens or investigational products, please complete Section 7: Hygiene Plan.
If specimens or investigational products are being processed/manipulated by another lab, you may stop and submit.

Who is Handling the Hazard?



Section 3: Risk Screening Questions
☐ 1. This project involves biological investigational product(s).
☐ 1a. The investigational product is infectious to humans.
☐ 2. This project involves recombinant or synthetic nucleic acid molecule based investigational product(s).
☐ 2a. The investigational product is a viral vector.
☐ 2b. The investigational product is a product created by a viral vector.
☐ 3. Human specimens, such as blood, or other biological materials are being collected.
☐ 2a. Our lab will be manipulating or processing collected samples.
☐ 2b. Our lab will collect specimens, but they are processed/manipulated by another lab.
☐ 2c. Specimens are coming from patients known to be or suspected of carrying a disease. • Specify:
☐ 4. We will be responsible for shipping materials to another facility.

Section 4: Specimen Processing and Manipulation	
☐ Collected specimens will be processed, manipulated, or shipped by another lab or core facility at the University. • Note that this lab is required to complete the Biological Hygiene Plan and be inspected annually by EHS.	
PI Name/Core Lab Facility:	
Contact Email for Lab:	
Contact Phone # for Lab:	
☐ Collected specimens will be processed/manipulated by a non-University entity.	
Name of Entity:	
Location of Entity:	



Section 5: Hazard Communication
Describe investigational product(s) or specimens collected by lab, their biological nature, & their associated hazards.
Provide an overview of the lab and how these biological materials function to serve the aims of the research.
How are the specimens being handled or collected by your lab?
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, 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

- Section 3 tells us what your role is
- Section 4 tells us who else is handling the specimens

- If your team is handling specimens, section 5 should reflect the risks of the hazards
  - This may just be BBP outline
  - However, primary emphasis on vector(s) if used
    - BBP also listed but secondary

Do NOT Use Old Form

Biological Ancillary Review Assessment Form

- *This form is part of a required review from the Biosafety Office for any IRB protocol involving the introduction of biological materials or the collection of human specimens. It may also be required by labs falling outside of the purview of the IBC but still requiring biosafety review.*
- *This form is both a review tool to assess/develop the safety practices of the lab, as well as a hygiene plan aimed at researchers outlining some of the safety standards and procedures associated with this protocol.*
- *All labs must complete the first page, sections 1-4, as well as the digital signature at the end. If your project involves risk group 2 organisms or higher, or upon request, the entire form must be completed.*
- *Please submit to the Biosafety Office at biosafety@umiami.edu for review when complete.*

Section 1: General Protocol Information			
PI Name:		PI Email:	
Protocol Title:			
Lab Building:	Room(s):		Biosafety Level: N/A
BSC type: N/A	BSC Lab Room Location:		

Section 2: Lab Members			
List the researchers in the lab who will be involved with any part of this portion of the project, including the PI, and their corresponding training dates.			
Name	Biosafety	Bloodborne Pathogens	Lab Safety
PI name / add researchers	Date Completed	Date Completed	Date Completed

Section 3: Pre-Screening Questions	
☐	1. This project involves the introduction of foreign biological materials.
☐	1a. The materials used are infectious, toxic, or otherwise risk group 2 or higher.
☐	2. Human specimens, such as blood, or other biological materials are being collected.
☐	2a. The lab will be manipulating or processing these samples to any extent.
☐	2b. Specimens will be collected, but shipped to and processed by another lab.
☐	2c. Specimens are coming from patients known to be or suspected of carrying a disease. • Specify:
☐	3. Materials in this lab are genetically modified, transgenic, or otherwise synthetic.
☐	4. Biological materials/specimens will be shipped to another facility. • Specify designated shipper: Shipping training completion: Date Completed

Section 4: Protocol / Pathogen Overview	
Type of Material	Specify Genus Species or Disease within Specimen
In lay terms, please provide an overview of the protocol. Be sure to list the purpose of and how each material listed above is being used, highlighting the aims of the research, and briefly describing how this will be accomplished:	

If any of the materials listed above are Risk Group 2 or higher, please proceed with the rest of the application. If not, you may scroll to Section 7, sign, and submit this application as complete. If your protocol requires an IBC application, you may sign the form at Section 7 and submit.

Section 5: Biohazard Risk Assessment

…es of this lab, from the moment materials are introduced/collected, to the point of

…cedures in this experiment? How are those risks being addressed by the lab?

…ection 4: what are the signs and symptoms of exposure and the potential routes of

…previous experience working with these agents or similar materials?

…ems be stored?

…is organism be addressed and treated?

…terials are being transported between facilities and/or shipped to other facilities:

…researchers in this lab:
… ☒ Lab Coat ☐ Face Shield ☐ Disposable Gown ☐ N95 Respirator

…s for researchers in this lab:
…e Pathogens ☐ Lab Safety ☐ Shipping

Section 6: Hygiene Plan Adoption

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

Part A: Engineering Controls

…y is always restricted, requiring a key or card access to gain entry.
…ecimens, traffic into the room will be limited to only that which is unavoidable.
…be allowed in the room while active work on this project is ongoing.
…tentially pathogenic materials will always be performed in the biosafety cabinet(s) listed.
…ormed carefully to minimize the creation of aerosols, and that which is unavoidable must
…safety cabinet, as is all work involved in the manipulation of the biohazardous material.
…e certified annually, or visually labeled so as to prevent work in them.
…ith infected samples or materials carrying viable pathogens is allowed under any
…work must be carried out in the biosafety cabinet.
…gical safety cabinet will be cleaned with 70% isopropanol before and after use.

Part B: Work Practice Controls

…eir hands with soap immediately after contact with potentially infectious materials,
…f protective gloves, and before exiting the lab.
…are prohibited: eating; drinking; smoking; application of cosmetics; handling of contact
…aration of food or drink.
…nto contact with potentially infectious materials (*e.g.*, pipettes, filter units, culture
…in biohazardous waste for decontamination off-site.
…ontaminated with a 1:10 dilution of bleach and poured down the drain.
…ntaminated at least once per day, and after any spill of viable material.
…ly infectious laboratory waste will be labeled, leak-proof, and closeable.
…d back and contained.
…ed needles, scalpels, and other sharps directly into a labeled, puncture-proof sharps
…following use, without any effort made to recap by hand, destroy or remove needles

…isk (broken skin, immunocompromised) should avoid working with potentially

…will be triple packed, meaning a leak-proof, sealed, inner container, a leak-proof,
…such as a Ziploc bag, and a sturdy outer container such as a cooler. The container
…om the point of pick-up to its delivery location, the site of manipulation, in the PI's
…ff to another individual for co-delivery, it will not be left in any location except at the
…ab directly.
…les remaining unused, or materials that have a chance of having been exposed to and
…must be placed in a sealable container and the outside surface decontaminated with
…osafety cabinet before the container can be removed and disposed of in a biological
…s bins containing any such hazards must have any openings covered and/or sealed
…osafety cabinet, prior to their disposal in a biohazardous bin.

Part C: Personal Protective Equipment

…r occupational exposure to infectious agents, protective clothing and devices must

…in the lab, all individuals present in the lab must wear protective clothing and
…es.
…rn when employees have the potential for direct or indirect contact with blood or
…materials. This includes during handling of closed vessels containing tissue, blood, or
…aminated with tissue or blood. Gloves will also be worn during all cleaning and
…s, and during handling of biomedical waste.
…inated before laundering or professionally cleaned.

Part D: Human Materials and Bloodborne Pathogens

…commended for biosafety level 2 (BSL-2) in terms of practices, safety equipment, and
…the concept of "universal precautions", which assumes that all blood, body fluids,
…etions from all persons are potentially infectious.
…pational exposure to blood or other potentially infectious materials have been
… Miami in accordance with Federal Regulations (Blood-Borne Disease Standard, 29
… 1910.1030).
…pathogenic microorganisms that are present in human blood, or blood components,
…humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and
…irus (HIV). HBV constitutes the primary occupational infection hazard to healthcare
…ately 18,000 cases occur annually. The risk of occupational infection with HIV is very
…nces are much more severe. Other bloodborne diseases that pose sporadic but
…ection risks include: hepatitis C, syphilis, malaria, babesiosis, brucellosis, relapsing
…ic viruses, viral hemorrhagic fever agents, and arboviruses.
…*therwise* healthy patients, not known to be infected with HBV, HCV, HIV, herpes, or
… pathogen.

Part E: Exposure, Spill, and Emergency

…, research staff will use sink/eyewash/safety shower located in room … for 15

…ult in exposures to infectious material are immediately reported to the PI, who will
… medical evaluation and follow-up, Employee Health, and the EHS Biosafety Office.
… exposures to potentially infectious materials or agents must prepare an
…n and submit it to Employee Health.
…y contained and cleaned up by appropriately trained individuals. The EHS Biosafety
… spill immediately to determine whether it can be cleaned up by lab staff or if
…eded.
… biosafety cabinet, the BSC will be left on to mitigate aerosol creation.

…nd E-Signature
…logical practices, containment equipment, personal
…he biosafety level applicable to this project. I will
…ill follow these recommendations as a condition of

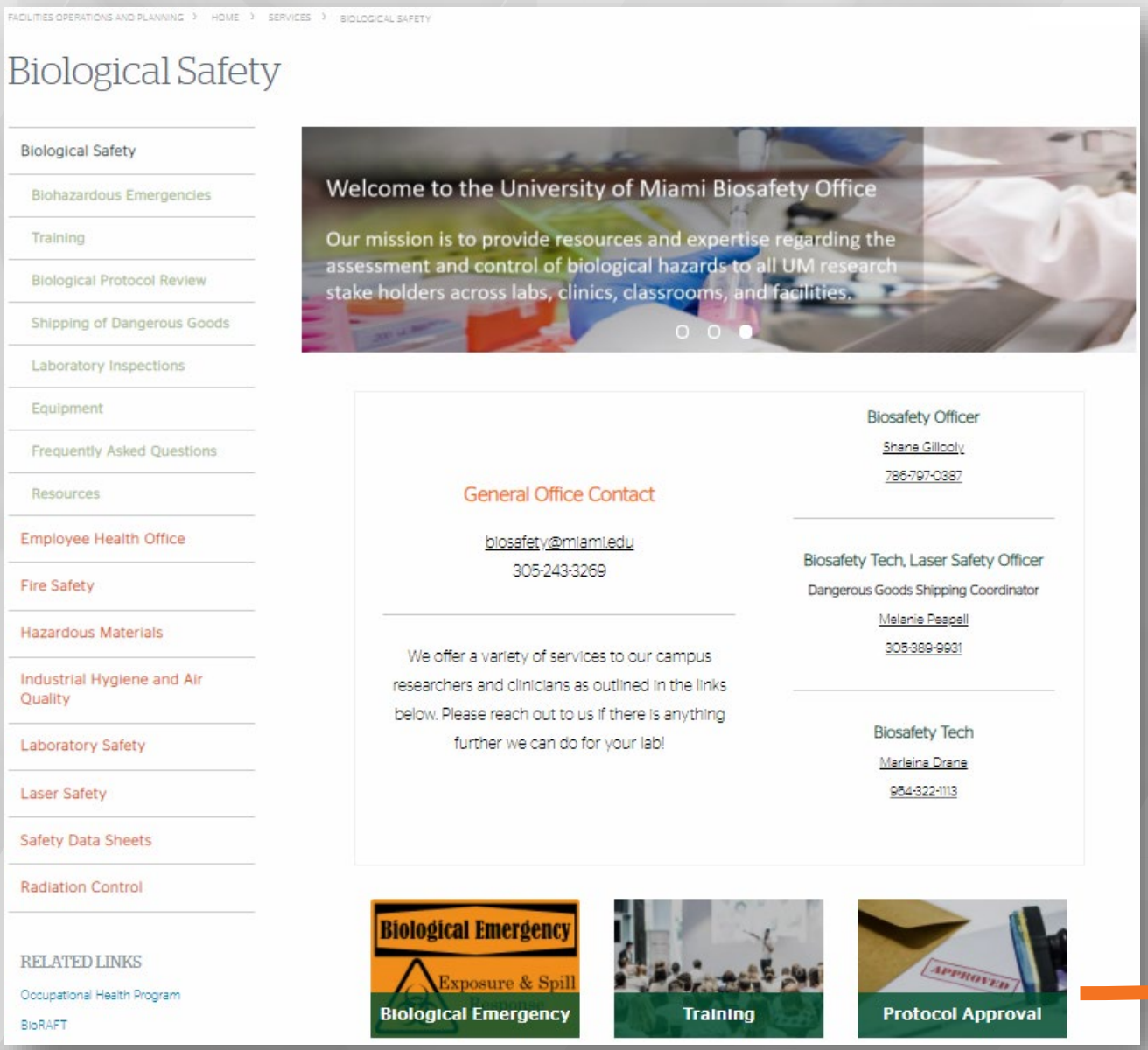
Completed

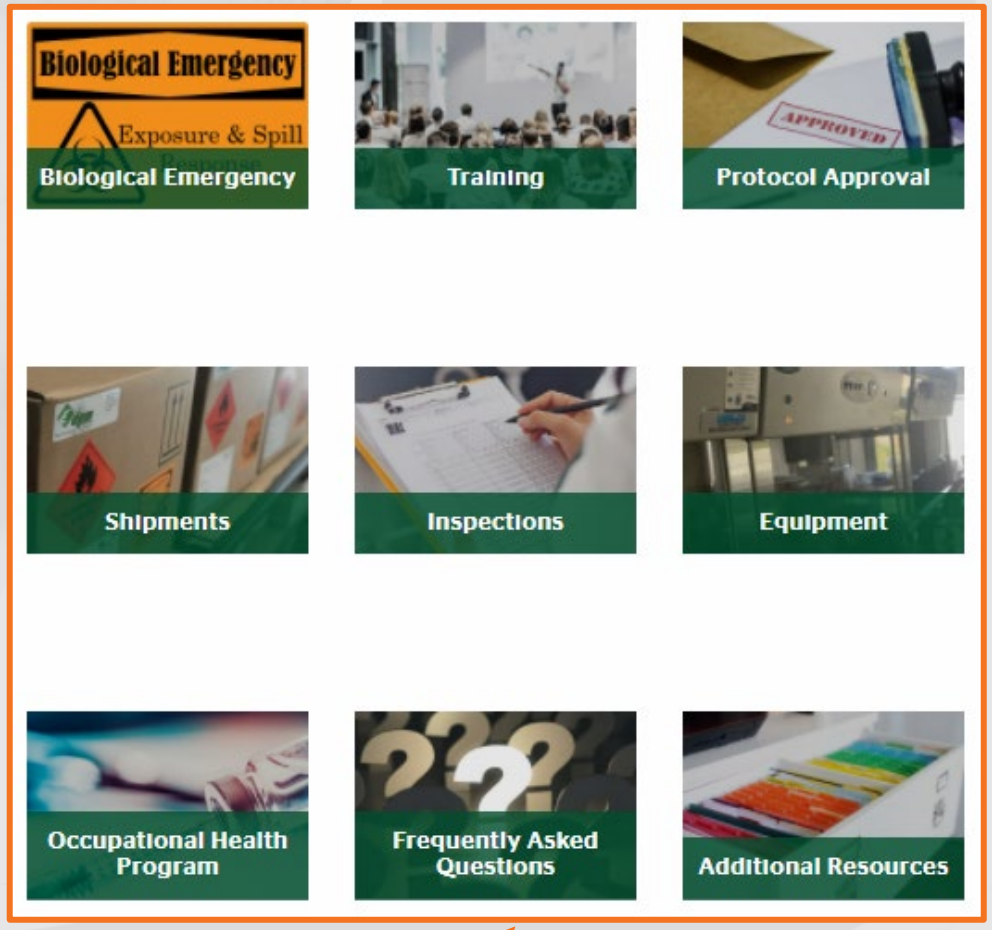
Future Process Changes

- May tweak some of the questions on the BARA form
- Goal is to incorporate Chemical Safety team as needed

Resources

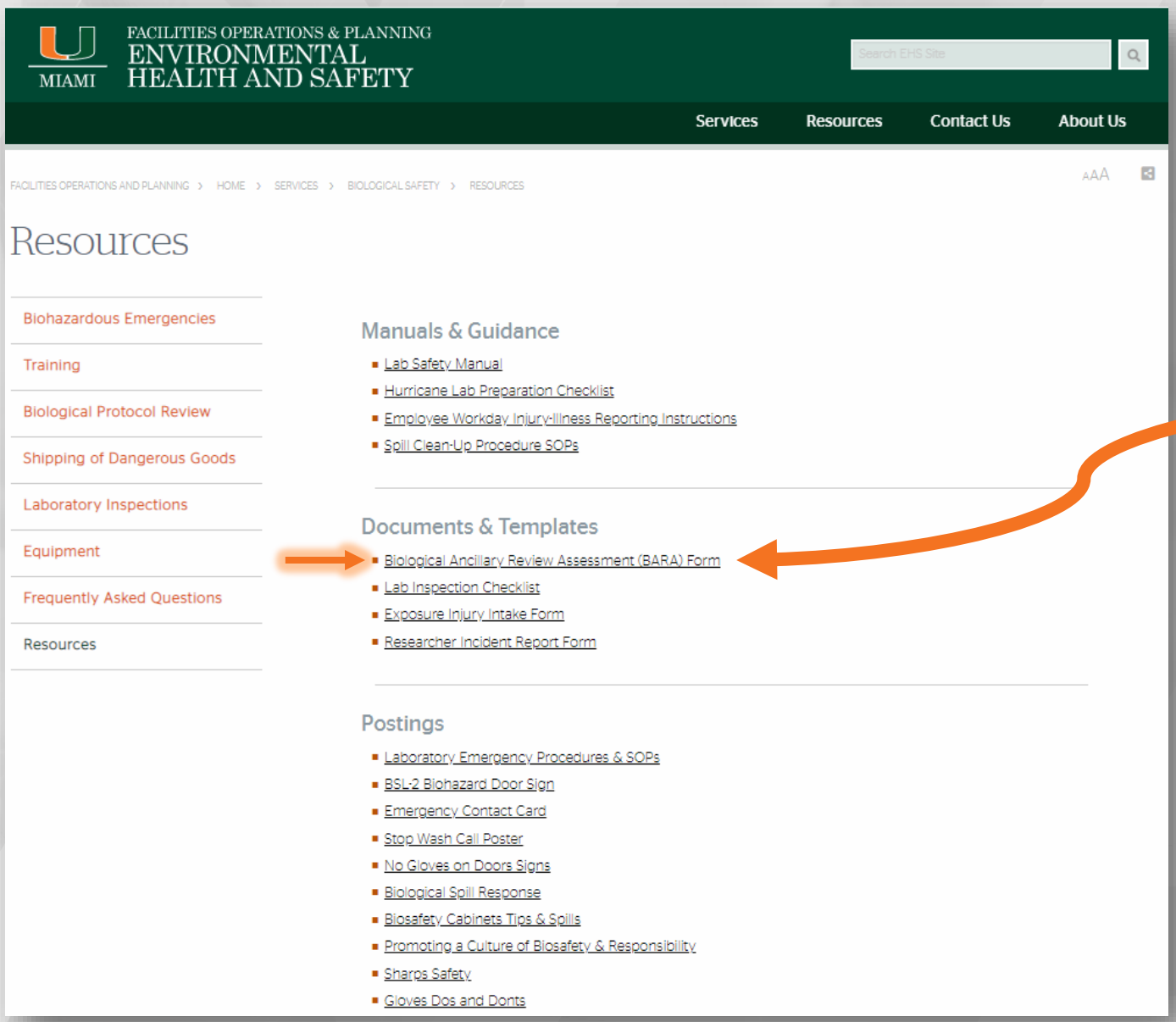
Biosafety Website





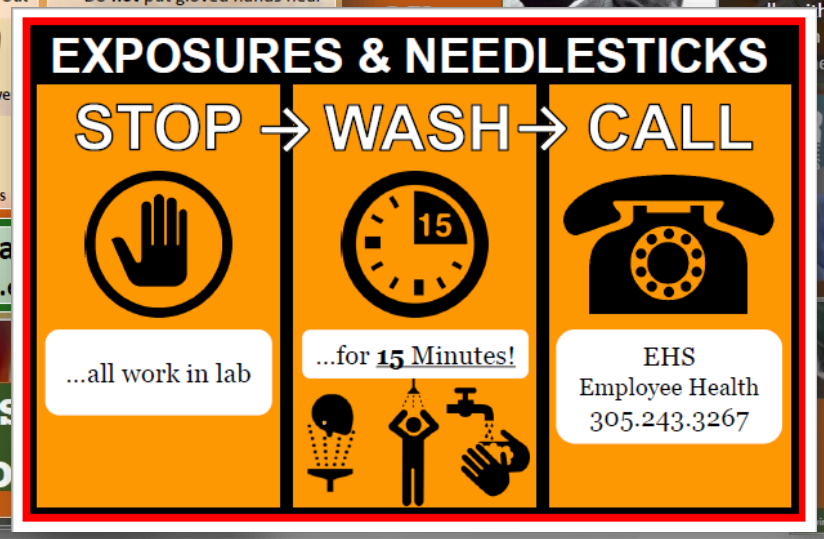
ehs.miami.edu/biosafety

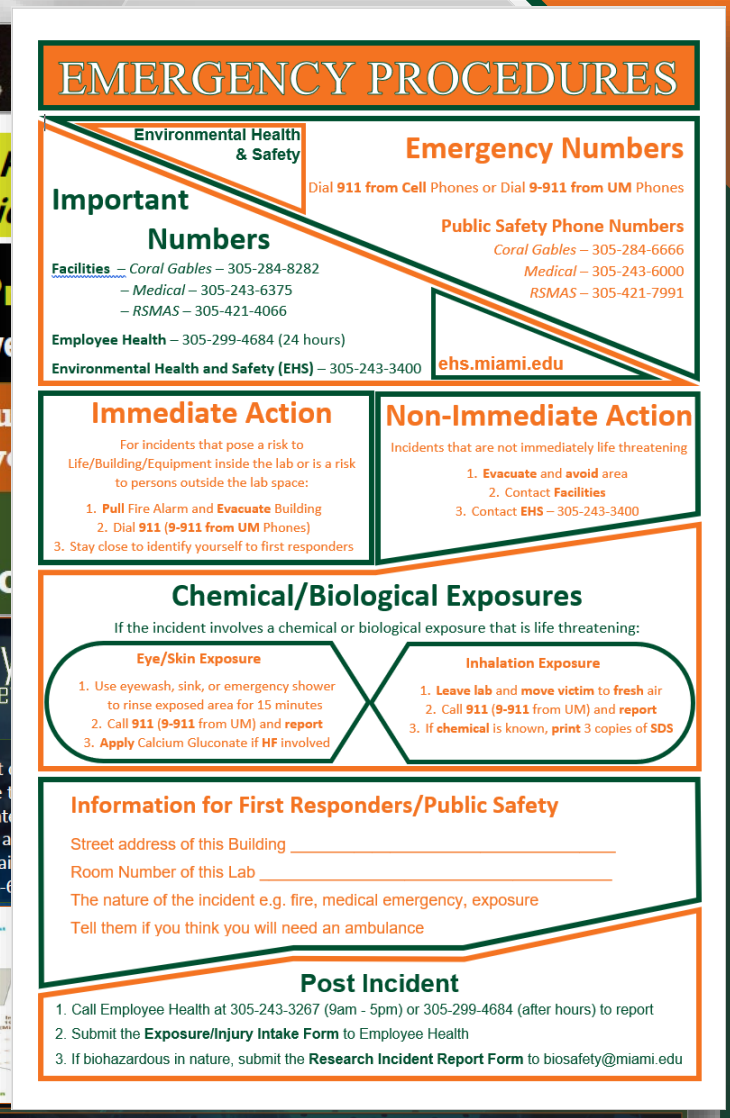
BARA Form Online

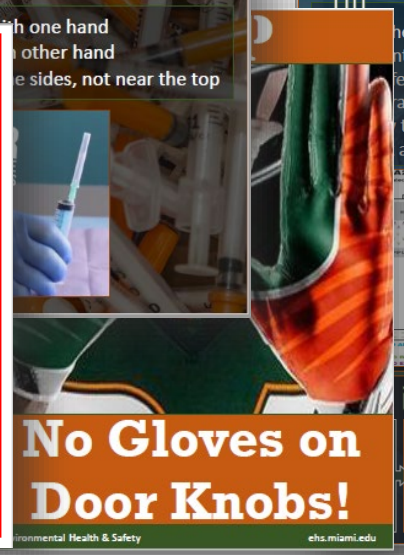


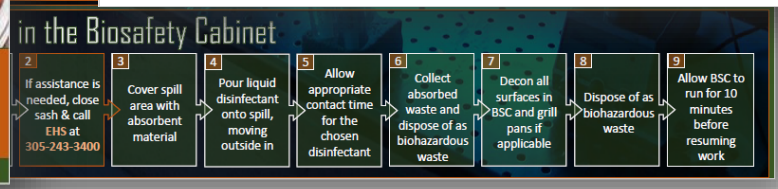
BARA Form

Signage & Postings









Questions

- Questions About a Pending Review:
  - BSO_Review@miami.edu
- Contact the Biosafety Office:
  - 305-243-3269
  - biosafety@miami.edu
- Visit our Website!
  - http://ehs.miami.edu
- Contact Shane directly:
  - 786-797-0387
  - sxg1519@miami.edu

Upcoming IRB Grand Round

February 19, 2026 (10-11 AM)

Guardians of the Data in the Digital Age

- Describe appropriate steps to ensure data security/ privacy/ confidentiality
- Identify potential vulnerabilities with data storage/ sharing
- Discuss AI in research & data analysis

Registration below

UNIVERSITY OF MIA
OFFICE of the VICE PROVOST
for RESEARCH & SCHOLARSHIP

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Thank you!

For additional information about today's presentation,

Please contact curatingconnection@miami.edu and reference

"IRB Grand Round 2026".

Continuing Medical Education (CME)

Below please find the claim credit link for session scheduled for 1.15.2026:
https://miami.cloud-cme.com/cme/ClaimCredit?P=850&eventid=18747

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2026 IRB Grand Rounds - Continuing Nursing Education (CNE) Credit Registration Form

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