

Set up for Success: Application, Reporting & System requirements

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Disclosure of Financial Relationships

Lory A. Hayes, PhD, CHRC, **Stewart MacIntyre**, III, Esq., **Rei Thompson**, MPA, CHC, CCEP, CHPC, **Kanchan Sakhrani** have no relevant financial relationships with ineligible companies to disclose.

The University of Miami Division of CME has mitigated all relevant financial relationships.

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Upcoming Change to Industry Clinical Research and Clinical Trial Submission Process- *D. Stewart MacIntyre III, Esq.*

From Disclosure to Determination Navigating COI Compliance: Requirements, Reviews, and Results- *Lory A. Hayes, PhD, CHRC*

**Clinical COI Policy and System Requirements and Processes: Considerations and Best *Practices*-
*Rei Thompson, MPA, CHC, CCEP, CHPC***

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Application, Reporting & System Requirements - *Kanchan Sakhrani*

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IRB Grand Rounds 2026 - Virtual Series

Time	Topic	SPEAKER
September 17, 2026, 10-11 am	Set up for Success: Application, Reporting & System requirements	RIC, ORA, COI/ RSP,HSRO
October 15, 2026, 10-11 am	Balancing Act: Biobanking, Big Data & Data Privacy	Data Brokers, AI, OTT,HSRO
November 19, 2026, 10-11 am	Ready, Set, Comply!	IITSU, RQA,CTD,HSRO
December 17, 2026, 10-11:30 am	Better Together: The Power of the Ancillary Network	EHS, Pathology, PRMC, HRSC, IBC,MCA, JHS,HSRO

Objectives

- Stay informed on recent policy updates
- Recognize key operating system requirements
- Adopt best practices to remain compliant

Upcoming Change to Industry Clinical Research and Clinical Trial Submission Process

D. Stewart MacIntyre III, Esq.

Executive Director, Office of Research Administration

Update on Current Structure

Medicare Coverage Analysis and Clinical Trials Budgeting Team, now called Clinical Trial Activation Team (CTAT), transitioned from ORA to MSOM Executive Dean for Research Office on March 1, 2026.

This structure will allow for closer alignment with the clinical research enterprise and reflects common practices across the industry.

Since March, ORA and the EDR office have continued to review process with the goals of improvement and streamlining.

What is Changing?

For industry-sponsored clinical research projects, departments will no longer submit an FP funding proposal in IBIS. They submit the agreement only. The change applies to industry clinical research and clinical trials, not to all grants.

Rollout:

- Piloting of this project was conducted in the month of August.
- Notification was sent to the research community of this change on Sept 1st with a full MSOM implementation starting October 1st.
- Research Symposium session hosted by MSOM and ORA on Sept 11th to introduce the new process.

How It Works?

- **Single Submission:** The agreement record will serve as the primary submission in IBIS; a separate funding proposal record will no longer be required.
- **Departmental Approval:** Departmental Approval of the submission will be tracked through an ancillary review prior to submission to ORA.
- **Budget Review Tracking:** Budget review and negotiation activities will be tracked through an ancillary review involving the Executive Dean for Research's office and CTAT.
- **Parallel Contract and Budget Review:** Contract negotiation and budget review will proceed simultaneously, helping reduce delays and improve coordination.
- **Workday Reporting Maintained:** Project activity and revenue reporting will continue to be captured in Workday.

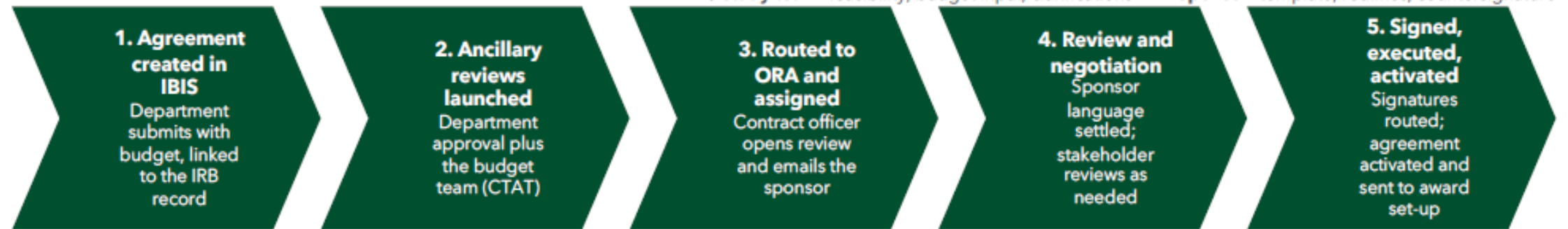
Benefits

This streamlined approach:

- Removes unnecessary proposal records for projects that do not have a true proposal stage,
- Improves transparency through visible workflow handoffs, and
- Helps accelerate agreement execution while maintaining compliance requirements.

New Process Flow:

Contract track



Budget track runs in parallel. The budget ancillary review opens at step 2 and stays open while the budget is negotiated. When the budget team closes it, that is the contract officer's signal that negotiation is complete and the agreement can move to signature.

One submission

The agreement is the submission – no separate funding proposal record for industry clinical research.

Visible hand-offs

Ancillary reviews keep budget status visible in IBIS, so no one waits on an email to know where things stand.

Faster to execution

Contract and budget advance together, and the executed agreement routes straight to award set-up.

Thank you!

If you have any questions regarding the Agreement Process, please contact the **Office of Research Administration** at MRA@miami.edu.

If you have any questions regarding the Budget/MCA Process, please contact the **Clinical Trial Activation Team (CTAT), EDRO** at CTATBudget@med.miami.edu.

From Disclosure to Determination Navigating COI Compliance: Requirements, Reviews, and Results

Lory Hayes

Director of Compliance & Research Security,
Research Security Officer

UM's Comprehensive Policy

Articulates that all Covered Persons, must

- Complete annual training (1st page of the disclosure form),
 - COI, Foreign Engagements*, Researcher-specific (*Research Security Training CBL delivered in ULearn)
- Disclose interests to UM on an annual basis, including:
 - Outside interests/activities irrespective of compensation (including non-compensated, consulting, gifts, royalties, travel, etc.) or type of entity (private, public, 501c3, professional associations, etc.)
 - Financial interests of spouse and dependent children related to UM responsibilities
 - Non-UM Scholarly Activities (e.g., teaching & research) and "C"-suite positions and fiduciary responsibilities
 - Financial interests in entities that do, or propose to do business with UM
 - Receipt of non-UM, "Other Support," and
 - Foreign affiliations/income/support
- Update for new interests within **30** calendar days
- Separate UHealth and Scholarly Activities sections

✓ Conflict of Interest, Conflict of Commitment, Foreign Influence, and Institutional Conflict of Interest Policy in Policystat



How Do I Achieve Compliance?

DISCLOSURE OF OUTSIDE INTERESTS

- Covered Persons must disclose through the University's online disclosure system, **UDisclose**.
- External study team members must disclose their interests through the **RedCap** *Interest Disclosure Form (IDF)*.

TRAINING

- Covered Persons must complete the **Foreign Influence** and **COI Training** within the **UDisclose System**.
- UM Employees must complete the **Research Security Training** through the **ULearn System**.
- Students must complete the **Research Security Training** through **CITI**.
- External study team members must complete the **COI Training and Research Security Training** within the **RedCap** *Interest Disclosure Form*.

STEP 1: Completing COI & Researcher-specific Training

UDisclose

≡ Validate Compare <<

Instructions and Policies

Entity Disclosure Information

Institutional Responsibilities

Foreign Engagement & Influence

Complete Disclosure Profile



Instructions and Policies

The University of Miami (UM) requires Covered Persons to complete a few simple steps in order to be compliant with UM's [Conflict of Interest \(COI\)](#), [Conflicts of Commitment](#), and [Foreign Influence Policy](#) and federal regulations.

The following steps are completed through this system.

- **Review and attest** to your understanding of the training below when you begin employment and on an annual basis.
- **Complete a Disclosure Profile** when you begin employment and on an annual basis. Even if you have no outside activities or interests with which you or an immediate family member has a relationship, you still need to complete the annual disclosure process.
- **Update** your Disclosure Profile **within 30 days** of acquiring or discovering a new outside activity or interest.
- Provide any additional information requested when the University reviews your Disclosure Profile.
- If a Management Plan is required for your disclosures, your agreement to the plan must be documented **prior to the release** of any related research funding.

Training and Education

Required Training Instructions

To fulfill the annual training requirements, please complete the following steps (*The PDFs referenced in this section are available for download under [Training Documents](#)*):

◀ Go to forms menu ▶ Print ▼ Help

1. **Review the Conflict of Interest (COI) Policy and Awareness PDF below.**
The [COI10 Training](#) document below outlines the University's Conflict of Interest (COI) policy and your responsibilities. Please read it carefully.
2. **Complete the Research Security Training (RST) course in ULearn.**
UM requires all [Covered Persons](#) to complete training on [Foreign Influence](#).
 - a. If you previously completed the PDF version of the RST that was available on your disclosure profile page between 12/31/24 and 10/24/25, you may confirm your completion by locating your name on the RST completion list in [DiscloserComplianceStatus - Power BI](#).
 - b. **For UM faculty, staff, and investigators who are employees:**
If you have not yet completed the RST within the past 12 months, please [ACCESS THE ONLINE RST COURSE VIA ULEARN BY CLICKING ON THIS LINK](#). (*Please make sure your pop-up blockers are disabled in order to proceed with this training.*)
 - The training should open in a pop-up window, and your ULearn transcript will appear in a new browser tab behind the pop-up window.
 - If this does not happen, you may be prompted to log into ULearn with your University credentials, and search for the course: **University of Miami Research Security Training**, and click on **Launch**.
 - Complete the RST with a passing (80% or higher) score, and then click "Exit" on the pop-up window to access your completion certificate for your records.
 - **IMPORTANT:** If you restart the training, the certificate of completion will only be available after you complete the session again.
 - c. **For Students and Non-UM Study Team Members:**
Students and Non-UM study team members are required to complete the RST in the [CITI PROGRAM VIA THIS LINK](#) to satisfy this requirement.
3. **Review the Researcher-specific Guidance PDF below.**
If you are assigned to a study team (in IBISResearch IRB or Grants), you will have access to the [Researcher Training](#) document that provides additional information tailored for investigators regarding research compliance and related disclosure expectations.

IMPORTANT: After completing the steps above, return to the UDisclose System and certify your understanding by checking the acknowledgement box below. This certification must be completed **annually** in order to remain in compliance.

Training documents:

- 📄 COI10 training(0.09)
- 📄 Researcher training(0.08)

...

Open and read training documents



Step 2: Research Security Training (RST)

UM Employees: Complete Research Security Training course in **ULearn**.



- The training should open in a pop-up window, and your ULearn transcript will appear in a new browser tab behind the pop-up window.
- If this does not happen, you may be prompted to log into ULearn with your University credentials, and search for the course: **University of Miami Research Security Training**, and click on **Launch**
- Complete the RST with a passing (80% or higher) score, and then click **"Exit"** on the pop-up window to access your completion certificate for your records.
- **IMPORTANT:** If you restart the training, the certificate of completion will only be available after you complete the session again

Students: Complete Research Security Training course in **CITI Program**.

- Complete course entitled **"Research Security Essentials: Training for UM Students & External Team Members"** with a passing (80% or higher) score.

For additional questions or assistance with the RST, please contact:
Phone: 305-243-6339 or **RSIE@miami.edu**



STEP 3: Confirming Training Completion (User)

Once all training is completed, return to the “Instructions and Policies” page in UDisclose and select the check box certifying that all required training has been completed. **This will satisfy the annual training requirement.**



IMPORTANT: After completing the steps above, return to the UDisclose System and certify your understanding by checking the acknowledgement box below. This certification must be completed **annually** in order to remain in compliance.

Training documents:

 [COI10 training\(0.09\)](#) ...

 [Researcher training\(0.08\)](#) ...

Your training has lapsed. The date on which you last completed your training is:
8/30/2023

1. * I certify that I have read and understand the training document above:  ☒



Confirming Training Completion (Admin)

As an administrator, you can confirm individual or departmental COI and RST training completion within the PowerBI [DiscloserComplianceStatus](#) report

Helpful Hint: Before starting a new search, ensure that all filters are cleared.

COI Training Compliance:

Discloser Compliance

Completed Research Security Training

Instructions

Employee ID

First Name

Last Name

Supervisory Organization

IBIS Cost

Academic Unit Rank

Academic Unit Hierarchy

Academic Unit

Discloser Profile Status

WD Cost Center

Please reference the **Instructions tab** (bottom left) for details on how the **Training Acknowledged** and **Last UDisclose Training Date** appears in the columns.

Employee ID	CNumber	First Name	Middle Name	Last Name	Discloser Profile Status	Disclosure Profile Completed in last 12 Months?	Last Disclosure Profile Submitted	Training Acknowledged in UDisclose	Last UDisclose Training Date
000000A	DMINZZ	System		Administrator	Action Required	No		No	

RST Training Compliance:

Discloser Compliance

Completed Research Security Training

Instructions

Source

Last Name

First Name

Cost Center / Department

Source	EmployeeID	CNumber	First Name	Last Name	Title	AccountDisabled	Completed Date	Status	CostCenter_Department
ULearn						No	6/23/2026 5:30:00 PM	Completed	MSOM - Pathology - Research
ULearn			Davis		In (A)	No	6/23/2026 5:13:00 PM	Completed	MSOM - Neurological Surgery GME a Education

Non-UM External Team Members

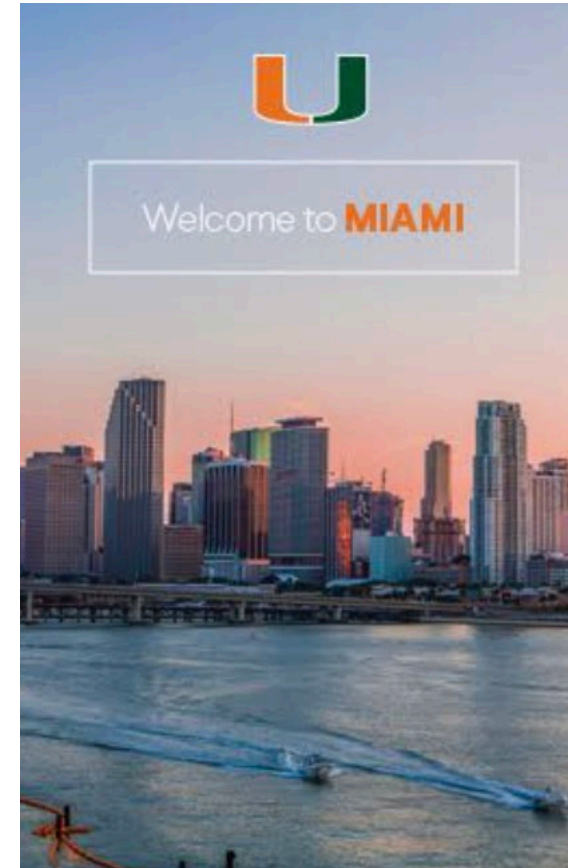
Disclosure Requirements:

Non-UM team members must complete the [Interest Disclosure Form \(IDF\)](#) through [RedCap](#).

- Open a COIC Ancillary Review (AR) on the study in the IBIS system indicating that an external team member will be participating on the project.
- Provide the external team member's full name and email address within the AR workspace.
- DSAM will provide the external team member the link to complete the IDF via email.

Training Requirements:

- The [IDF](#) contains PDF files with the necessary [COI training](#) and [Research Security Training](#).



Ancillary reviews process update

- **DSAM Ancillary Reviews:**
- Now have two options in IBISResearch
 - DSAM – COI
 - DSAM – Research Security Program (RSP)
- **When to use**
 - COI – forms for disclosures, OCOI, non-UM team members, etc
 - RSP – forms asking about M/FTRPs, Research Security Training, etc.
- **Enhances DSAM's**
 - Ability to respond
 - Response time
 - Tracking of issues for metrics
 - Enhances quality of our customer service



Add Ancillary Review

1. * Select either an organization or a person as reviewer:

Organization: conflict ...

Person: ☒ Organization Org Parent
IRBAC007 **Conflict of Interest Committee (COIC)**

2. * Review type:

3. After-the-Fact- ATF
Compliance COI
Co-PI

4. Cost Share
Department Chair/Center Director
Disclosures & Scholarly Activities Management (DSAM) - COI
Disclosures & Scholarly Activities Management (DSAM) - Research Security
DURC/PEPP

An orange arrow points from the text 'DSAM – COI' in the list to the 'Disclosures & Scholarly Activities Management (DSAM) - COI' option in the review type dropdown.



Add Ancillary Review

1. * Select either an organization or a person as reviewer:

Organization: Research security ...

Person: ☒ Organization Org Parent
RSIE0001 **Research Security Ancillary Group**

2. * Review type:

Disclosures & Scholarly Activities M:

3. After-the-Fact- ATF
Compliance COI
Co-PI

4. Cost Share
Department Chair/Center Director
Disclosures & Scholarly Activities Management (DSAM) - COI
Disclosures & Scholarly Activities Management (DSAM) - Research Security
DURC/PEPP

An orange arrow points from the text 'DSAM – Research Security Program (RSP)' in the list to the 'Disclosures & Scholarly Activities Management (DSAM) - Research Security' option in the review type dropdown.

Check Disclosure Status in IRB

IRB > Submissions > fads

Pre-Submission

Last updated: 3/24/2023 1:57 PM

Next Steps

Edit Study

Printer Version

Submit

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

20230331: fads

Principal investigator: Lory Hayes

Submission type: Initial Study

Primary contact: Lory Hayes

PI proxies:

IRB office: HSRO

IRB coordinator:

Pre-Submission

Pre-Review

IRB Review

Post-Review

Review Complete

Clarification Requested

Clarification Requested

Modifications Required

History

Funding

Contacts

COI

Documents

Reviews

Snapshots

CITI Information

Team Members without Certifications

History

Funding

Contacts

COI

Documents

IRB Assignment Details

Reviews

Snapshots

CITI Information

Most Recent Certifications

Filter by ?

Discloser First N

Enter text to search

Q

+ Add Filter

X Clear All

Discloser First Name

Discloser Last Name

Date Created

Status

Last Profile Update Date

Determination

Determination Date

Management Plan

Plan Status

Status Column Meaning

ng Contacts COI Documents IRB Assignment Details Reviews Snapshots CITI Information

ifications

Discloser First N ▼ Enter text to search 🔍 + Add Filter ✕ Clear All

Discloser Last Name Date Created Status Last Profile Update Date Determination Determination I

Awaiting Profile Update	* Notify team member to complete Disclosure Profile in UDisclose
No Review Required	* No action required by study team member; * No rationale to contact DSAM
Under Review	* No action required by study team member; * Significant interests have been disclosed; ** Wait 3 days from the "Entered IRB" date before contacting DSAM
Committee Review	* No action required by study team member; * Pending review at upcoming COIC meeting, please contact DSAM for more information
Review Complete	* No action required by study team member; * No rationale to contact DSAM

KEY:

No action required by study team or DSAM

Action required by team member

Action required by DSAM

ICF Disclosure Required

Determination Column Meaning

Documents

IRB Assignment Details

Reviews

Snapshots

CITI Information

arch

Q

+ Add Filter

✕ Clear All

Date Created

Status

Last Profile Update Date

Determination

Determination Date

Management Plan

No Review Required	* No action required by study team member; * No rationale to contact DSAM
Unrelated	* No action required by study team member; * No rationale to contact DSAM
No Conflict	* A related interest exists, but is not a COI; ICF Disclosure is required
Requires Management Plan	* ICF Disclosure is required (See plan status column)

KEY:
No action required by study team or DSAM
Action required by team member
Action required by DSAM
ICF Disclosure Required

Management Plan Status Meaning

apshots	CITI Information				
					
Last Profile Update Date		Determination	Determination Date	Management Plan	Plan Status

Drafting:	* No action required by study team member; * Wait 3 days after the "Determination Date" to contact DSAM for an update	
Pending Discloser Acceptance:	* Notify team member to accept plan within UDisclose System	
Active:	* No action required by study team member; * No rationale to contact DSAM	ICF Req'd
Satisfied	* No action required by study team member; * No rationale to contact DSAM	

KEY:
No action required by study team or DSAM
Action required by team member
Action required by DSAM
ICF Disclosure Required



CONTACT US!

For questions regarding COI,
disclosures, and utilizing the
UDisclose System

Contact DSAM:

Email: DSAM@miami.edu
Help Line: 305-243-0877

For technical assistance or questions
regarding access to the UDisclose System

Contact OVPRS Help Desk:

Email: OVPRSHelpDesk@miami.edu
Help Line: 305-243-2314

For questions regarding Foreign
Engagement or Research Security
Training

Contact RSIE:

Phone: 305-243-6339
Email: RSIE@miami.edu

Clinical COI Policy and System Requirements and Processes: Considerations and Best Practices

Rei Thompson

Director of Compliance, Conflicts of Interest & Special Projects

Clinical COI Policy Requirements and Processes

- Per policy, UHealth Covered Persons (i.e. UMMG faculty, UHealth clinical providers, etc.) must disclose financial interests in, and activities with, entities relating to institutional responsibilities, or with entities that do or propose to do business with UM on an annual basis.
- UHC regularly reviews disclosures entered in UDisclose by UHealth Covered Persons based on pre-established parameters.
- UHC investigates any potential COIs based on review of the disclosures in UDisclose, or via allegations received, or identified via auditing & monitoring activities. Based on confirmed findings, UHC may escalate to UHealth Leadership, including any recommended corrective actions.
- UHC reviews Pre-Approval Requests (PARs) submitted via UDisclose by UHealth Covered Persons for newly proposed, compensated consulting activities.

Clinical COI Requirements and Processes

- Consulting is permitted, provided that the faculty's full-time obligation to the University is met.
- UMMG Faculty and UHealth clinical providers must submit proposed, fee-for-service consulting agreements as a **Pre-Approval Request (PAR)** via UDisclose for UHC review to meet policy and regulatory requirements. Department Chair is the ultimate approval authority in the process.
- Written contract must outline the specific services, compensation, and basis for payment.
- Consulting services must be primarily **scientific and educational** in nature and not constitute marketing or promotion.
- Consulting services cannot be materially similar or the same as UM responsibilities
- Lecture content must be determined by the faculty speaker, not the vendor/sponsor, and it must be clear that the content reflects the views of the lecturer, not UM or UMMG.
- The Personal Services Safe Harbor to the Federal Anti-Kickback Statute requires that compensation be fair market value.

PAR Review Workflow

- 1) UHealth Covered Person submits a PAR in UDisclose.
- 2) UHC reviews and provides initial recommendations and contract revisions.
- 3) UHealth covered person responds with updates from external entity on UHC recommendations/contract revisions.
- 4) Process may be repeated until policy/regulatory requirements are met.
- 5) UHC submits request to Division Chief/Chair for final determination
- 6) UHC submits determination in UDisclose and the UHealth covered person is notified. UHealth covered person updates their disclosure upon receipt of compensation.

Why are PARs required for clinical faculty?

- ❖ UHC reviews private fee-for-service consulting agreements to **mitigate potential regulatory risk** for the individual clinical provider and institution.
- ❖ **AKS and Stark violations** incur **heavy criminal and civil penalties**. Such violations could implicate UHealth as an entity requesting bills from the government.
- ❖ **Risk:** If a clinical provider engages in a relationship with an outside entity that implicates Stark/AKS **without the protection of a safe harbor/exception**, the compensation that is exchanged between the parties may be seen as an **inducement** to refer or arrange for the referral of business that is reimbursable to the government.
- ❖ **RISK MITIGATION:** Adherence to policy requirements and regulatory protections.

Clinical COI Best Practices

- ❑ UHealth clinical providers are **permitted** to engage in activities and/or relationships with outside entities that do not interfere with their institutional responsibilities and conduct such activities only after receiving approval and disclosing appropriately.
- ❑ As part of the PAR and regular auditing/monitoring processes, UHC may request ancillary review by stakeholder departments and flag certain relationships to the Purchasing COI and/or Research Committees for further review in order to support a holistic approach toward compliance efforts across the system.

UHealth Compliance Resources

- Rei Thompson, Director of Compliance, COI
rxt1493@miami.edu
- Cristina Garcia-Delgado, Executive Director
c.delgado16@miami.edu
- Julie Dean, Chief Compliance & Privacy Officer
julie.dean@med.miami.edu

<https://umiamihealth.org/en/uhealth-compliance>
- Compliance Help General Inbox:
compliancehelp@miami.edu

SET UP FOR SUCCESS

Application, Reporting & System Requirements

IRB Grand Rounds 2026 | September 17, 2026

Kanchan Sakhrani
Supervisor, Business Systems Analyst
Research Intelligence & Capacity (RIC)



**Practical system habits
that protect data integrity,
support compliance, and
reduce rework.**

Disclosure & AI use notice

Required presenter disclosures for this educational activity

FINANCIAL DISCLOSURE

No relevant financial relationships with ineligible companies to disclose.

AI USE NOTICE

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All content was reviewed and edited by the presenter. No PHI, PII, confidential learner data, or non-approved sensitive information was entered into public AI tools.

What success looks like

Three habits to carry into every IRB submission and follow-on activity

1

Enter it right

Complete, current, and accurate study information at the point of submission.

2

Connect it

Keep related records aligned across IBISResearch, Velos, REDCap, e-Regulatory Binders, and downstream reviews.

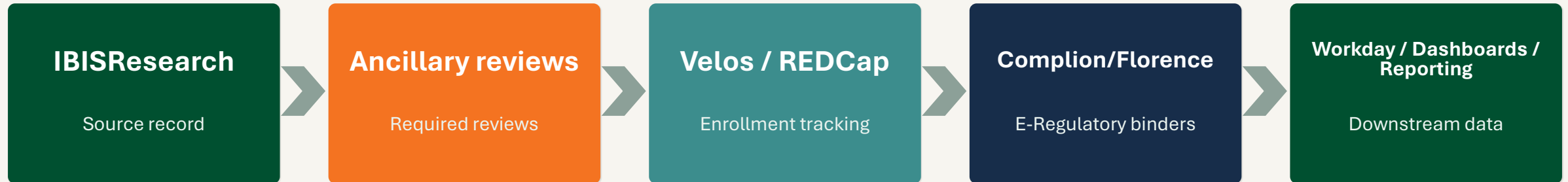
3

Maintain it

Update approvals, enrollment, personnel, and study status throughout the full study lifecycle in a timely manner.

The IRB record is part of an ecosystem

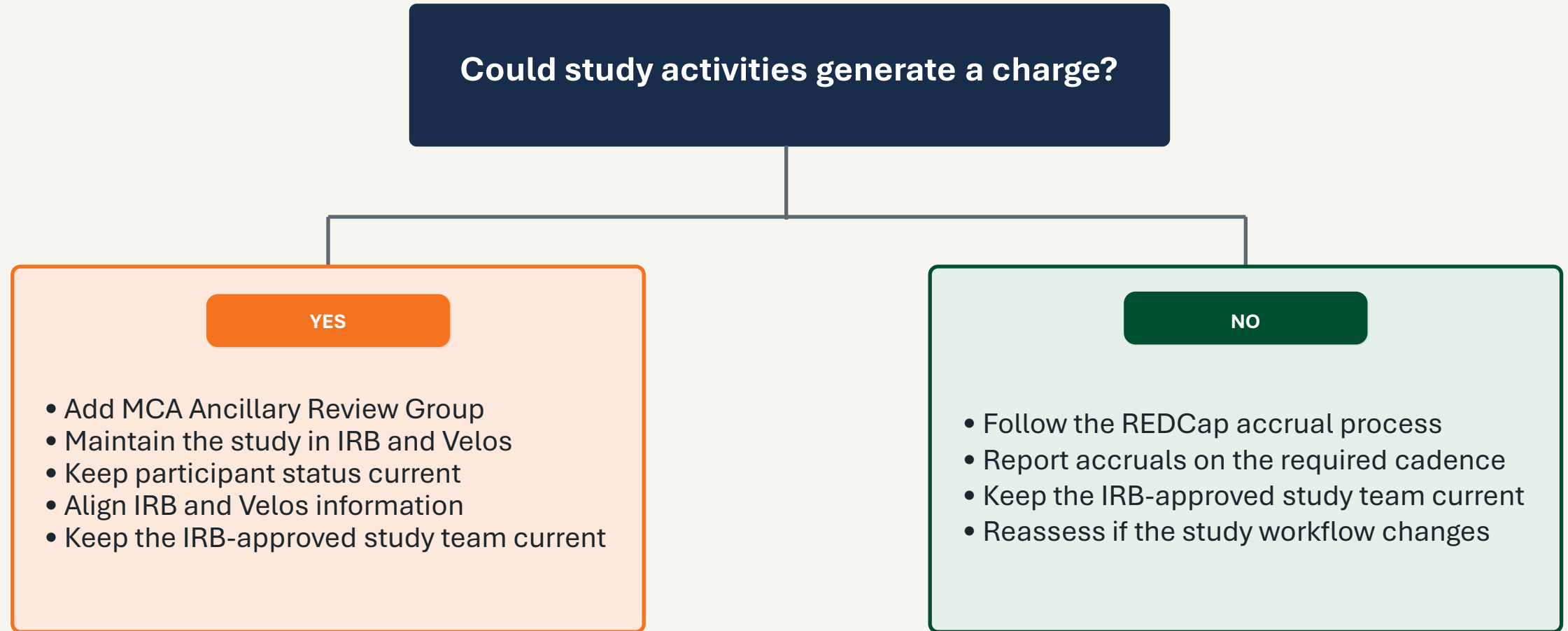
A single answer can trigger work in multiple systems and offices



Best practice: Treat each field as shared data, not a one-time form answer. When the study changes, update the source record and every required downstream system as applicable. Integrations exist to help reduce the administrative burden

Answer the billing question by the actual study workflow

The answer determines the enrollment-tracking path



Clinical Trial Management and Participant Enrollment and Tracking Policy

Enrollment Tracking Using REDCap



External IRB studies still require local record stewardship

The reviewing IRB may be external, but the UM record must remain usable and current

1

IRB of record

Know which IRB holds regulatory oversight and where authoritative approvals live.

2

Current documentation

Upload external approvals and supporting letters in the expected local document location.

3

Local status

Maintain accurate local status, study team, and reporting information.

4

Lifecycle follow-up

Do not assume the UM record will automatically lapse or close when an external approval changes.

When you cannot quickly determine the current approval, status, or responsible study team, the record is not operationally ready.



Close the loop, not just the IRB study

Study closure is a coordinated data and operations decision

1

Confirm

No ongoing participant interaction or new identifiable data access

2

Reconcile

IRB status, participant status, accrual reporting, binder documents

3

Document

External letters, final approvals, closure rationale, and responsible owner

4

Close

Use the approved process and notify downstream teams when needed

If identifiable data access or participant interaction continues, confirm the appropriate IRB status before closing.

Five practices that prevent avoidable rework

Use this as a pre-submission and follow-on submission checklist

01 Use current people and organizations

Select valid personnel, sponsors, funding sources, and account information.

02 Name documents consistently

Make the document type, version, and date easy to identify.

03 Link related records

Use available relationship activities so offices can see the complete project.

04 Update systems promptly

Keep follow-on submissions, participant statuses, and approvals synchronized.

05 Ask before guessing

Use the OVPRS Help Desk, HSRO Office Hours, or the responsible office for ambiguous scenarios.

[Get Help | Research and Scholarship | University of Miami](#)



A 60-second record readiness check

Before you click Submit, can the next reviewer answer these questions?

- ✓ Who is responsible for the study?
- ✓ What is the current protocol and approval?
- ✓ Which systems must track enrollment?
- ✓ Are related grants, agreements, and reviews connected?
- ✓ What changed, and is the change reflected everywhere in a timely manner?

READY

The record is
complete,
connected, current,
and understandable
without side
conversations.

That is system
readiness.

When in doubt, use the right support path

Resolve ambiguity before it becomes a data-quality or compliance issue

RIC / OVPRS Help Desk

System access or technical issue

Submit a support request with the study ID, screen, and exact error.

HSRO

IRB interpretation or regulatory question

Ask about review status, external IRB documentation, closure, and regulatory requirements.

Velos et al. working group

Enrollment or clinical- trial operations

Confirm NCT, participant tracking, MCA, CRRC monitoring, and cross-system reconciliation.

Questions?

Continuing Medical Education (CME)

Below please find the claim credit link for session scheduled for 9.17.2026: <https://miami.cloud-cme.com/cme/ClaimCredit?P=850&eventid=18755>



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



The University of Miami School of Nursing and Health Studies is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.



Upcoming IRB Grand Round

October 15, 2026 (10-11 AM)

Balancing Act: Research Integrity and Innovation

1. Recognize data sensitivity and its regulatory implications
2. Examine data in action—its power and impact
3. Safeguard data in motion to ensure security and compliance

Speakers: Data Broker, IT, OTT

Registration:



**Please use your Miami email address
when submitting your request.**

Thank you!

For additional information about today's presentation,

Please contact curatingconnection@miami.edu and reference

“IRB Grand Round 2026”.