VPRS Administrative Updates

February 25, 2022

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Agenda

- Contracts with Urgent Deadlines
- Pre-Award Contracts Team Reorganization
- SF424
- ORA Contact Person
- Move to Login.gov
- IRB Re-Implementation
- AAALAC Accreditation
- RIC Office Hours-Complion Support
- Other Upgrades/Items of Note
- New UDisclose
- UM's Conflicts of Interest Policy & the New UDisclose Sys.
- New MSOM Company in Workday
- Childcare Cost on NRSA Awards
- Travel on State of Florida Awards
- Capital Equipment Threshold
- Effort Certifications

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Contracts: Reminders and Best Practices

Laura Kozma

*Associate Vice President
Research Administration*

Contracts with Deadlines

Deadlines

- ORA makes every effort to honor *sponsor's* hard deadlines

- Include the deadline and documentation about the deadline

- Communicate internal requests for deadlines – ORA will try to accommodate based on other deadlines and outstanding contracts

Contracts Dos and Don'ts

Dos and Don'ts
- *Do* upload a copy of the sponsor's email
- *Do* provide the name and email contact at the sponsor
- *Do* make sure the contract matches the FP (inclusion of human subjects, etc.)
- *Do not* sign the agreement
- *Do not* submit to ORA until you have all required documents and information
- *Do not* duplicate documents already provided to ORA/in the FP

Other Best Practices
- Provide the agreement in Word whenever possible
- Ensure the agreement is in English or includes an English translation
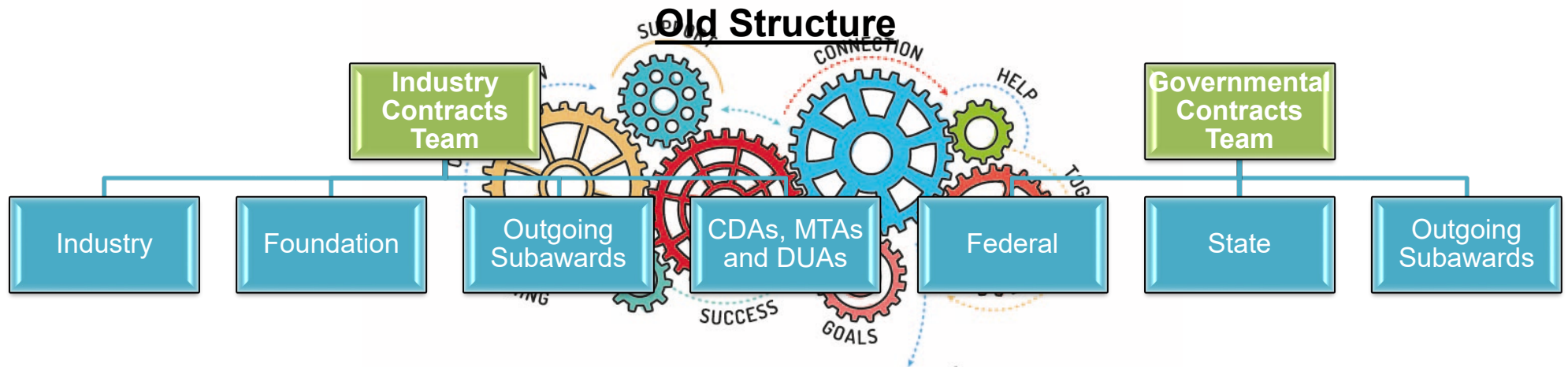
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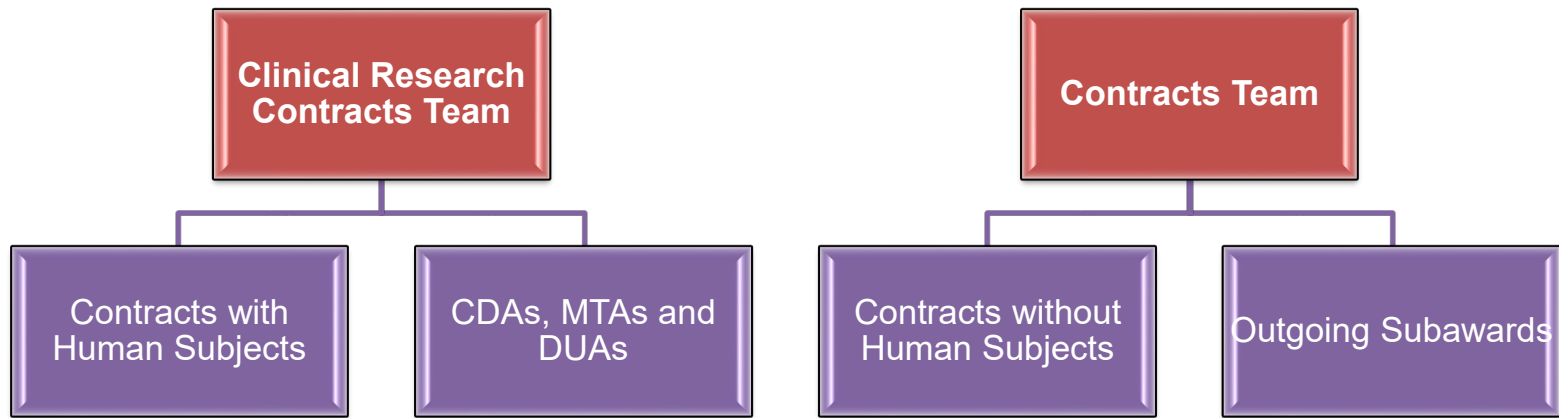
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Pre-Award Contracts Team Reorganization

Laura Kozma

*Associate Vice President
Research Administration*

Pre-Award Contract Team Reorganization

Old Structure

- **Industry Contracts Team**
  - Industry
  - Foundation
  - Outgoing Subawards
  - CDAs, MTAs and DUAs
  - Federal
- **Governmental Contracts Team**
  - State
  - Outgoing Subawards

New Structure

- **Clinical Research Contracts Team**
  - Contracts with Human Subjects
  - CDAs, MTAs and DUAs
- **Contracts Team**
  - Contracts without Human Subjects
  - Outgoing Subawards

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SF424

K. Brandon Strickland, J.D.
Executive Director, Research Administration

SF424

Unable to set display order on Research & Related Senior/Key Person Profile (Expanded) V4.0 and Project/Performance Site Location(s) V4.0 forms

HURON

Problem - The display order can be modified on the Research & Related Senior/Key Person Profile (Expanded) V4.0 form and the Project/Performance Site Location(s) V4.0 form, but the modified display order is not being saved.

Known Issue - This has been identified as a bug and will be addressed in SF424 10.4.0.

SF424

Modify display order in the Research & Related Senior/Key Person Profile (Expanded) V4.0 form

HURON

1. In an SF424 application that includes the Research & Related Senior/Key Person Profile (Expanded) V4.0 form, navigate to the form.
2. Enter at least 3 additional senior/key persons.
3. Modify the display order and save.
4. The modified display order should be saved, but it is not saving in SF424 10.3.0.

▼ PROFILE - Senior/Key Person 1-99

PROFILE - Senior/Key Person(s)

+ Add

	Last Name	First Name	Department	Title	Project Role	Project Role Category	Bio Sketch	Current & Pending Support	Display Order	
☑ Update	Davidson	Gina	Research	Technician	Technician		Yes	No	99.00	✇
☑ Update	Lambert	Ava	Research	Grants Specialist	Faculty		Yes	No	99.00	✇
☑ Update	Myers	Jordan	Research	Study Staff	Faculty		Yes	No	99.00	✇

ORA Contact Person

K. Brandon Strickland, J.D.
Executive Director, Research Administration

ORA Contact Person

Move to Login.gov

K. Brandon Strickland, J.D.

Executive Director, Research Administration

Move to Login.gov

Beginning February 21, 2022, all non-federal Grants.gov users will be required to use Login.gov credentials to sign in to Grants.gov.

- This change to the Grants.gov sign-in process improves user security and complies with Executive Order 14028, improving the nation's cybersecurity.

- Login.gov allows users to access multiple government websites, including Grants.gov, with a single username and password.

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Move to Login.gov

To prepare for this transition and link your Grants.gov account with Login.gov, you can follow this three-step process:

1. Click the Login.gov button on the Grants.gov login screen.
2. Complete the login process on Login.gov using your Login.gov username (an email address) and password, or create an account.
3. You will then be directed back to Grants.gov to log in with your Grants.gov username and password.

This will complete the account linking process.

Grants.gov will remove the username/password login option as of February 21, 2022

IRB Re-Implementation

Allen Mora

Executive Director, Research Intelligence & Capacity (RIC)

IRB SaaS Implementation

Goals

- High degree of **interoperability** with existing UM systems
- Ability to conduct, manage, and support the processing of sIRB reviews for **multi-site studies**
- Facilitate **collaboration** between UM faculty, staff, central offices, and external institutions
- Maintain **compliance** with federal regulations, UM policies, and AAHRPP
- Further the larger strategic plan for **Research Administration Systems**

IRB SaaS Implementation - Personnel

Governance

Erin Kobetz, Executive Sponsor
Frank Azuola, Executive IT Stakeholder
Johanna Stamates, Executive Stakeholder

Project Team

Allen Mora, Project Sponsor
Amanda Rodriguez, Project Manager
Kanchan Sakhrani, Business Analyst
Aymee Ortiz, Programmer/SME

Core Team

Adriana Robledo, HSRO SME

Key Stakeholders

Human Subjects Research Office – Kenia Viamonte and Cindy Gates
Disclosures & Scholarly Activities Management- Lory Hayes
Office of Research Administration - Laura Kozma
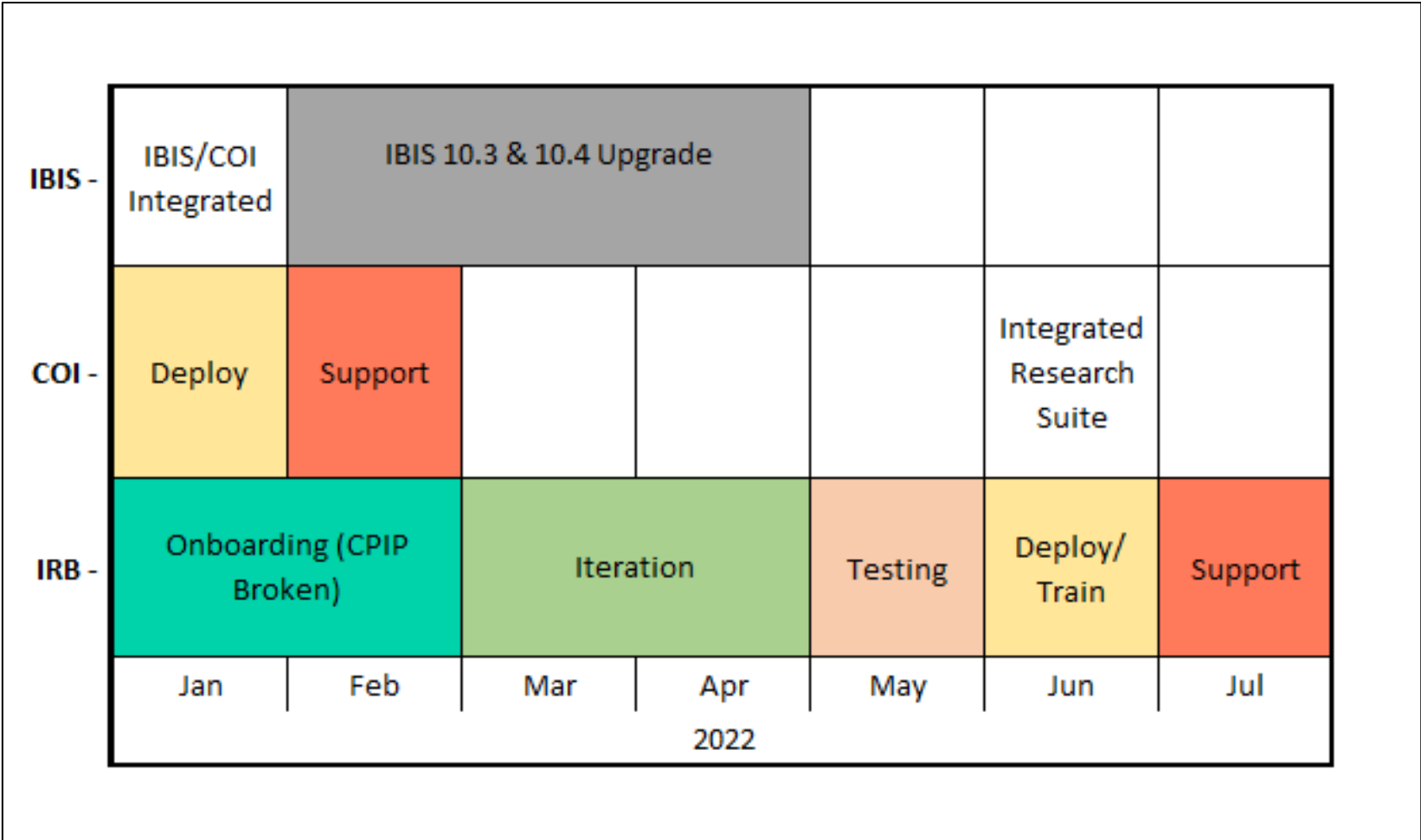Ancillary Review Committees

Project Champions

Key faculty and staff TBD

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IRB Project Timeline

	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
IBIS -	IBIS 9.2 Upgrade						IBIS 10.0 Upgrade								IBIS/COI Integrated	IBIS 10.3 & 10.4 Upgrade					
ECC -			ECC Upgrade																		
COI -				Pre Work & Discovery		Process Analysis & Transformation *UM only*		Onboarding		Iteration				Testing/ Training	Deploy	Support				CPIP Restored	
IRB -				Discovery		Draft/Review Deliverables		Steering Decision					HRPP Toolkit		Onboarding (CPIP Broken)		Iteration		Testing	Deploy/ Train	Support
	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
	2020		2021												2022						

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IRB Project Timeline

	Jan	Feb	Mar	Apr	May	Jun	Jul
IBIS -	IBIS/COI Integrated	IBIS 10.3 & 10.4 Upgrade					
COI -	Deploy	Support				Integrated Research Suite	
IRB -	Onboarding (CPIP Broken)		Iteration		Testing	Deploy/ Train	Support

2022

AAALAC Accreditation

Allen Mora

Executive Director, Research Intelligence & Capacity (RIC)

AAALAC International Reaccreditation Visit Scheduled for March 14-17

AAALAC International Accreditation

AAALAC International: A private, non profit organization that promotes humane treatment of animals in science through voluntary accreditation and assessment programs.

UM is assessed for reaccreditation by [AAALAC International](), every three years.

A multidisciplinary team will visit our facilities, review our documentation, and interact with faculty, staff and students doing work on animal research projects.

UM is one of nearly 1,000 universities, hospitals, government agencies and other research institutions in 49 countries to have earned AAALAC accreditation, demonstrating our commitment to responsible animal care and use.

Participation is voluntary and occurs in addition to complying with the local, state and federal laws that regulate animal research.

The University is proud to earn this accreditation and places high value on its continued maintenance.

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Why is AAALAC Accreditation important?

- It represents quality
- It promotes scientific validity
- It provides assurance in a global marketplace
- It demonstrates accountability
- It stimulates continuous improvement
- Some funding agencies (e.g., DOD) will provide funding only to facilities with AAALAC approval

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How are we preparing?

Group meetings *Wednesday, February 16, 2022, and Tuesday, March 1, 2022, at noon.* Last chance Q&A *Monday, March 7, 2022*

- To provide information on what to expect during the four days they are at UM.

- It is required that at least one representative from each laboratory attend one session, but entire research teams are welcome.

- Join Zoom Meetings

- https://us02web.zoom.us/j/85708261081?pwd=ZmY4elZJYjRybkhpNGdhZ1l5ZUZTQT09

- Meeting ID: 857 0826 1081

- Passcode: 568491

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RIC Office Hours-Complion Support

Allen Mora

Executive Director, Research Intelligence & Capacity (RIC)

RIC Office Hours – Complion Support

RIC office hours: Wednesdays from 1:00pm – 2:00pm

- Informal Q & A session to address questions, issues, requirements, and wish lists
- Stay as short or long as you would like

1-2pm

Use of E-Binder For FDA-Regulated Studies

Policy to use Complion as e-binder for all FDA-regulated studies

Current Status: *Active*   Policy Stat ID: 9930092

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Origination:	*04/2021*
Effective:	*06/2021*
Last Approved:	*06/2021*
Last Revised:	*06/2021*
Next Review:	*06/2023*
Owner:	*Helen Miletic: Executive Director, Research Compliance*
Area:	*Research Compliance and Quality Assurance*
References:	
Applicability:	*University of Miami System-Wide*

Use of Electronic Regulatory Binders in FDA-Regulated Research

PURPOSE:

The purpose of this policy is to streamline the organization and retention of regulatory records in FDA-regulated studies conducted at the University of Miami, through the use of the electronic regulatory binder system, Complion™.

SCOPE:

This policy applies to all researchers at the University of Miami who are conducting FDA-regulated human subject research, including industry-sponsored studies, federally-funded studies, and Investigator-initiated studies conducted under an Investigational New Drug/Investigational Device Exemption (IND/IDE) application.

POLICY:

It is the policy of the University of Miami that all new FDA-regulated studies submitted to the Office of Research Administration (ORA) on or after June 1st, 2021 must use the Complion™ system as their electronic regulatory binder.

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Other Upgrades/Items of Note

Allen Mora

Executive Director, Research Intelligence & Capacity (RIC)

Other Upgrades/items of note

- Topaz upgrade – March 2022

- Velos upgrade – May 2022

- Complion upgrade – 2/3/2022

- RedCap upgrade – February 2022

- Hyland 21 CFR Part 11 Validation – May 2022

New UDisclose

Allen Mora

Executive Director, Research Intelligence & Capacity (RIC)

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UDisclose

- System live 1/24/2022
- Only one disclosure per year for Researchers
- Expanded population

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Covered Persons Subject to the Policy

Inclusive of a broad spectrum of the UM community

- University Officials
- Faculty and academic appointees including:
  - Voluntary, full/part-time, visiting scholars
- Graduate and foreign students
- Postdoctoral associates
- Volunteers
- Employees in key stakeholder departments

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Covered Persons Subject to the Policy

- UMMG and UHealth employees including:
  - All UMMG faculty
  - A clinical provider who performs clinical services at UHealth
  - An affiliated volunteer who provides services to UHealth
  - A full-/part-time employee of a third party contracted with UHealth to provide temporary staffing services
  - Miller School deans, and assistant/associate deans

- Individuals responsible for the design, conduct, or reporting of _Scholarly Activities_

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UM's Conflicts of Interest Policy and the NEW UDisclose System

Lory A. Hayes, PhD, CHRC

Director, Disclosures & Scholarly Activities Management (DSAM)
Office of the Vice Provost for Research & Scholarship

New Comprehensive Policy

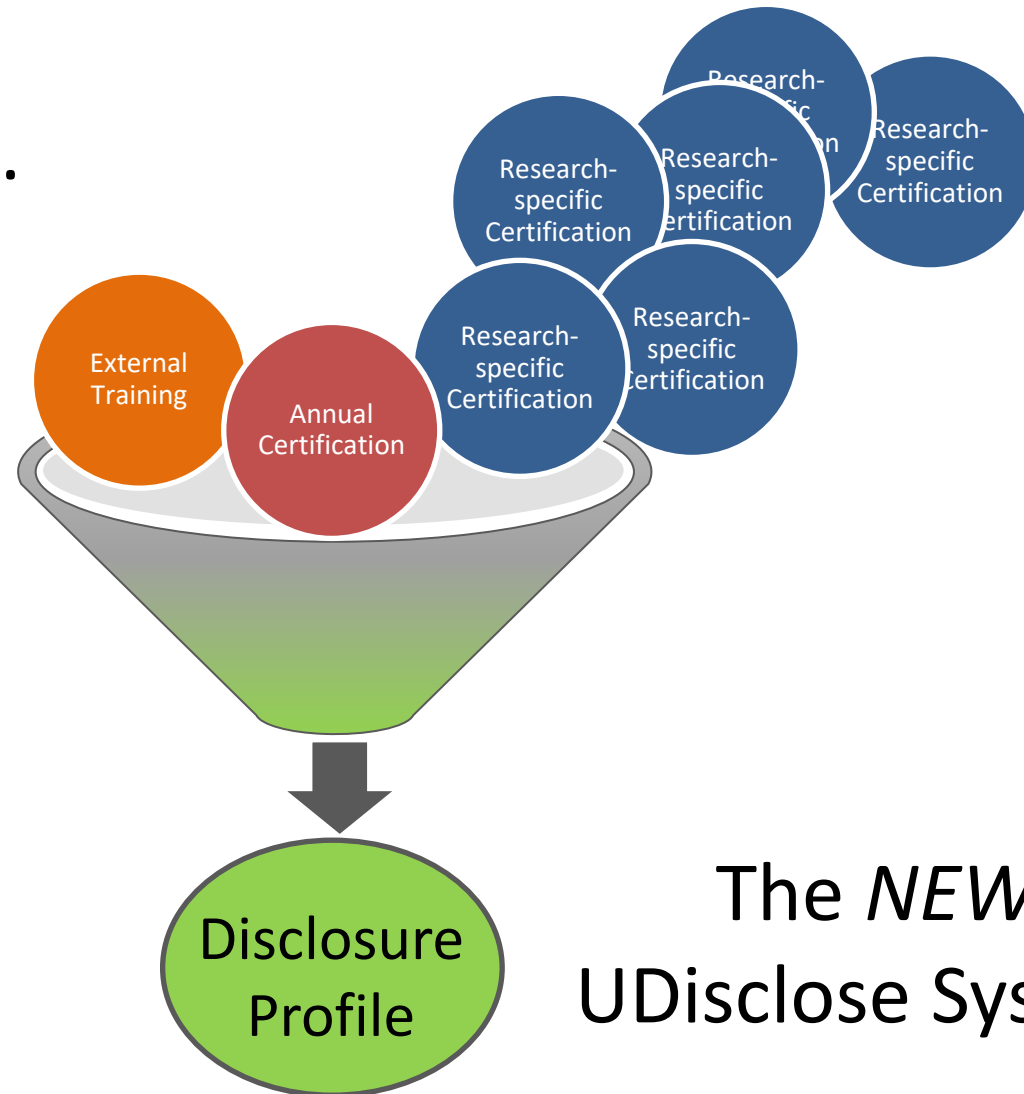*Conflict of Interest, Conflict of Commitment, Foreign Influence, and Institutional Conflict of Interest Policy*

- Approved by UM Faculty Senate and Board of Trustees
- Articulates that annually, all *Covered Persons* must complete *Foreign Engagement* and policy training
- Available in
  - PolicyStat
  - OVPRS website ("Research.miami.edu, keyword "UDisclose")
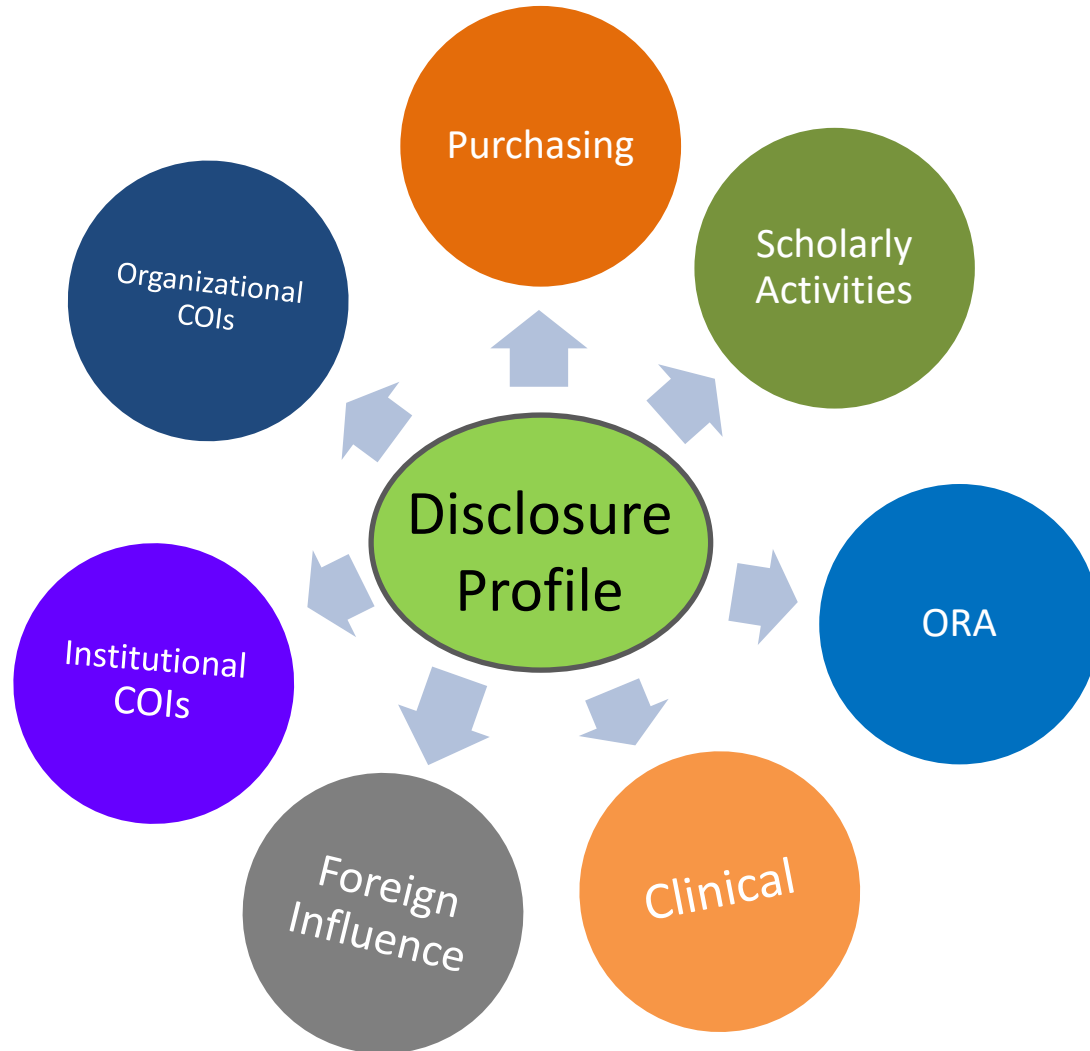 - Within the UDisclose System, Disclosure Profiles

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Conflicts? Foreign Influence?

A *conflict* arises when the interests of a *Covered Person*, or those of the University at large, influences, affects or is affected by the University's educational, clinical care, and *Scholarly Activities*.

Conflicts are situation dependent, and *not* a judgment of character.

Foreign Influence is any circumstance involving an interest in or with a non-US entity that could influence the activities of a *Covered Person*.

Disclosure Profile

Submitting a Disclosure Profile

Benefits For All Investigators

- In system training

- No project-specific questions

- Restructures review process to open accounts/launch projects more rapidly

- Encourages a "Know Your Collaborator" culture via Restricted Party Screening (RPS) awareness

HSR Investigators

Policy streamlines disclosure of relationship(s)
to participants

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Disclosures to Submit via UDisclose System

Royalties, Innovations or Intellectual Property Rights	Holding an IND/IDE	Receipt of other support from any non-UM entity for research and/or scholarship	Receipt of any gifts from an entity, organization, or individual
Sponsored/ reimbursed travel	Consulting fees, honoraria, stocks/equity	Board of Directors/fiduciary responsibilities	An interest in a company doing business with UM

Want to learn more?

For issues with the UDisclose System, contact OVPRShelpdesk@miami.edu

For help with…	Resource
Questions about Disclosures or Foreign Engagements	Disclosures & Scholarly Activities Management (DSAM; formerly DRM) UDisclose website DSAM@miami.edu 305-243-0877
Technical Issues with the UDisclose System	Research Intelligence & Data Infrastructure resinfo@med.miami.edu 305-243-2314
Questions about requirements for UHealth, Jackson Health, Miller School faculty, or University of Miami Medical Group	UHealth Compliance compliancehelp@miami.edu 305-243-6296
Questions about Restricted Party Screening	Export Control Compliance Office 305-284-9558 exportcontrol@miami.edu

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Want to learn more?

For help with…	Resource
Questions about Research Administration (Funding, Other Support, etc.)	UM Research Administration Who is my ORA Contact Person?
Questions about Human Subject Research	Human Subject Research Office hsro@miami.edu 305-243-3195
Questions about Royalties, Innovations or Intellectual Property Rights	Office of Technology Transfer techtransfer@med.miami.edu 305-243-5689
Questions about IND/IDE submissions	Clinical Research Management & Support Office (CRMSO) https://ctd.uresearch.miami.edu 305-243-4219

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New MSOM company in Workday
Edwin Bemmel

Executive Director, Office of Research Administration

Currently, all awards and related grants are set up in Company 200 (Academy)

- The university is creating a new company for MSOM and all MSOM awards will roll up to this company

- UM has retained a consultant to assist with the work and ORA is partnering with EBS and the consultants in this effort

Company 200 (Academy)

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Expected changes:

This only affects MSOM awards (Gables/RSMAS are not affected)

- Existing award numbers (AWD-xxxxxx) will not change

- Existing grant numbers that will continue beyond this fiscal year will automatically be closed as of 5/31/2022

- A new grant will be created effective 6/1/2022

- Number structure for converted grants is the old GR, appended by -1 (eg GR000001 will become GR000001-1)
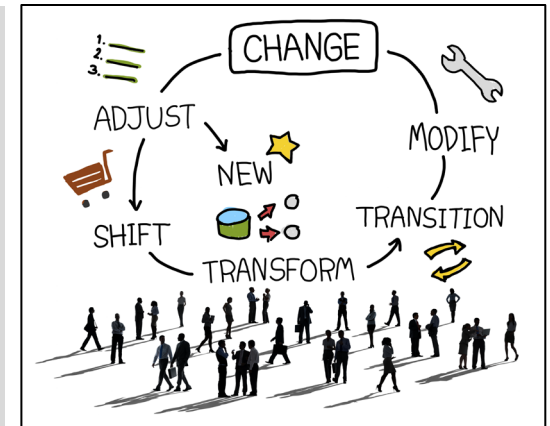

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New MSOM Company in Workday

Expected changes:

- If you have a subaward that will continue beyond this fiscal year, the existing SPC will automatically be closed as of 5/31/2022

- A new SPC will be created effective 6/1/2022

- Number structure for converted SPC is the old SPC, appended by -1 (eg SPC-00001 will become SPC-00001-1)

Additional changes may be required and will be communicated as applicable

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Childcare cost on NRSA award

Permitted for dependent children living in the eligible full-time predoctoral or postdoctoral NRSA trainee's home

- Age: birth until the age of 13, or, for children who are disabled, until age 18
- Childcare must be provided by a licensed childcare provider
- Recipients must maintain all supporting documentation (e.g., proof provider is licensed) and make it available to NIH officials upon request
- When childcare costs are awarded, they are restricted

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Childcare cost on NRSA award

Related to fellowships: funds must be requested

Related to trainee grants:

- NIH will provide an annual $2,500 per each full-time predoctoral or postdoctoral NRSA trainee appointment slot at the time the new, renewal, or continuation award is made.

- NIH will not provide childcare support for short-term predoctoral or postdoctoral NRSA trainees regardless of the activity code.

- For active awards, NIH anticipates beginning to award the additional $2,500 in childcare costs per trainee slot at the time of the next continuation award starting in Fiscal Year 2022.

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Travel on State of Florida Awards

Edwin Bemmel

Executive Director, Office of Research Administration

Travel cost of State of Florida Awards

Awards funded by the state of Florida require that all travel expenditures be subject to Florida Statutes FS112.061:

- Limitations on lodging cost
- Per diem rates are limited to $6 (breakfast); $11 (lunch); and $19 (dinner)
- A state voucher is **required** for all reimbursements
- This form must be completed and attached to each expense report
- Booking sites (booking.com, Travelocity, etc) cannot be used

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Capital Equipment
Kimberly Croft
Executive Director, Research Accounting and Cost Analysis

Capital Equipment Threshold

- New threshold = $5,000
- Effective date: 6/1/22
- Reason for change
  - Alignment with peers
  - Reduced administrative burden for faculty and staff
  - Reduced burden for Property Inventory
- Impact on Sponsored Awards
  - Proposals
  - Existing awards

Effort Certifications

Kimberly Croft

Executive Director, Research Accounting and Cost Analysis

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Effort Certifications

- Reporting period 6/1/21 – 11/30/21
  - Compliance challenges
- Reporting period 12/1/21 – 5/31/22
  - Less flexibility for meeting deadline
  - MSOM Retro Pay

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Open Forum
Questions