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OVPRS Administrative Updates

May 25, 2021

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Agenda

- Introduction to Vice Provost for Research & Scholarship (VPRS) Units and Website
- Foreign Influence/COI System Implementation Updates
- Required use of Complion for Human Subjects Research
- Update on the Clinical Trial A/R Billing Project
- Research Navigator Introduction
- Office of Research Administration Updates
  - Proposal Deadline Policy/Exception Process
  - Cost Sharing Approval Process
  - Effort on Sponsored Awards Policy

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Agenda Continued

- T32 Trainees and other grants
- New Biosketch & Other Support Forms
- Use of FORMS-F
- ORA FY Closing Calendar
- Updated Travel Guidance & New Portal
- Travel on State of Florida awards
- Payroll Costing Allocations From Tidemark

- Q&A

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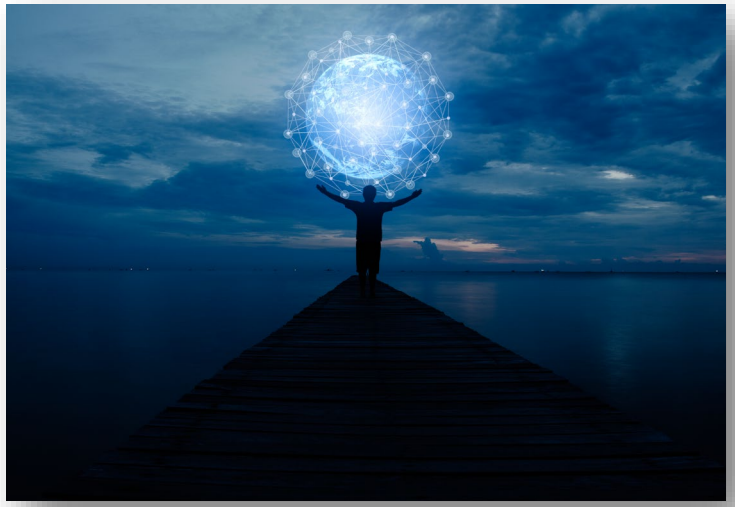
Introduction to Vice Provost for Research & Scholarship (VPRS) Units and Website

Dr. Erin Kobetz

Office of The Vice Provost for Research & Scholarship (OVPRS)

OVPRS - Introduction

We are over 250 professionals with expertise in guiding faculty, staff, and learners through the entire Research Lifecycle, from project conception and grant submission to sharing your results with the world and creating commercial opportunities.



OVPRS - Introduction

In 2021, we're reimagining the research and scholarship organization, guided by four goals in the University's first ever Research & Scholarship Strategic Plan:

- Improve Research Enabling Services to Support Growth in Scale and Impact of Research
- Advocate for Diversity in Research and Scholarship
- Coordinate the Development and Promote Effective Utilization of Research Facilities and Capacity
- Support Growth of Research and Scholarship and Facilitate Interdisciplinarity

OVPRS Research + Scholarship Units

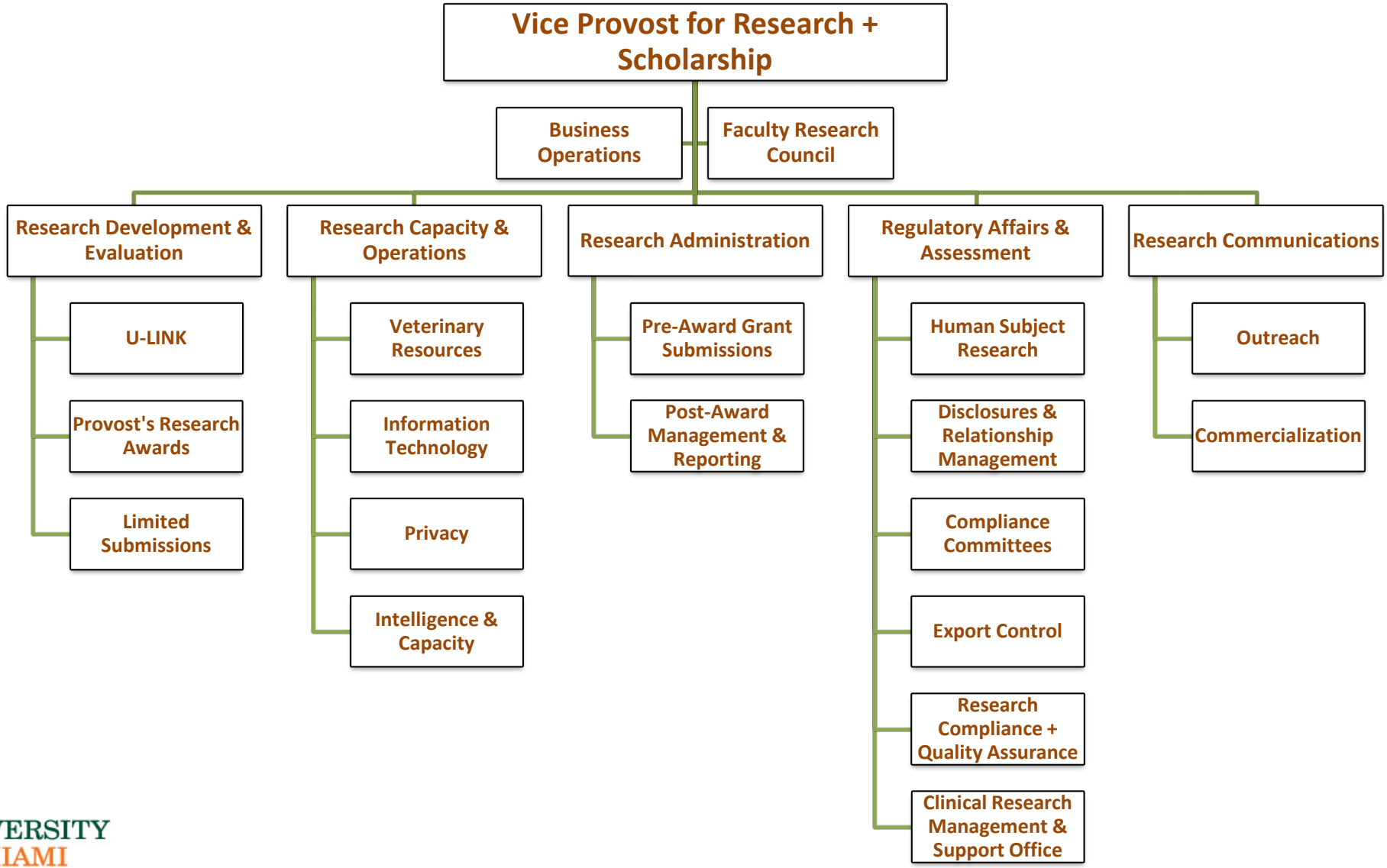
Research Development & Evaluation

Research Capacity & Operations

Research Administration

Regulatory Affairs & Assessment

OVPRS Research + Scholarship Units



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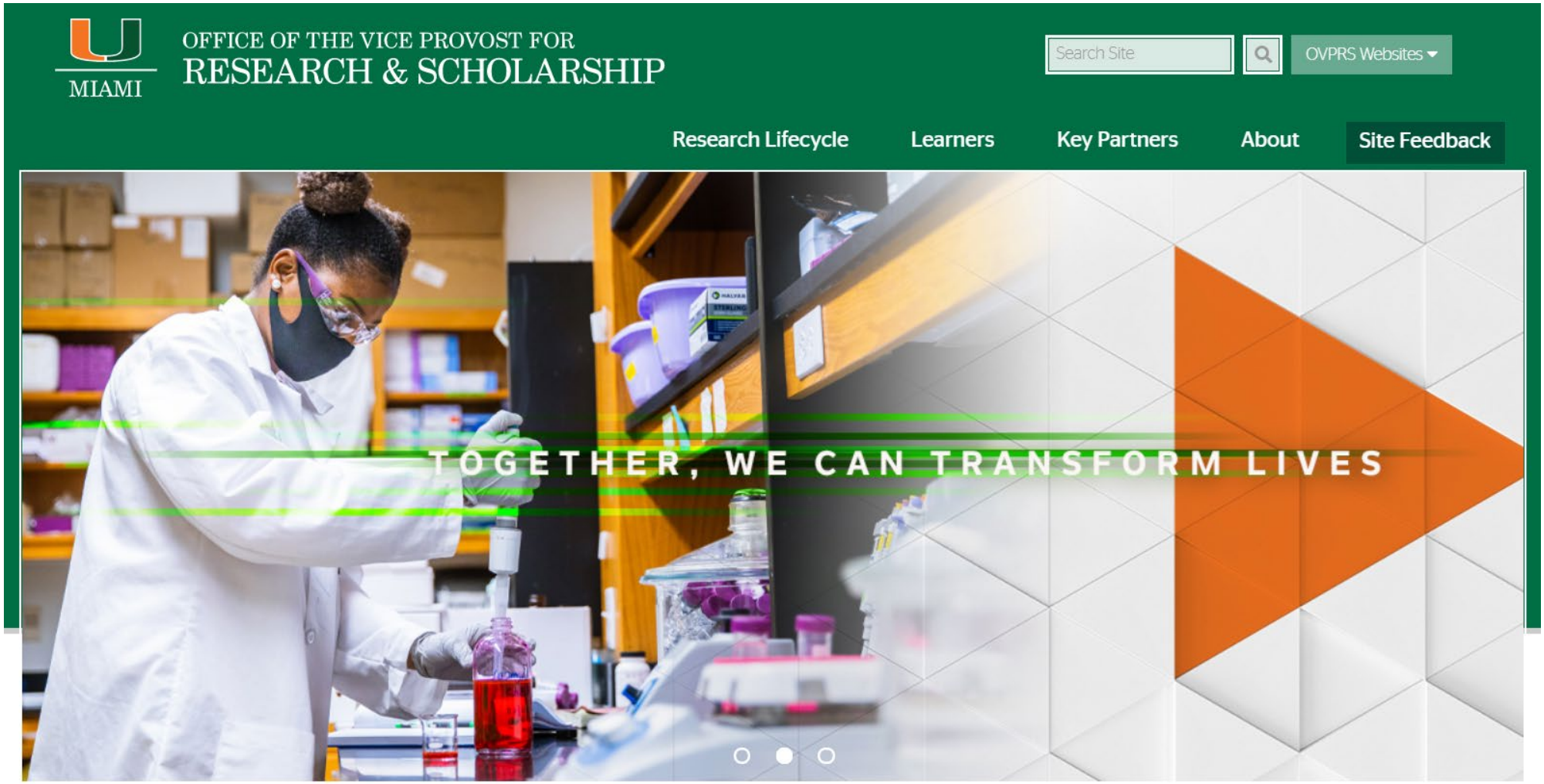
OVPRS - New Website



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https://research.miami.edu

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Foreign Influence/COI System Implementation Updates

Lory Hayes Ph.D.

Director,

Disclosures & Relationship Management

Regulatory Affairs & Assessment

(OVPRS)

Addressing Foreign Influence

The Federal Government is taking action to ensure US research and scholarship is protected from inappropriate foreign influence with significant consequences for non-compliance with disclosure requirements

Consequences to the Individual

- Suspension or debarment from participating in federal funds
- Termination of existing federal awards
- Criminal charges – ***numerous indictments and arrests have been made***

Consequences to UM

- Withholding payments and not reimbursing/paying for costs incurred
- Loss of expanded authorities
- Suspension or debarment from receiving federal funds

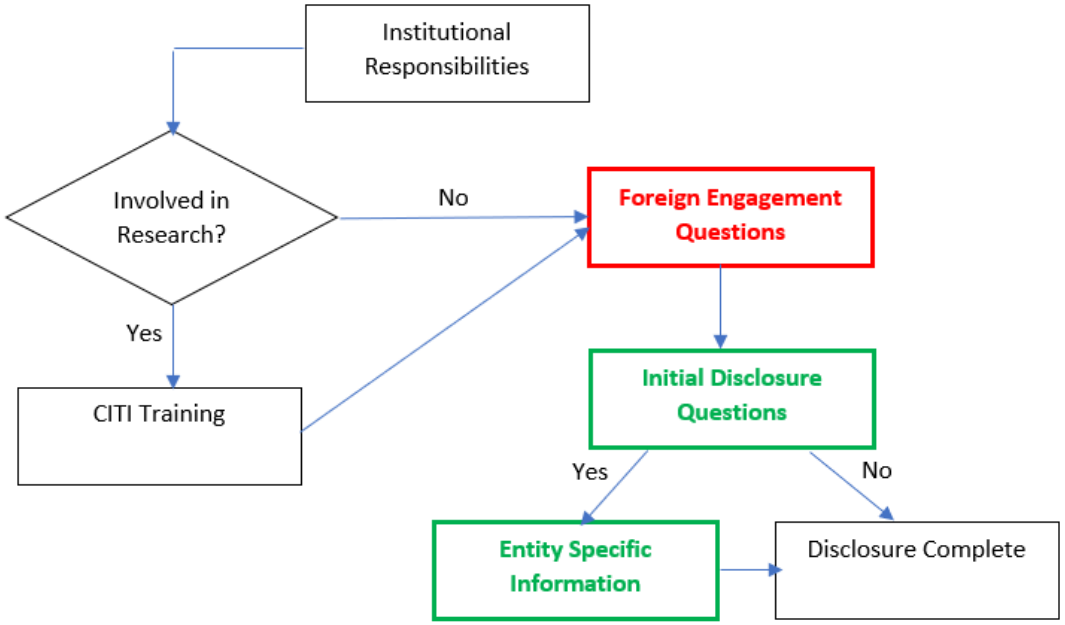
UM had no mechanism for faculty disclose leaving UM and faculty vulnerable to the consequences above

Updates to UDisclose

- UM is committed to ***supporting faculty*** and their international collaborations
- ***Information collected is limited*** to only what is required to meet mandatory disclosure requirements for sponsored funding and to identify and manage potential conflicts
- Questions were ***developed with faculty input***
- Faculty must update between ***March 18th*** and ***May 31st***

Updates to UDisclose

- New ***Foreign Engagement Questions*** to address potential foreign influences and required disclosures.
- Addition of a question on the ***Initial Disclosure Questions*** to ask about other support provided to faculty in support of research or scholarship.
- Addition of ***Entity Specific Information*** questions.



Updates to UDisclose

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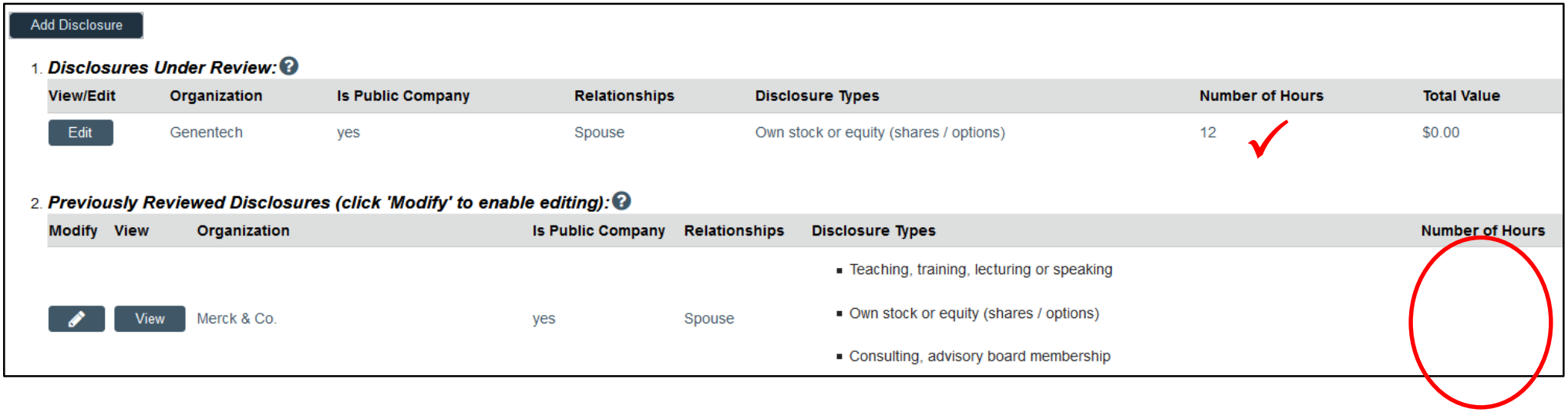

Add Disclosure

1. ***Disclosures Under Review:***

View/Edit	Organization	Is Public Company	Relationships	Disclosure Types	Number of Hours	Total Value
Edit	Genentech	yes	Spouse	Own stock or equity (shares / options)	12	$0.00

2. ***Previously Reviewed Disclosures (click 'Modify' to enable editing):***

Modify	View	Organization	Is Public Company	Relationships	Disclosure Types	Number of Hours
					▪ Teaching, training, lecturing or speaking	
	View	Merck & Co.	yes	Spouse	▪ Own stock or equity (shares / options)	
					▪ Consulting, advisory board membership	

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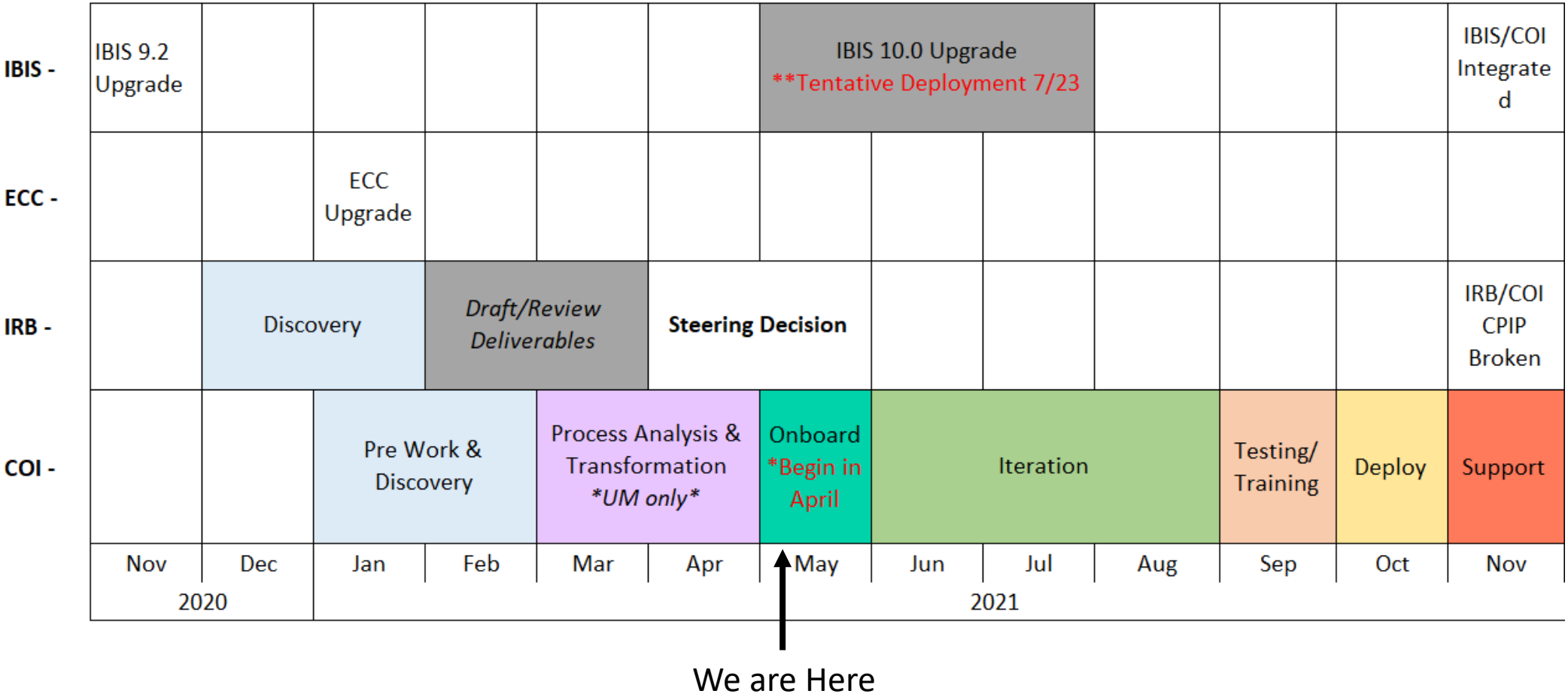
COI System Implementation



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Required use of Complion for Human Subjects Research

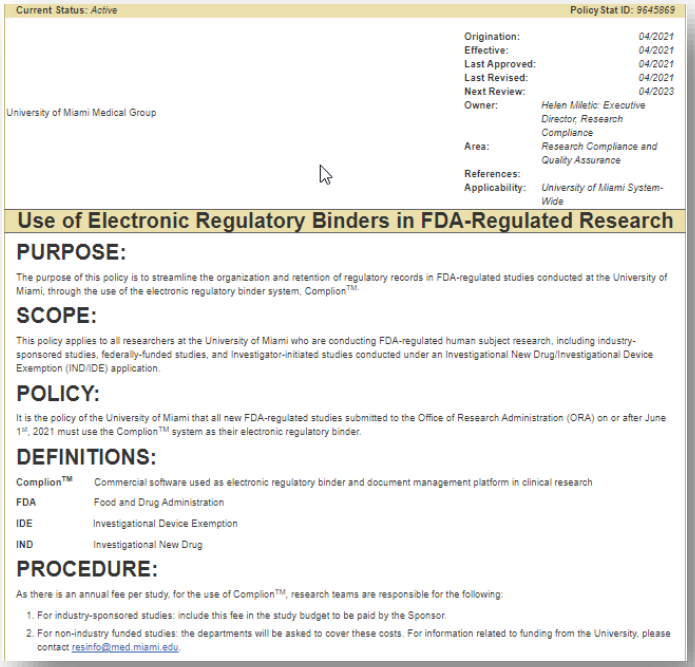
Helen Miletic

Interim Executive Director, Research Compliance & Quality Assurance (OVPRS)

Complion Implementation

Implement the electronic Regulatory Binder system called Complion:

- To streamline the organization and retention of regulatory records in FDA-regulated studies
- New policy requires all new FDA-regulated studies submitted to ORA on or after June 1st, 2021 to use Complion



Current Status: *Active* — Policy Stat ID: *9645869*

University of Miami Medical Group

Origination: *04/2021*
Effective: *04/2021*
Last Approved: *04/2021*
Last Revised: *04/2021*
Next Review: *04/2023*
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.

DEFINITIONS:

Complion™	Commercial software used as electronic regulatory binder and document management platform in clinical research
FDA	Food and Drug Administration
IDE	Investigational Device Exemption
IND	Investigational New Drug

PROCEDURE:

As there is an annual fee per study, for the use of Complion™, research teams are responsible for the following:

1. For industry-sponsored studies: include this fee in the study budget to be paid by the Sponsor.
2. For non-industry funded studies: the departments will be asked to cover these costs. For information related to funding from the University, please contact resinfo@med.miami.edu.

Complion Implementation

Use of Electronic Regulatory Binders in FDA-Regulated Research

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.

This policy applies to all researchers conducting FDA-regulated human subject research, including:

- industry-sponsored studies
- federally-funded studies
- investigator-initiated studies

conducted under an Investigational New Drug or Investigational Device Exemption (IND/IDE) application.

Complion Implementation

As there is an annual fee per study, for the use of Complion, research teams must:

- include this fee ($1250) in the study budget to be paid by the Sponsor for industry-funded studies.

For non-industry funded studies:

- departments will be asked to cover the cost.
- For information related to funding from the University, contact resinfo@med.miami.edu.

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Update on Clinical Trial A/R Billing Project

Allen Mora

Executive Director, Research Intelligence & Capacity (OVPRS)

Clinical Trials A/R Billing Initiative

Objective

To close the Award/'Payment received' gap by identifying achieved invoiceable milestones related to a study and track them in one system from invoice-sent to payment-received.

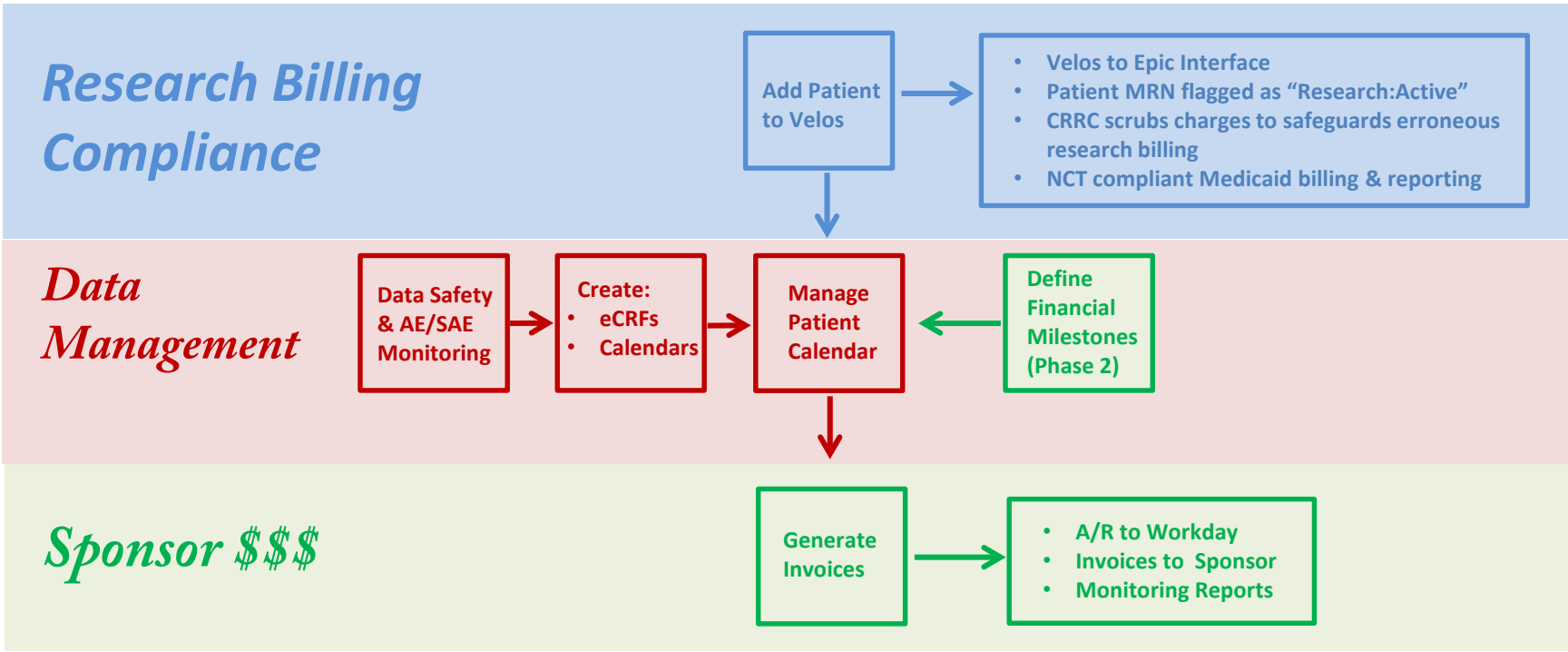
Stakeholders

Executive Dean of Research (EDR) office; Office of Research Administration (ORA); Cancer Center (SCCC), Research Development & Support (RDS), CRORS, Research IT

Pain Point

Departments using their own A/R processes. No central repository identifying A/R and outstanding balances. Billing windows close, study teams face attrition, and achieved financial milestones go unpaid by sponsors.

Velos eResearch: Overlapping Workflows



3 Themes:

- ✓ Safeguard research participant billing
- ✓ Data Integrity in research
- ✓ Get paid for Industry-Sponsored research

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velos

Clinical Trials A/R Pilot Project

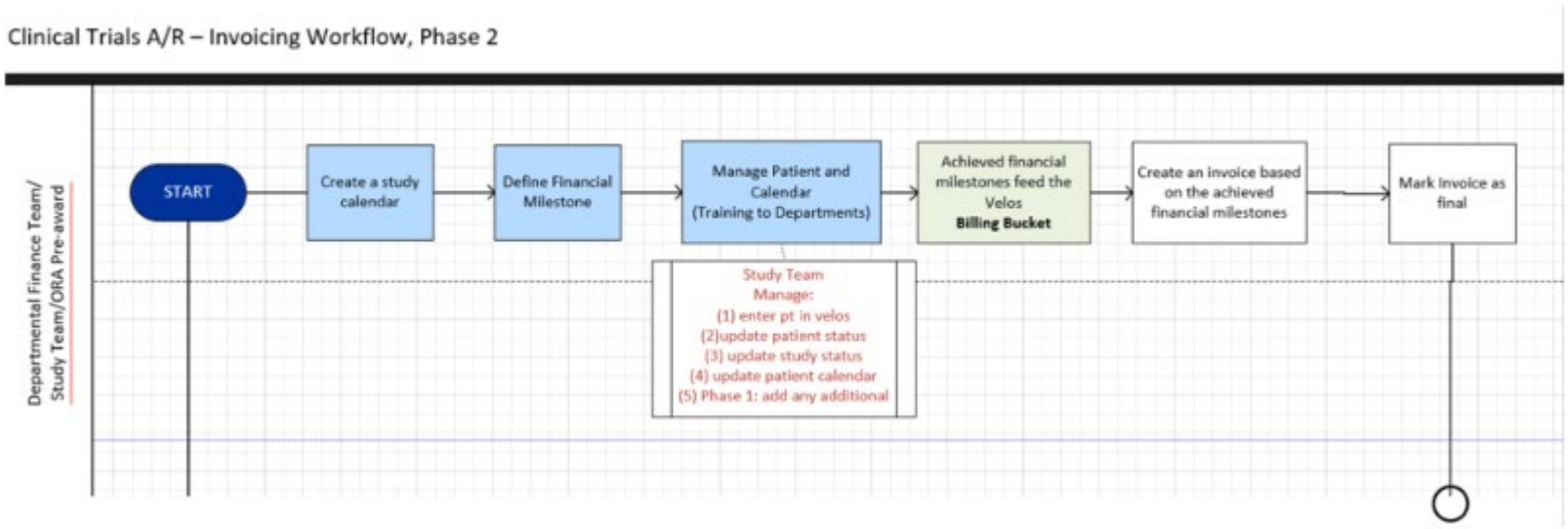
Phase I: To create and implement a process that generates invoices in Velos as a general “catchall bucket” (integration with Workday)

Status: Complete ✓

Clinical Trials A/R Pilot Project

Phase II: To create invoices with more granularity and generate invoices in Velos by study and participant level milestones

Participating departments: SCCC, Dermatology, ENT, Schiff Center



Status: In progress

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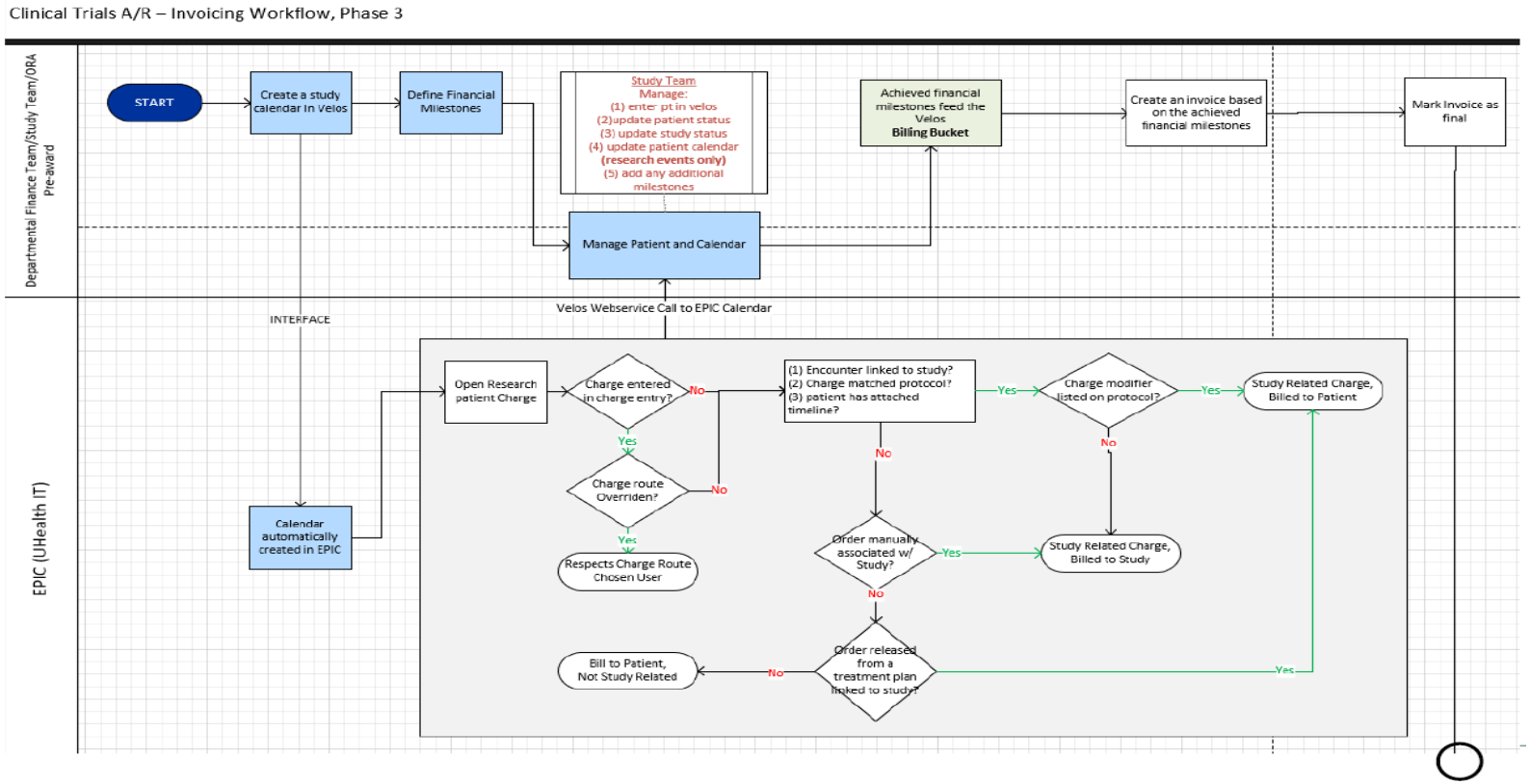
Clinical Trials A/R Pilot Project

Phase III: Velos-Epic integration



Status: Not started

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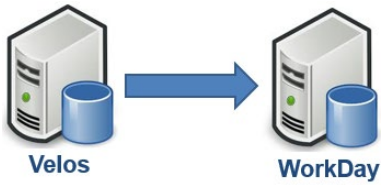
Clinical Trials A/R Keys to Success



Keys to Success

- ✓ Leadership support
- ✓ Enforcement arm
- ✓ Capable IT solutions
- ✓ “Easy-button” initial process plan
- ✓ Successful pilot project
- ✓ Training plan
- ✓ Manageable implementation plan
- ✓ End-to-end monitoring plan
- ✓ Policy: Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy

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Research Navigator Introduction

Patty Atkinson

Research Navigator

Research Intelligence & Capacity (OVPRS)

Growing Research Enterprise

- Nationally recognized Research 1 university
- Approximately $380 million in research activity annually
- Actively engaged in wide variety of research, scholarship, creative activities
- Multiple campuses, schools, colleges, centers
- Very large, complex research enterprise
- Vast research support services

Vast Support Services

Office of Research Administration (ORA)	Human Subject Research Office (HSRO)	Imaging Centers	Disclosures & Relationship Management (DRM)	Clinical and Translational Science Institute (CTSI)
Libraries	Office of the Vice Provost for Research + Scholarship (OVPRS)	Core Facilities	Office of Technology Transfer (OTT)	Development
Institutional Animal Care & Use Committee (IACUC)	Human Resources	Executive Dean for Research (EDR)	Research Development & Support (RDS)	Clinical Research Operations & Regulatory Support (CRORS)

Research Challenges

- Finding funding opportunities
- Getting help with grant writing
- Understanding how to submit proposals
- Locating expertise for collaboration
- Finding information, resources, services
- Understanding policies, systems, requirements
- Facing bureaucracy and roadblocks
- Managing research projects

Research Navigator

New customer-friendly, concierge-style service to aid faculty in navigating the research enterprise successfully

Enable faculty to focus on research not roadblocks

Goals

- Expedite research through improved navigation and access to resources
- Reduce administrative burden for faculty
- Provide enhanced support to streamline onboarding of new faculty/researchers
- Improve customer service
- Build more collaborative environment
- Improve communications and expand educational opportunities
- Foster process improvement

Research Navigator Services

- Provide one-stop shopping for research-related questions
- Deliver customer-friendly, timely support
- Assist with locating resources for finding funding opportunities
- Provide guidance on available resources, services, and expertise
- Assist with navigating administrative processes, policies, requirements, forms
- Advise on tools and systems for facilitating research
- Liaise between faculty, research team, and administrators to expedite research
- Identify where to go for more in depth assistance

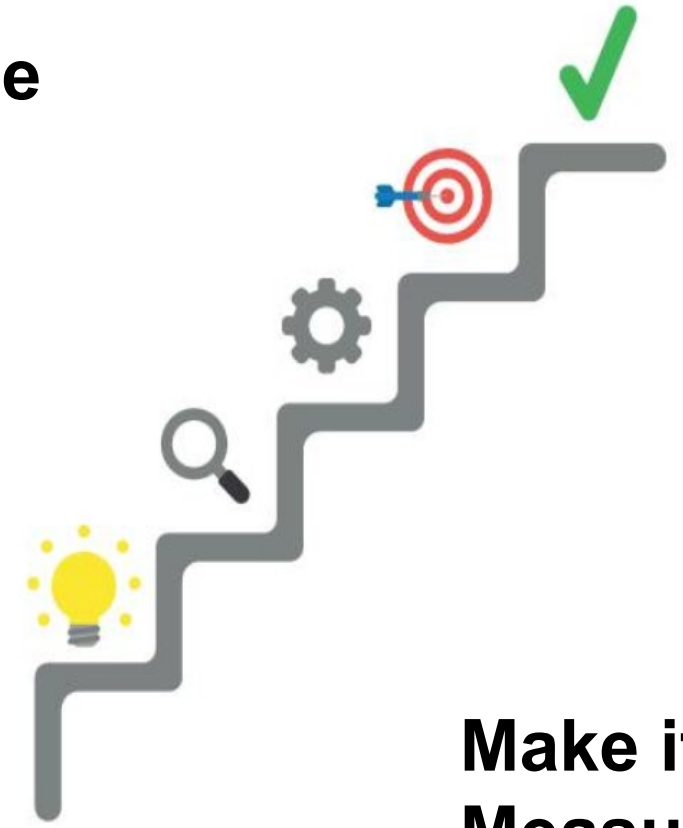
Timeline

Set Goals

Determine Scope

Get Feedback

Communicate



Fall 2021

January 2021

Make it Happen

Measure Success

Continuous Improvement

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Feedback

We'd like to hear from you!

Contact navigator@miami.edu

with comments or suggestions.

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Office of Research Administration Updates

Laura Kozma

AVP, Research Administration (ORA)

Application Deadline Policy - Exception Process

Application Deadline Policy

- All applications except SBIR/STTR
  - Submitted to ORA in final form (except for science) 3 days prior to the deadline
- SBIR/STTR
  - Submitted to ORA in final form (including final scope of work) 5 days prior to the deadline
- Exceptions under very limited circumstances
  - Opportunity was posted 3 weeks or less prior to the deadline (ORA approves)
  - Other rare and extenuating circumstances (Dean/designee and VPRS approve)

Application Deadline Policy - Exception Process

Request for Exception Process:

- **ORA approved: provide supporting documentation in IBIS**
- **Dean/VPRS approved: ancillary review (use "other" category)**

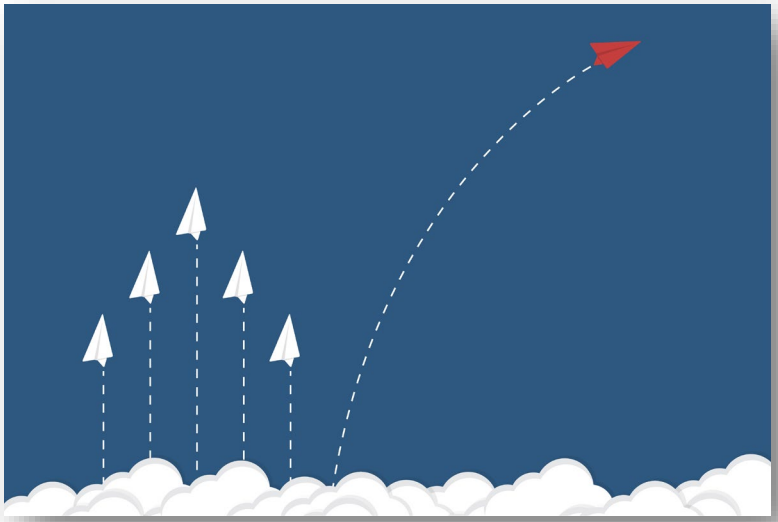
Exceptions Reviewed and Approved by both the Dean (or his/her designee) and the Vice Provost for Research and Scholarship (VPRS) (submitted as an ancillary review)

- Family emergency
- Last minute notice (three weeks or less) of proposal opportunity from external collaborator
- Very large and complex proposals ***and*** extenuating circumstances leading to unavoidable delays
- Last minute changes to the application requested by the sponsor prior to submission

Applications received late on or after June 1st without a documented approval will not be reviewed or submitted

Cost Sharing Approval Process

- Update to Ancillary Review Process (effective immediately):
- Medical Proposals: Route to Patricia Wahl who will complete an initial review before routing to Dr. Schulman
- Gables/RSMAS Proposals: Route to Laura Kozma



Effort on Sponsored Awards Policy

Minimum Effort

- Minimum as required by the program and scope of the project
- Generally, effort should be paid from the sponsored award

Maximum Effort

- 12-month appointment: No more than 95% of time on sponsored awards (or less based on other responsibilities)
- 9-month appointment: No more than 2.5 months of summer pay from sponsored awards (salary savings from pay on sponsored awards during the academic year may be paid to faculty during the summer)
- Some research staff postdocs and other employees may be charged 100% to sponsored awards

Effort on Sponsored Awards Policy

Unallowable Activities When Paid from Sponsored Award

- Any activity not directly in support of the award:
  - Teaching
  - Service
  - Administrative tasks
  - Proposal preparation
  - Institutional governance

T32 Trainees & Working on Other Grants

- NIH Grants Policy Statement:
  - May spend up to 25% (e.g., 10 hrs/week) on part time research, teaching or clinical employment
  - Activity cannot interfere with or prolong the duration of the T32 trainee program
  - Activity cannot be the same research supported by the T32
  - Must be paid as an employee (not as a stipend)

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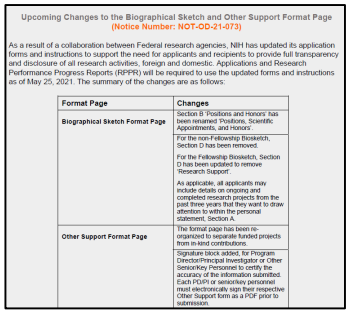
Office of Research Administration Updates

Brandon Strickland

Executive Director, Research Administration (ORA)

New Biosketch and Other Support Forms

- As **announced** in March, updated biosketch and other support format pages and instructions are available for use in applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs). Use of the new format pages is preferred immediately and required for due dates and submissions on or after January 25, 2022 (**NOT-OD-21-110**).
- This represents a change from the original May 25, 2021 requirement date for the updated formats and other support signatures.
- Applicants and recipients can use this time to align their systems and processes with the new formats and instructions.
- Failure to follow the appropriate formats on or after January 25, 2022 may cause NIH to withdraw applications from or delay consideration of funding.



Upcoming Changes to the Biographical Sketch and Other Support Format Page
(Notice Number: NOT-OD-21-073)

As a result of a collaboration between Federal research agencies, NIH has updated its application forms and instructions to support the need for applicants and recipients to provide full transparency and disclosure of all research activities, foreign and domestic. Applications and Research Performance Progress Reports (RPPR) will be required to use the updated forms and instructions as of May 25, 2021. The summary of the changes are as follows:

Format Page	Changes
Biographical Sketch Format Page	Section B 'Positions and Honors' has been renamed 'Positions, Scientific Appointments, and Honors'. For the non-Fellowship Biosketch, Section D has been removed. For the Fellowship Biosketch, Section D has been updated to remove 'Research Support'. As applicable, all applicants may include details on ongoing and completed research projects from the past three years that they want to draw attention to within the personal statement, Section A.
Other Support Format Page	The format page has been re-organized to separate funded projects from in-kind contributions. Signature block added, for Program Director/Principal Investigator or Other Senior/Key Personnel to certify the accuracy of the information submitted. Each PD/PI or senior/key personnel must electronically sign their respective Other Support form as a PDF prior to submission.

New Biosketch and Other Support Forms

Applicants and recipients remain responsible for disclosing all research endeavors regardless of the version of the forms used, including:

- If asked by NIH staff, supporting documentation, which includes copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. If the contracts, grants or other agreements are not in English, recipients must provide translated copies.
- Immediate notification of undisclosed Other Support. When a recipient organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR, as applicable, the recipient must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.

New Biosketch and Other Support Forms

- https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html
- https://grants.nih.gov/faqs#/other-support-and-foreign-components.htm?anchor=alphaHeader4226

Use of Forms-F

- https://grants.nih.gov/news/new-nih-forms-f-grant-application-forms-and-instructions-coming-due-dates-or-after-may-25-2020
- https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-026.html

Clinical Trial Budget & MCA Routing

- Must at least have the protocol and budget before routing
  - ORA prefers to have informed consent and any other document provider as well
- Funding Proposals without these document attached will be returned
- Budgets should not be negotiated at the department/PI level
- If the MCA developed by ORA is not approved by the PI within 48 hours we will consider that the PI has no objects or comment and mark it as final

CDA/NDA Routing Change

Reminder:

- Send all CDAs related to clinical trials (except IITs) to ORA to review and execute
  - These previously went to OTT
- Everything else remains the same

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Office of Research Administration Updates

Edwin Bemmel

Executive Director, Research Administration

(ORA)

ORA FY Closing Calendar

- The Controller's Office has issued the final year-end calendar for FY21
- It is important to understand and adhere to the posted deadlines
- In the meantime:
  - FY 21 supplier invoices due to AP by June 2nd @ 5pm
  - Cost Transfers affecting grants due to ORA by June 4th
  - Review and clear all payroll suspense accounts asap

Updated Travel Guidance & New Portal

- New travel guidance issued in April 2021
- Requires for travel to only be considered when there is no alternative to physical presence
- All travel requires prior approval from supervisor and dean or VP
- Travel portal to reserve business related airfare

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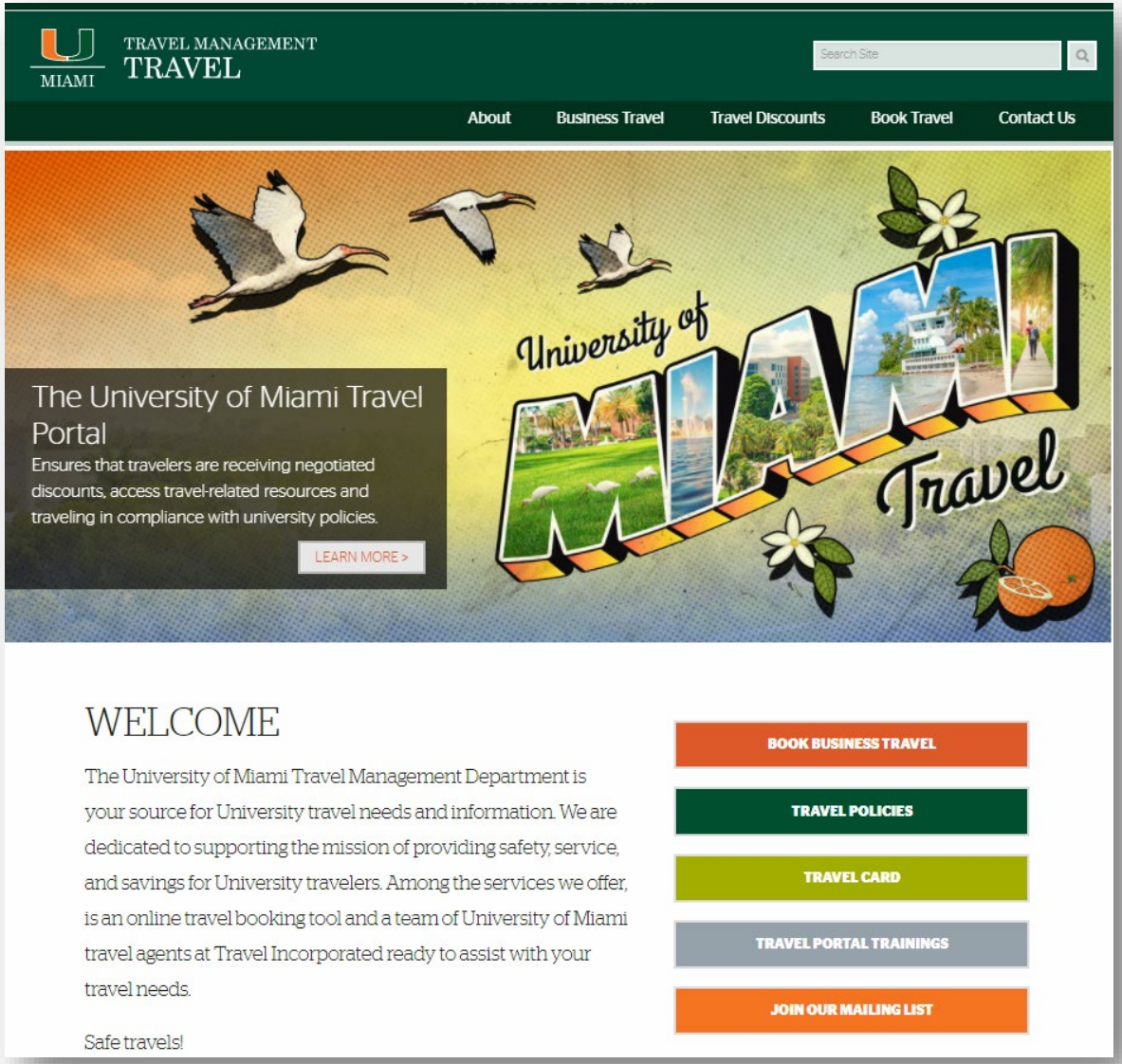
Updated Travel Guidance & New Portal



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https://travel.miami.edu

Updated Travel Guidance & New Portal

- Travel Portal & Bookings
- Travel Portal Trainings
- Travel Card
- Travel Policies
- Travel Reimbursements
- International Travel

The University of Miami Travel Portal

The University of Miami Travel Portal is the University's tool for air, hotel, and rental car bookings. The portal comprises of a suite of tools and services that together aim to: ensure the safety of faculty, staff, and students while they travel; deliver exceptional travel-related services; streamline the expense reporting process; and reduce travel costs.

University travelers, travel arrangers, and students can take advantage of both the online booking tool housed inside the portal and booking directly through a University dedicated agent.

BOOK TRAVEL NOW!

Award Travel Restrictions & Requirements

UNIVERSITY OF MIAMI

Origination:	04/2021
Effective:	04/2021
Last Approved:	04/2021
Last Revised:	04/2021
Next Review:	04/2023
Owner:	Humberto Speziani: Assoc. VP, Business Services
Area:	Business Services
References:	
Applicability:	University of Miami System-Wide

Travel Policy

POLICY:

Necessary-consideration should be given to utilizing more cost and time effective means of conducting business such as teleconferencing and web-based meetings. For conferences and similar meetings and when not accessible in an online format, the travel should be discussed and authorized by the supervisor prior to making travel arrangements. When business travel is required and authorized, airfare reservations must be made through the University of Miami Travel Portal to comply with this policy.

University travel restrictions may prevent travel to certain locations or to any location. When traveling to or from certain locations, precautionary measures may be required including self-quarantine and/or testing. Travelers must comply with University requirements to protect themselves and others.

All faculty, staff, undergraduate, graduate, and professional students traveling on University business, conducting research, representing the University (e.g., extracurricular activities, attending academic conferences), and/or using University funds (including operating budget, gifts, or grant funds) are required to register their travel itineraries and contact information in the University's Travel Portal.

The University requires Travelers to document a business purpose and secure approval from appropriate supervisor(s) prior to committing University funds or incurring expenses. Furthermore, Travelers are to exercise prudency when making travel reservations by always selecting the lowest fares available.

Travelers are responsible for understanding and adhering to specific restrictions imposed by the source funding the travel. Any travel requirements from the granting agency supersede what is outlined in this policy.

The University of Miami Travel Portal is the University's official and required travel management service for Travelers and designated Travel Assistants. Special University negotiated rates for air travel, car rental, and lodging are available through the Travel Portal. Use of the University Travel Portal supports the guiding principles to spend appropriately and supports the University's Duty of Care responsibility for all Travelers.

The University Travel Card is the university's preferred method of payment, but the same policy must be followed in the case of reimbursement payment to the Travelers.

The Fly America Act/Open Skies Agreement requires all flights charged to federal awards be booked with U.S. flag air carriers.

It is expected that there will be no exceptions to the University's Travel Policy, which are designed to support the University's Duty of Care and financial stewardship responsibilities and assure compliance with University policies and governmental requirements. Any request for exception based on extraordinary circumstances must be approved, in advance of the travel, by an Executive Vice President or designee. Expenses submitted for reimbursement which are deemed to be in violation of this policy may not be reimbursed to the employee/Travelers.

For business expenses including meals and entertainment, see Electronic Travel & Business Expense Reimbursement Policy.

Award Travel Restrictions & Requirements

Travel restrictions & requirements on State of Florida awards

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Travel Restrictions & Req on FL Awards

- Recent awards with the Florida Department of Health include the following:

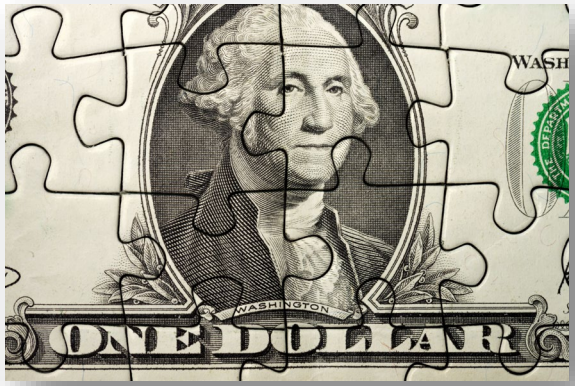
  *The Grantee **will not** be reimbursed for reservations made through third party travel sites (e.g. Booking.com, Expedia, Orbitz)*

- Other Florida agencies have not followed suit, but we expect that they will

It is important to comply!

Payroll Costing Allocations From Tidemark

- Costing Allocations created at the beginning of the fiscal year are based on how the budgets were entered
- Workday validations do not check costing allocation end dates against award end dates
- Monthly reconciliations should include reviewing payroll charges and ensuring they post correctly
- Allocations should be updated timely



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Open Forum
Questions

Open Forum - Questions

Newsletters

OFFICE OF THE VICE PROVOST FOR RESEARCH & SCHOLARSHIP

MIAMI

RESEARCH EVENTS ROUND-UP

The Office of the Vice Provost for Research & Scholarship gathers all the research events posted to our listservs into a once-weekly email, and we also feature them on our new online calendar. Check out our primer on how to promote your event or email vprs@miami.edu for help.

SPOTLIGHT TUESDAY @ 12PM!

C2C U INNOVATION Concept to Commercialization

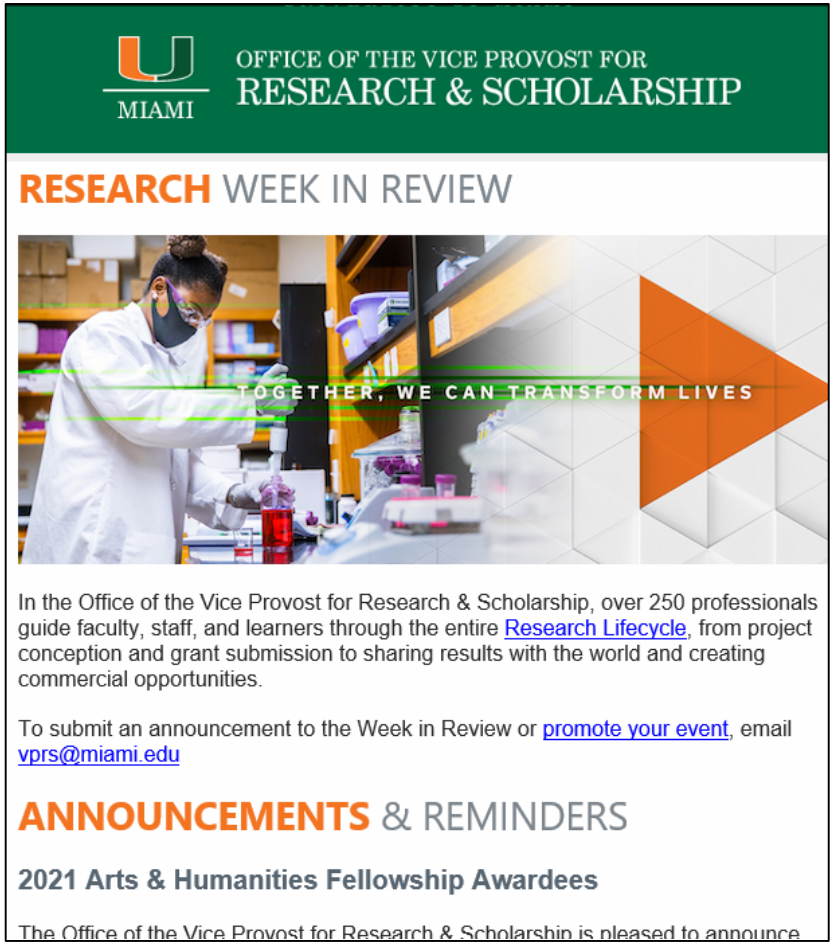
Tuesday, May 18, 12:00 p.m. - 1:00 p.m.

U Innovation Concept to Commercialization Seminar Series

Enrique Triay, M.B.A., Venture Consulting Manager, The Launch Pad at UM presents: *4 Key Things Investors Look at When Evaluating Your Startup + An Overview of The Launch Pad's Idea to Monetization Workshop*. Register here.

SAVE THE DATE

Research Events Round-Up



OFFICE OF THE VICE PROVOST FOR RESEARCH & SCHOLARSHIP

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RESEARCH WEEK IN REVIEW

TOGETHER, WE CAN TRANSFORM LIVES

In the Office of the Vice Provost for Research & Scholarship, over 250 professionals guide faculty, staff, and learners through the entire Research Lifecycle, from project conception and grant submission to sharing results with the world and creating commercial opportunities.

To submit an announcement to the Week in Review or promote your event, email vprs@miami.edu

ANNOUNCEMENTS & REMINDERS

2021 Arts & Humanities Fellowship Awardees

The Office of the Vice Provost for Research & Scholarship is pleased to announce

Research Week in Review

Thank You

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