OVPRS Administrative Updates
May 25, 2021
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
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
Introduction to Vice Provost for Research & Scholarship (VPRS) Units and Website

Dr. Erin Kobetz

Office of The Vice Provost for Research & Scholarship (OVPRS)
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.
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
Foreign Influence/COI System Implementation Updates

Lory Hayes Ph.D.

Director,

Disclosures & Relationship Management
Regulatory Affairs & Assessment
(OVPRS)
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

- 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.
COI System Implementation

We are Here

IBIS -
- IBIS 9.2 Upgrade
- IBIS 10.0 Upgrade
  **Tentative Deployment 7/23
- IBIS/COI Integrated

ECC -
- ECC Upgrade

IRB -
- Discovery
- Draft/Review Deliverables
- Steering Decision
- IRB/COI CPIP Broken

COI -
- Pre Work & Discovery
- Process Analysis & Transformation
  *UM only*
- Onboard
  *Begin in April
- Iteration
- Testing/Training
- Deploy
- Support

<table>
<thead>
<tr>
<th>Nov</th>
<th>Dec</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>We are Here</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Required use of Complion for Human Subjects Research

Helen Miletic

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

Research Billing Compliance

Add Patient to Velos
- Velos to Epic Interface
- Patient MRN flagged as “Research:Active”
- CRRC scrubs charges to safeguard erroneous research billing
- NCT compliant Medicaid billing & reporting

Data Management

Create:
- eCRFs
- Calendars

Manage Patient Calendar

Define Financial Milestones (Phase 2)

Sponsor $$$

Generate Invoices
- A/R to Workday
- Invoices to Sponsor
- Monitoring Reports

3 Themes:
- Safeguard research participant billing
- Data Integrity in research
- Get paid for Industry-Sponsored research

Velos eResearch: Overlapping Workflows

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

Status: Complete ✔
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
Phase III: Velos-Epic integration

Clinical Trials A/R Pilot Project

Status: Not started
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
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
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

Make it Happen
Measure Success
Continuous Improvement

January 2021

Fall 2021
Feedback

We’d like to hear from you!
Contact **navigator@miami.edu**
with comments or suggestions.
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
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
Unallowable Activities When Paid from Sponsored Award

• Any activity not directly in support of the award:
  o Teaching
  o Service
  o Administrative tasks
  o Proposal preparation
  o 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)
Office of Research Administration

Updates

Brandon Strickland

Executive Director, Research Administration
(ORA)
• 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.
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/faqs#/other-support-and-foreign-components.htm?anchor=alphaHeader4226](https://grants.nih.gov/faqs#/other-support-and-foreign-components.htm?anchor=alphaHeader4226)
Use of Forms-F

New NIH "FORMS-F" Grant Application Forms and Instructions Coming for Due Dates on or after May 25, 2020

• 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
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
Office of Research Administration Updates

Edwin Bemmel

Executive Director, Research Administration

(ORA)
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 2\textsuperscript{nd} @ 5pm
– Cost Transfers affecting grants due to ORA by June 4\textsuperscript{th}
– Review and clear all payroll suspense accounts asap
• 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
Updated Travel Guidance & New Portal

The University of Miami Travel Portal
Ensures that travelers are receiving negotiated discounts, accessing travel-related resources, and traveling in compliance with university policies.

WELCOME
The University of Miami Travel Management Department is your source for University travel needs and information. We are dedicated to supporting the mission of providing safety, service, and savings for University travelers. Among the services we offer, is an online travel booking tool and a team of University of Miami travel agents at Travel Incorporated ready to assist with your travel needs.

Safe travels!

https://travel.miami.edu
Updated Travel Guidance & New Portal

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!

https://travel.miami.edu
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 prudence 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/Traveler.

For business expenses including meals and entertainment, see Electronic Travel & Business Expense Reimbursement Policy.
Travel restrictions & requirements on State of Florida 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
Open Forum

Questions
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 Concept to Commercialization

Tuesday, May 18, 12:00 p.m. - 1:00 p.m.
U Innovation Concept to Commercialization Seminar Series

SAVE THE DATE

Research Week in Review

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...
Thank You

Your success is our goal!