Agenda

- Introduction of New Leaders
- May New Hires Promotions & Departures
- Contract Status in IBISResearch
- COI Disclosure Deadline
- Hurricane Preparedness
- Jackson on Subaward Budgets
- Charging Salary Above the Salary Cap Amount
- Workday MSOM Conversion and Reporting Changes
- Effort Certification
- ECC New Format
- PAA Approval
- Internal Service Delivery (ISD) and iLab Reminder
- AAHRPP Reaccreditation
- IRB SaaS Implementation
Introduction of New Leaders

Laura Kozma
Associate Vice President
Research Administration
Oversees:

- The infrastructure expansion of the Clinical Research Management and Support Office (CRMSO), to allow for the expansion of investigator-initiated multi-center trials and institution-held Investigational New Drug (IND)/Investigational Device Exemption (IDE) trials.
- The Research Compliance and Quality Assurance (RCQA) Office as well as the Research Intelligence and Capacity Office.
Executive Director, Research

- Oversees Research Compliance and Quality Assurance, develop and implement dashboards for performance enhancement and efficiency gains
- Supports investigator/user training and curriculum design
- Initiates Velos/Workday integration pathways supporting timely and accurate representation of accounts receivable on Clinical Trials

Scott Streibich
MBA, MHS, CHRC, CPB, CRCR, CSPR, CBE
Assistant Provost for Research Integrity

Dr. Caban-Martinez will support the Office of the Vice-Provost for Research + Scholarship in preventing and addressing cases of research misconduct, research fabrication and authors issues.
Hilary has dual privacy roles – the Privacy Officer for OVPRS and the Data Protection Officer for the Academy. In both, she will be overseeing existing privacy compliance functions and the Data Broker Services team.
Manager, Administrative Operations

Eli is responsible for executive support, calendar scheduling, travel and event preparation, communication, and special project management.
May Departures

Laura Kozma
Associate Vice President
Research Administration
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Akilah Laster</td>
<td>Director, Communications</td>
</tr>
<tr>
<td>Johanna Stamates</td>
<td>Assoc. VP, Research Compliance</td>
</tr>
</tbody>
</table>
Contract Status in IBISResearch

Laura Kozma

Associate Vice President
Research Administration
Check IBIS First:

- IBIS contains the latest updates
- Contact your ORA representative if you have additional questions
- ORA spends a significant amount of time answering questions that are available in IBIS, this could be time spent getting your contract executed!
COI Disclosure Deadline

Laura Kozma
Associate Vice President
Research Administration
Disclosers need to complete their disclosure profile update by June 15th
• The University of Miami implemented the new Conflict of Interest, Conflict of Commitment, Foreign Influence, and Institutional Conflict of Interest Policy, which addresses institutional vulnerabilities related to Conflicts of Interest (COI) and Foreign Influence.

• To protect the University’s mission and exceptional reputation, the new policy widens the breadth of UM’s previous COI policies, requiring Covered Persons, to disclose their outside interests to UM.

• A COI arises when the interests of a Covered Person, or those of the University at large, influence, affect or are affected by the University’s educational, clinical care, and scholarly activities.
Hurricane Preparedness

Matthew Shpiner
Executive Director, Emergency Management

Vincent Torres
Director, Emergency Preparedness
Agenda

- Hurricane Planning
- Personal Preparedness
- University Hurricane Plan Overview
- Research Preparedness and Resources
- Questions & Answers
- We Are Here to Help!
# 2022 Forecast

## Hurricane Season: June 1st to November 30th

<table>
<thead>
<tr>
<th>Storm Type</th>
<th>National Hurricane Center</th>
<th>Colorado State University</th>
<th>AccuWeather</th>
<th>Average Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Named Storms (39 mph and higher)</td>
<td>14-21</td>
<td>19</td>
<td>16-20</td>
<td>14.4</td>
</tr>
<tr>
<td>Hurricanes (74 mph or higher)</td>
<td>6-10</td>
<td>9</td>
<td>6-8</td>
<td>7.2</td>
</tr>
<tr>
<td>Major Hurricanes (Cat 3+) (111 mph or higher)</td>
<td>3-6</td>
<td>4</td>
<td>3-5</td>
<td>3.2</td>
</tr>
</tbody>
</table>

Season Peak: September 10th
Early Season: Caribbean Generation
Secondary Peak: October 5th
Later Season: Cape Verde Type

**The Number That Really Matters is 1!**
Forecast

Understanding the Cone

- The cone represents the probable track of the CENTER of a tropical cyclone.
- The size of the cone is drawn so that about two-thirds of the time, the center of the storm will remain in the cone.
- The cone does NOT take into account the size of the storm.
- A hurricane is not a point; impacts often occur well outside of the cone.
- The cone is used to show the forecast up to 5 days out from the last recorded position of the storm.
Personal Preparedness

Ensure You Have the Right Coverage for Your Needs

EDISON

Sit Down and Talk with Your Family

Develop a Plan to Address the Complexities of Your Situation

- General Items
  - Look for shelf stable BOGO deals at Publix throughout hurricane season.
  - Review key documents - ensure they are digitized and available in a secure cloud based storage solution

- Hurricane Supply Kit

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 gallons of water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Battery Powered Lantern</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Battery Powered Fans</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Batteries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shelf Stable Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gas Stove</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash ($300-500)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marcel (Dog) Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First Aid Kit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand Saw</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baby Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First Aid Kit</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 120-72 Hours
  - Test all shutters to verify they remain operable
  - Make final evacuation plan for all people in home
  - Purchase any items that are needed in hurricane supply kit and not already accounted for
  - Ensure all security camera batteries are charged
  - Ensure all drill batteries are charged
  - Tape closed all exterior electrical boxes
  - Bring in all outside hoses
  - Remove and bring in outside hose rack (west side of garage)
  - Do laundry in anticipation of power going out
Now is the Time for Action!

- Each Campus Faces Unique Challenges
  - Coral Gables Campus – Evacuation for Cat 3+
  - Marine Campus – Barrier Island
  - Medical Campus – Critical Facilities Remaining Occupied
- Our Facilities, Labs, and Other Areas Have Unique Vulnerabilities

We can reduce risk through mitigation and planning!
IT TAKES ALL OF THE U!

- Review Best Practices / Lessons Learned
- Review FEMA / Insurance Reimbursement Guidelines
- Review/Update Contracts with Disaster Vendors
- Pre-Season Building & Grounds Preparation
- Conduct Meetings with Key University Units
- Update Emergency Preparedness Website
- Prepare Pre-Season Communications
- Review Plans and Procedures
- Meet with Government Partners
Threat Monitoring

Information Flow

- NHC, NWS, County EM Offices
- UM Emergency Management
- University Crisis Decision Team
- Individual Campus Crisis Decision Teams
- University Community
- Unit Leadership to Faculty/Staff

Threat Area
General Pre-Storm Preparation

- Ensure all **data** is on cloud storage
- Print **critical documents**, plans, contact lists
- Secure all **windows** and close blinds
- Disconnect & elevate all electrical equipment.
- Take all **valuable personal** belongings home
- Take **pictures** of all valuable equipment and general workspaces
- Verify/update **contact information** in Workday
Protecting Our Mission
Emergency Workforce

Update Tier Designations and Discuss Roles and Expectations

- Review tier (essential) designations for all employees
- Set Clear Expectations
- Discuss Responsibilities
  - Pre
  - During
  - Post-Storm

Contact your HR Partner for a list of designated employees in your unit
Preparedness for Research

Access the Checklist
https://prepare.miami.edu/_assets/pdf/hurricane-season-checklists-for-research-labs.pdf
Now is the Time to Plan!

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UReady

- All units are required to utilize the UReady continuity planning portal to create their own Continuity of Operations Plan (COOP).
- Plans support a unit’s ability to restore or sustain critical operations following an emergency or disaster impacting their space, staff, equipment, and sensitive information.
- Well-developed UReady Plans include:
  - Minimum requirements for continued operations
  - Emergency contact information for employees
  - IT systems required to support critical operations
  - An overview of critical equipment and supplies
  - Methods for coping when lacking key resources
  - Photo documentation of all workspaces and equipment
Post-Storm Response & Recovery

Pre-Staged Resources to Expedite Recovery

Debris Removal
Phase 1 – Access for Emergency Responders
Phase 2 – Push Debris from All Roadways
Phase 3 – Moving Debris to Staging Site
Phase 4 – Dispose Mulched Debris to Landfill Site

Building Assessments
Phase 1 – Initial Exterior Campus Assessment
Phase 2 – Initial Interior Assessment of All Buildings
Phase 3 – Stabilize Major Impacts
Phase 4 – Detailed Assessment of All Buildings
Phase 5 – Stabilization of All Impacts

[Images of debris and buildings]
Long-Term Recovery

Returning to Normal

- Temporary Solutions to Resume Critical Research Functions
- Permanent Solutions to Address Impacts
- Return to Pre-Disaster State
- Financial reimbursement is lead by Finance and Risk Management
  - Before / After Photos
  - Document all actions and expenditures
  - Decisions consistent with existing plans
  - Prepare Preliminary Cost Estimates
Resources

• Prepare Website
  www.prepare.miami.edu

• University of Miami Emergency Guide
  www.miami.edu/emergency-guide

• Hurricane Preparedness Information
  www.prepare.miami.edu/hurricane

• Active Shooter Response Training
  www.miami.edu/activeshooter

• University of Miami Weather Stations
  miamidade.weatherstem.com/umiami

• Follow @UMiamiENN on Facebook, Twitter, and Instagram
Thank You

Please email oem@miami.edu with questions or opportunities to further collaborate

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Executive Director of Emergency Management
University of Miami
Office of Emergency Management
Cell: (305) 984-4467
Office: (305) 284-3250
Email: mshpiner@miami.edu

Vincent Torres
Director of Emergency Management
UHealth / Miller School of Medicine
Department of Public Safety
Cell: (305) 989-5987
Office: (305) 243-9466
Email: vjt3@miami.edu
May Transfers

Sheela Dominguez
Executive Director, Strategic Operations
## Transfers

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patricia Atkinson</td>
<td>Research Navigator</td>
</tr>
</tbody>
</table>
May New Hires and Promotions

K. Brandon Strickland, J.D.

Executive Director, Research Administration
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joselyn Estrugo</td>
<td>Contract and Grants Analyst</td>
</tr>
<tr>
<td>Rebecca Carrasco</td>
<td>Contract and Grants Analyst</td>
</tr>
<tr>
<td>Name</td>
<td>Title</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Bianca Krysztof</td>
<td>Sr. Manager, Research Administration</td>
</tr>
</tbody>
</table>
Jackson on Subaward Budgets

K. Brandon Strickland, J.D.
Executive Director, Research Administration
Jackson on Subawards Budgets
May New Hires

Allen Mora

Executive Director, Research Intelligence & Capacity (RIC)
# New Hires

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofia Aymerich</td>
<td>Research Training Specialist</td>
</tr>
<tr>
<td>Cynara Deveaux</td>
<td>Project Manager</td>
</tr>
<tr>
<td>Sophie Zhang</td>
<td>Business Systems Analyst</td>
</tr>
</tbody>
</table>
May Transfers

Dr. Alberto Caban-Martinez
Assistant Provost for Research Integrity
# Transfers

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jerry Engel</td>
<td>Quality Assurance Auditor</td>
</tr>
</tbody>
</table>
May Departures

Edwin Bemmel
Executive Director, Office of Research Administration
Departures

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glenda Jimeson</td>
<td>Sr. Grant Assistant</td>
</tr>
</tbody>
</table>
Charging Salary Above the Salary Cap Amount

Edwin Bemmel

Executive Director, Office of Research Administration
Several federal sponsors (including NIH and DoD) utilize the Executive level II salary as maximum allowable salary cost on sponsored projects. Salary cost above this amount will not be reimbursed by these sponsors and must be absorbed by the university.

In a recent review, we found numerous grants with salary charges above the cap. It is important to properly calculate the salary cap and above the cap amount and split the costing allocations accordingly.

Use the Salary Cap Cost Share Calculation Worksheet, available in the Grants Toolbox to determine the proper split.

Use this information to create the costing allocations in WD.

Use Multi Drivers (GR/PG or GR/BG combination for the above the cap amount)

Reconcile timely to ensure that the correct amount is charged to the sponsor.
Workday MSOM Conversion and Reporting Changes

Edwin Bemmel
Executive Director, Office of Research Administration
## Workday MSOM Conversion

**MSOM awards have been converted to company 500:**

- Award lines and grant #’s have been created
- All converted grants have a -1 appended at the end (GR000001 is converted to GR000001-1)
- Legacy grants (GR000001) should no longer be used, except for PAA credits which default to the original charge
- Converted grants (GR000001-1) should be used for all new transactions effective FY 23
- Unspent balances will be converted to the new grants towards the end of the month
- For MSOM, transactions must be created in company 500
- New SPC’s are created to replace the legacy company 500 SPC’s
  - They will have new numbers (no longer including the old number with the dash-1)
- WD will provide both the legacy and the converted SPC when typing either of the numbers
- Use multi drivers for all cost share and salary cap transactions
- Cost share or above the salary cap expenditures will post to a transaction line consisting of both a GR and department worktag (eg PG or BG)
Below is an illustration of total salary shared to an award of $4,182.94 with $2,005.88 funded by the sponsor and $2,177.06 above the salary cap.

The portion funded by the sponsor will be posted similar to how it is today (GR028272 in this case).

The above the cap portion will not be posted to a salary cap grant.

Instead, it will post to your sponsored grant (GR028272 in the below example) combined with (based on the example below): PG009987.

<table>
<thead>
<tr>
<th>Grant</th>
<th>Program</th>
<th>FD010</th>
<th>FD014</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>GR028272</td>
<td>PG009987</td>
<td>2,177.06</td>
<td></td>
<td>2,177.06</td>
</tr>
<tr>
<td>GR028272</td>
<td></td>
<td></td>
<td>2,005.88</td>
<td>2,005.88</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>2,177.06</td>
<td>2,005.88</td>
<td>4,182.94</td>
</tr>
</tbody>
</table>
Reports are being modified to distinguish between sponsor funded vs institutional cost

- For example, the Award Transaction Audit includes a new section on the bottom to reflect the Institutional Cost, which is all cost share and salary cap.

When running reports, ensure that the company is pulled through the company hierarchy

- Select Academy/MSOM
- Always pull in the legacy and the converted grants to get the full LTD balance.
### FIN-GRA Award Transaction Audit (Central)

<table>
<thead>
<tr>
<th>Award Period</th>
<th>FY2022-Jun</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company/Academy/MOCO</td>
<td>Award</td>
</tr>
</tbody>
</table>

#### Sponsor Direct Cost & Facilities and Administration

<table>
<thead>
<tr>
<th>Award</th>
<th>Lead Principal Investigator</th>
<th>Sponsor Direct Cost Facilities and Administration</th>
<th>Sponsor Direct Cost &amp; Facilities and Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Budget</td>
<td>Actuals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Original</td>
<td>Adjustment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>405,212.34</td>
<td>0.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>405,212.34</td>
<td>0.00</td>
</tr>
</tbody>
</table>

#### Facilities and Administration

<table>
<thead>
<tr>
<th>Award</th>
<th>Lead Principal Investigator</th>
<th>Sponsor Direct Cost Facilities and Administration</th>
<th>Sponsor Direct Cost &amp; Facilities and Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Budget</td>
<td>Actuals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Original</td>
<td>Adjustment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>405,212.34</td>
<td>0.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>405,212.34</td>
<td>0.00</td>
</tr>
</tbody>
</table>

#### Program Income

<table>
<thead>
<tr>
<th>Award</th>
<th>Lead Principal Investigator</th>
<th>Sponsor Direct Cost Facilities and Administration</th>
<th>Sponsor Direct Cost &amp; Facilities and Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Budget</td>
<td>Actuals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Original</td>
<td>Adjustment</td>
</tr>
<tr>
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<td></td>
<td>405,212.34</td>
<td>0.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>405,212.34</td>
<td>0.00</td>
</tr>
</tbody>
</table>

*Exclude ledger account types Asset, Equity, Income and Liability.*
Effort Certification

Kimberly Croft
Executive Director, Research Accounting and Cost Analysis
Important Dates:

- **PAA’s**
  - Monthly employees due no later than June 24
  - Bi-weekly employees due no later than August 22
- **ECC load**
  - Approximately July 11
- **Certification period**
  - 60 days from ECC load
- **Process for exceptions for late certification**
- **What happens if effort is not certified on time?**
- **Training forthcoming**
ECC New Format

Kimberly Croft
Executive Director, Research Accounting and Cost Analysis
The current Effort Certification format is as follows:

The new Effort Certification format is as follows:

1. Grant ID
2. Non C/S Payroll %
3. Cost Share %
4. Total Payroll + C/S Dollars
5. Computed Effort
6. Certified Effort
7. Certify
The current Project Statement format is as follows:

The new Project Statement format is as follows:

1. Employee
2. Cost Center
3. Non C/S Payroll %
4. Cost Share %
5. Total Payroll + C/S Dollars Computed Effort
6. Computed Effort
7. Certify
8. Action
Payroll Accounting Adjustment (PAA) Process

Kimberly Croft
Executive Director, Research Accounting and Cost Analysis
Submit to Post-Award with justification to include:

- Why it was charged incorrectly
- Why it should be allocated somewhere else
- How you are preventing this from occurring in the future

“And now round two of ‘Justify It’. We’ll start with you.”
General guidelines for approving and rejecting exception requests:

<table>
<thead>
<tr>
<th>Acceptable</th>
<th>Unacceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to put cost on the grant was out of the department’s control (i.e., award wasn’t set up to put costs on grant when they were initially incurred) – Once the account is open, must put costs on the grant within a month</td>
<td>Department failed to review payroll default and suspense accounts in a timely manner</td>
</tr>
<tr>
<td>Moving from grant to grant on the same award on fellowship/training grants</td>
<td>Failure to review and submit corrections for costs going on a grant in a timely manner (except fellowship/training grants)</td>
</tr>
<tr>
<td>Corrections within 4 months of the end of the performance period (i.e., performance period ends 11/30 and 5/31)</td>
<td>Corrections to move costs onto a grant more than 4 months after the end of the performance period</td>
</tr>
<tr>
<td>Costs coming off a grant to a departmental account, regardless of period</td>
<td>Frequent requests from the same department to correct for errors</td>
</tr>
<tr>
<td>Removal of terminal vacation time for employees and other unallowable costs, regardless of period</td>
<td>Short staff, lack of time, etc.</td>
</tr>
</tbody>
</table>

Reopened statements must be certified within **2 weeks**
Internal Service Delivery (ISD) and iLab Reminder

Kimberly Croft
Executive Director, Research Accounting and Cost Analysis
Internal Service Delivery (ISD) and iLab Reminder

- If you’re using iLab for the billing process, invoices are electronically uploaded in Workday – attachments are not needed.

- If you’re creating a manual ISD, an attachment is still needed.
AAHRPP Reaccreditation

Kenia Francis

Director, Human Subject Research (HSRO)
## Reaccreditation Process

1. **Application Step 1 – Self-Assessment**
   - Deadline: June 10, 2022
   - Submitted

2. **Application Step 2 – Site Visit**
   - Pending AAHRPP review of Step 1 materials
   - Visit date TBD

3. **Site Visit Report**
   - Draft Site Visit Report
   - UM’s response

4. **Council on Accreditation Meeting**
   - Accreditation determination
<table>
<thead>
<tr>
<th>Objectives/Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>High degree of interoperability with existing UM systems</td>
</tr>
<tr>
<td>Further the larger strategic plan for Research Administration Systems</td>
</tr>
<tr>
<td>Facilitate collaboration between UM faculty, staff, central offices, and external institutions</td>
</tr>
<tr>
<td>Maintain compliance with federal regulations, UM policies, and AAHRPP accreditation standards</td>
</tr>
<tr>
<td>Integration between Grants, Agreements, UDisclose, and IRB</td>
</tr>
<tr>
<td>Intuitive and simplified smart forms for submissions</td>
</tr>
<tr>
<td>Easier collaboration with relying sites and External IRBs via Huron’s IRB Exchange</td>
</tr>
<tr>
<td>Enhanced workspace with new tabs that will display CITI training data and UDisclose (COI) research certification status</td>
</tr>
</tbody>
</table>
IRB SaaS Implementation

Kenia Francis
Director, Human Subject Research (HSRO)
### Reasons for IRB Re-Implementation

<table>
<thead>
<tr>
<th>Streamline protocol review process</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>o Focus on the information needed for review</td>
<td></td>
</tr>
<tr>
<td>o Remove extraneous/duplicate information</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remove customizations</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Costly to maintain</td>
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<tr>
<td>Challenging to upgrade</td>
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<table>
<thead>
<tr>
<th>Integration between Grants, Agreements, UDisclose, and IRB</th>
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<tbody>
<tr>
<td>o IRB project workspace will display UDisclose (COI) Research Certification information</td>
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<tr>
<td>o New activity will allow users to connect a related Grant to IRB Protocol submission</td>
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HRPP Toolkit implementation and adaptation process to accommodate local needs.

Huron led in-depth review of IRB functionality to determine system configurations.

Cycles of detailing requirements, planning, configuring, process testing, and acceptance tasks.

User acceptance testing, piloting future business processes, and system verification.

System GO Live! Transitioning to end-user community.

Supporting end users, resolving bugs, and transitioning old systems and roles.
Project Updates

HSRO Website: hsro.uresearch.miami.edu
- All project information
- FAQs
- Contact form

Newsletters
- HSRO
- OVPRS

Email
- Amanda Rodriguez, Project Manager: axr1694@miami.edu
May New Hires

Yolanda Davis
Director, CRMSO
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Harshini Mahanti</td>
<td>Sr. Clinical Research Monitor</td>
</tr>
</tbody>
</table>
Clinical Research Management & Support Office (CRMSO)

About Us

Yolanda Davis

Director, CRMSO
Clinical Research Management & Support Office (CRMSO)
Year One Brief Overview

As of March 2022

Authored by Yolanda Davis
Director, CRMSO

Prepared by Katrina Guanche
Project Management Coordinator, CRMSO
Clinical Research Management & Support Office

Serve as a central resource for principal investigators, study staff and departments involved in clinical research and for sponsor-investigators seeking to conduct clinical trials at the University of Miami.

- **Regulatory**: Provide regulatory support for IND/IDE management and coordination of communication with the FDA.
- **Project Management**: Oversee harmonization of protocol activities and coordinate communication to effectively complete a study.
- **Site Management**: Provide oversight of the clinical trial and ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs and GCP.
- **Data Management**: Design, collect, clean and manage study data needed in support of the research question while complying with regulatory standards.
- **Clinical Trial Disclosure**: Provide support to study teams to ensure that study information and results are disclosed publicly in compliance with regulatory standards and other requirements.
For questions or additional information, please contact:

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Director
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Open Forum Questions