VPRS Administrative Updates

June 13, 2022

Agenda

UNIVERSITY OF MIAMI

- 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*

Mikki O'Neal

Associate Vice President, Research Operations & Infrastructure

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.
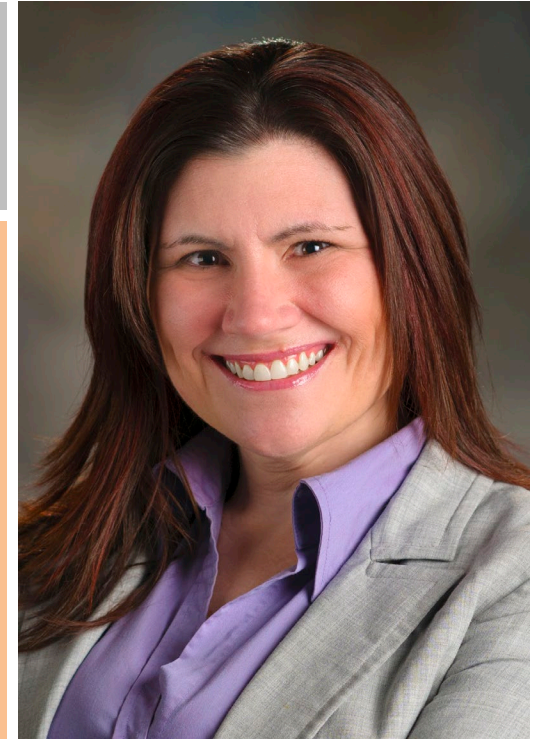
MBA, CCRP, CCRC, CHRC

Scott Streibich

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
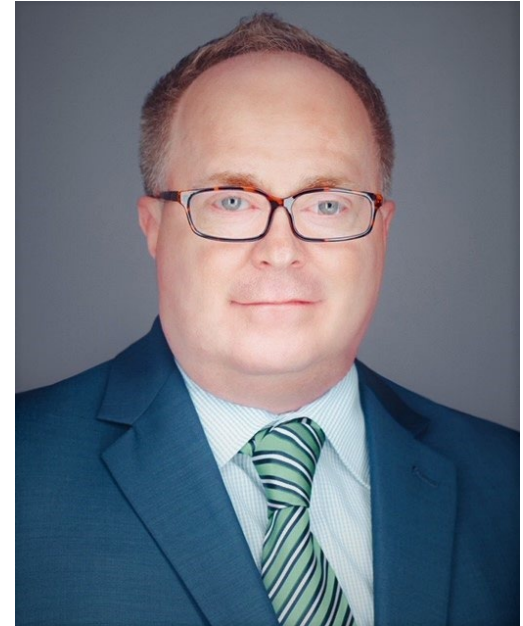
MBA, MHS, CHRC, CPB, CRCR, CSPR, CBE

Dr. Alberto Caban-Martinez

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.

DO, PhD, MPH, CPH

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Hilary Cox

Executive Director, University & Research Privacy

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.
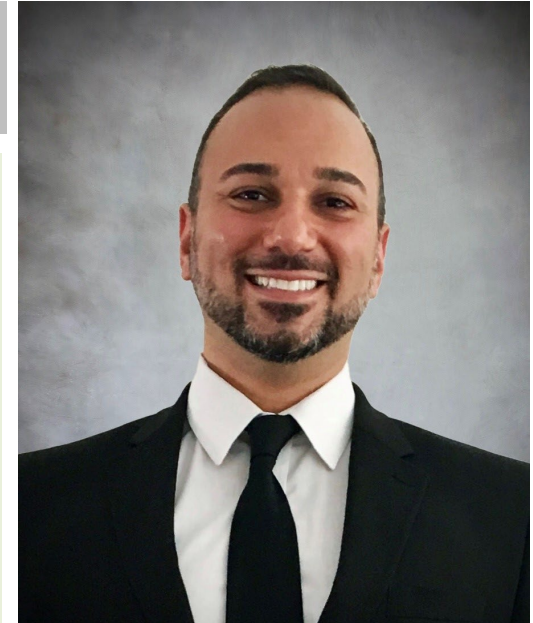
JD, CIPP/US

Eli Mizrahi

Manager, Administrative Operations

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

JD, CIPP/US

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May Departures

Laura Kozma

*Associate Vice President
Research Administration*

Departures

Name	Title
Akilah Laster	Director, Communications
Johanna Stamates	Assoc. VP, Research Compliance

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Contract Status in IBISResearch

Laura Kozma

Associate Vice President
Research Administration

Contract Status in IBISResearch

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

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Disclosers need to complete their disclosure profile update by June 15th

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COI Disclosure Deadline – June 15

- 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.

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HURRICANE PREPAREDNESS FOR THE RESEARCH COMMUNITY

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

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

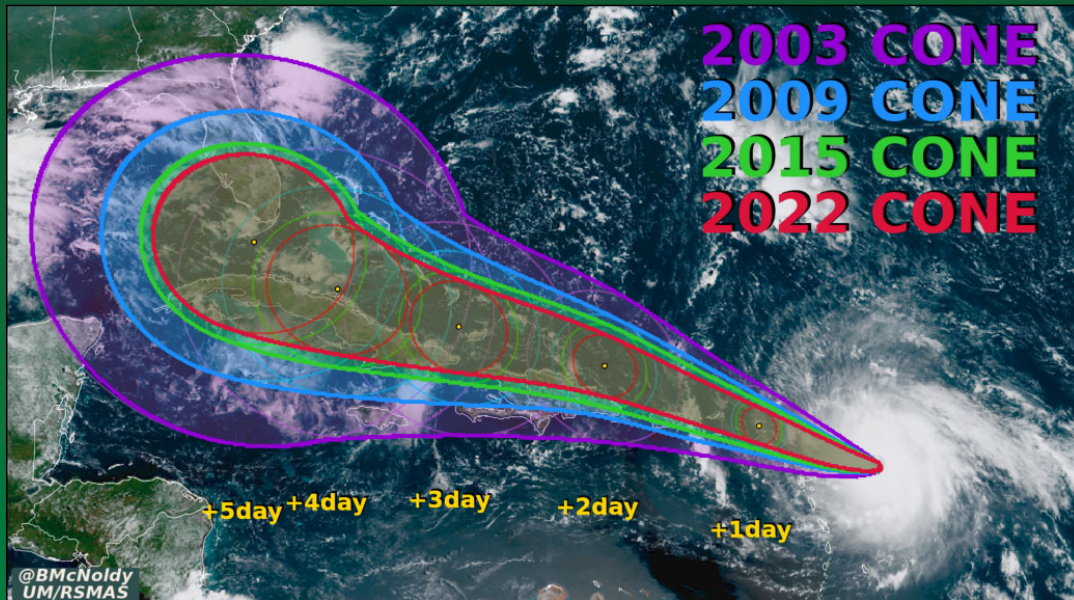Season Peak: September 10th

Early Season: Caribbean Generation

Secondary Peak: October 5th

Later Season: Cape Verde Type

The Number That Really Matters is 1!

Forecast

Understanding the Cone

Personal Preparedness

Sit Down and Talk with Your Family

Ensure You Have the Right Coverage for Your Needs

EDISON COMPANY

Homeowners Policy

- **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**

20 gallons of water	Shelf Stable Food	Gas Stove
Battery Powered Lantern	Cash ($300-500)	Marcel (Dog) Food)
Battery Powered Fans	First Aid Kit	Hand Saw
Batteries	Baby Food	First Aid Kit

**Develop a Plan to Address the Complexities of Your Situation**

- **120-72 Hours**
  - Test all shutters to verify they remain operable
  - Make final evacuation decision for family and animal
  - 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

Unique Challenges

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
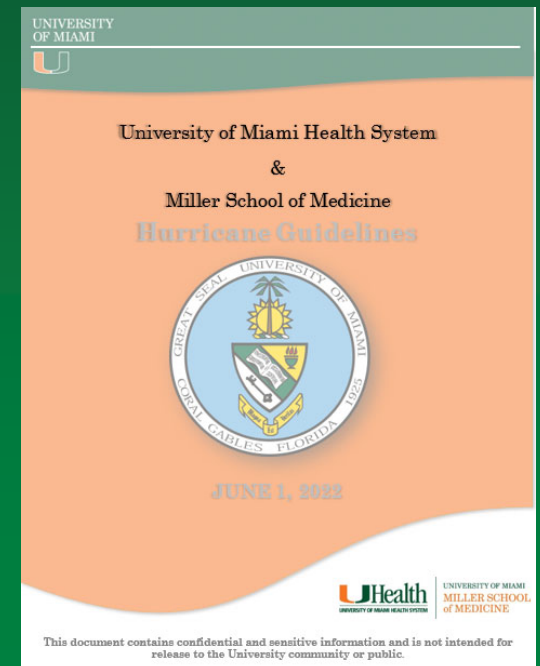- Our Facilities, Labs, and Other Areas Have Unique Vulnerabilities

We can reduce risk through mitigation and planning!
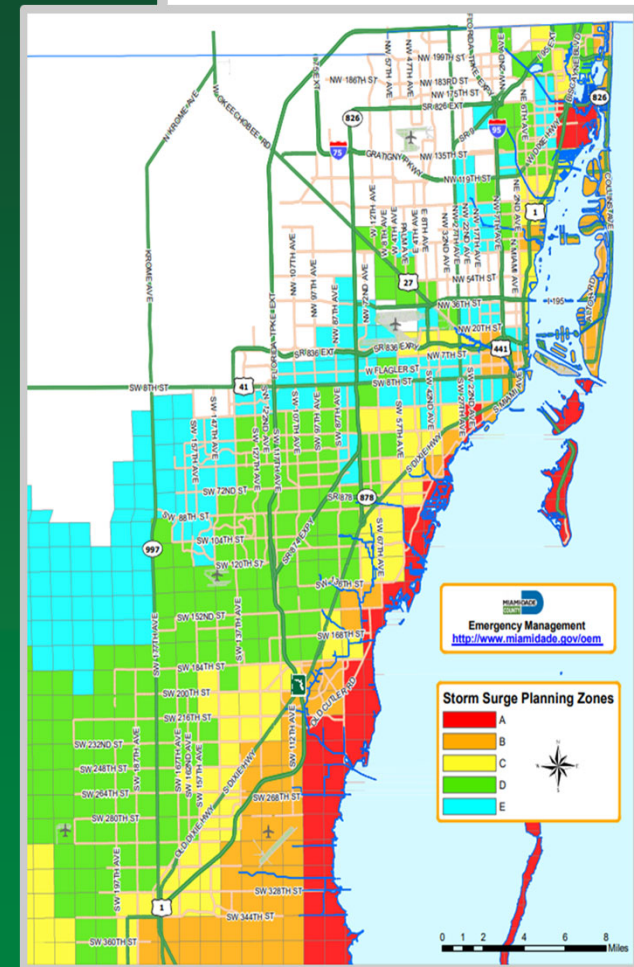
Pre-Season Preparation

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

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University of Miami Health System
&
Miller School of Medicine

Hurricane Guidelines

JUNE 1, 2022

UHealth | UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

This document contains confidential and sensitive information and is not intended for release to the University community or public.

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
  o Pre
  o During
  o Post-Storm

workday.

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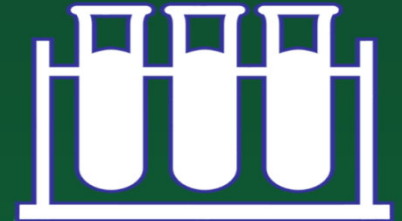
Preparedness for Research

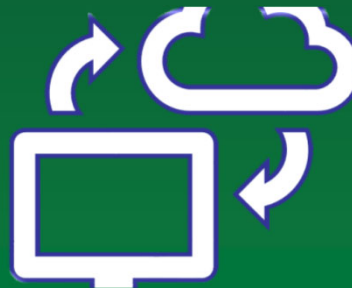**Principle Investigator Research Checklist**

Hurricane Kit

Critical Equipment

Preparing Samples and Lab Equipment

Photo Document

Data Storage

Register Critical Equipment with Public Safety

Access the Checklist

https://prepare.miami.edu/_assets/pdf/hurricane-season-checklists-for-research-labs.pdf

Research Preparedness Checklist

Now is the Time to Plan!

Table of Contents

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

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

Resilient & Renewed

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

University of Miami — 84°F

U of Miami Health System — 82°F

U of Miami Rosenstiel School — 79°F

Thank You

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

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Vincent Torres
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UHealth / Miller School of Medicine
Department of Public Safety
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Office: (305) 243- 9466
Email: vjt3@miami.edu

May Transfers

Sheela Dominguez
Executive Director, Strategic Operations

Transfers

Name	Title
Patricia Atkinson	Research Navigator

May New Hires and Promotions

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

New Hires

Name	Title
Joselyn Estrugo	Contract and Grants Analyst
Rebecca Carrasco	Contract and Grants Analyst

Promotions

Name	Title
Bianca Krysztof	Sr. Manager, Research Administration

Promotion

Jackson on Subaward Budgets

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

May New Hires

Allen Mora

Executive Director, Research Intelligence & Capacity (RIC)

New Hires

Name	Title
Sofia Aymerich	Research Training Specialist
Cynara Deveaux	Project Manager
Sophie Zhang	Business Systems Analyst

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May Transfers

Dr. Alberto Caban-Martinez
Assistant Provost for Research Integrity

Transfers

Name	Title
Jerry Engel	Quality Assurance Auditor

May Departures

Edwin Bemmel
Executive Director, Office of Research Administration

Departures

Name	Title
Glenda Jimeson	Sr. Grant Assistant

Charging Salary Above the Salary Cap Amount

Edwin Bemmel

Executive Director, Office of Research Administration

Charging Salary Above the Salary Cap

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

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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)

Cost Share/Salary Cap and Multidimensional DWT

- 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

Grant	Program	FD010	FD014	Total
GR028272	PG009987	2,177.06		2,177.06
GR028272			2,005.88	2,005.88
Total		2,177.06	2,005.88	4,182.94

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Reports

Reports are being modified to distinguish between sponsor funded vs institutional cost

- o 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

- o Select Academy/MSOM

- o Always pull in the legacy **and** the converted grants to get the full LTD balance

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Reports

Effort Certification

Kimberly Croft

Executive Director, Research Accounting and Cost Analysis

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Effort Certification

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

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ECC New Format

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

ECC New Format

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

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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."

PAA Process

General guidelines for approving and rejecting exception requests:

Acceptable	Unacceptable
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	Department failed to review payroll default and suspense accounts in a timely manner
Moving from grant to grant on the same award on fellowship/training grants	Failure to review and submit corrections for costs going on a grant in a timely manner (except fellowship/training grants)
Corrections within 4 months of the end of the **performance** period (i.e., performance period ends 11/30 and 5/31)	Corrections to move costs onto a grant more than 4 months after the end of the performance period
Costs coming off a grant to a departmental account, regardless of period	Frequent requests from the same department to correct for errors
Removal of terminal vacation time for employees and other unallowable costs, regardless of period	Short staff, lack of time, etc.

Reopened statements must be certified within **2 weeks**

Internal Service Delivery (ISD) and iLab Reminder

Kimberly Croft

Executive Director, Research Accounting and Cost Analysis

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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.
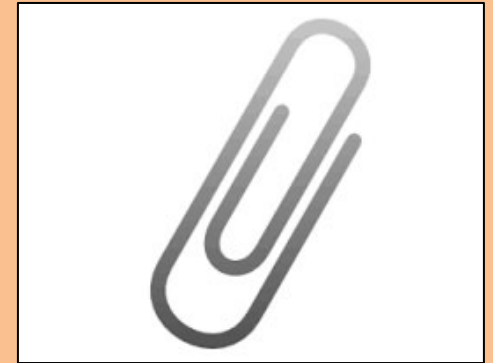
AAHRPP Reaccreditation

Kenia Francis

Director, Human Subject Research (HSRO)

AAHRPP Reaccreditation

Association for the Accreditation of Human Research Protection Programs:

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

Project Objectives / Benefits

Objectives/Benefits

High degree of interoperability with existing UM systems

Further the larger strategic plan for Research Administration Systems

Facilitate collaboration between UM faculty, staff, central offices, and external institutions

Maintain compliance with federal regulations, UM policies, and AAHRPP accreditation standards

Integration between Grants, Agreements, UDisclose, and IRB

Intuitive and simplified smart forms for submissions

Easier collaboration with relying sites and External IRBs via Huron's IRB Exchange

Enhanced workspace with new tabs that will display CITI training data and UDisclose (COI) research certification status

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IRB SaaS Implementation

Kenia Francis

Director, Human Subject Research (HSRO)

Reasons for IRB Re-Implementation

Streamline protocol review process

- o Focus on the information needed for review
- o Remove extraneous/duplicate information

Remove customizations

Costly to maintain

Challenging to upgrade

Integration between Grants, Agreements, UDisclose, and IRB

- o IRB project workspace will display UDisclose (COI) Research Certification information
- o New activity will allow users to connect a related Grant to IRB Protocol submission

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Methodology & Timeline

Oct – Dec 2021 **HRPP Toolkit**	**Jan – Feb 2022** **Onboarding**	**Mar – May 2022** **Iteration**	**Jun – Jul 2022** **Testing**	**Aug 2022** **Deployment and Training**	**Aug - Sep 2022** **Support**
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

Project Information

Benefits of New System — Reduce Administrative Burden, Enhance Transparency, Allow Parallel Processing — Benefits of Upgrade

Project Personnel

Frequently Asked Questions — FAQs

HELP

Question or Comment?

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May New Hires

Yolanda Davis
Director, CRMSO

New Hires

Name	Title
Harshini Mahanti	Sr. Clinical Research Monitor

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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

About Us

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 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.

RESEARCH & SCHOLARSHIP
REGULATORY AFFAIRS & ASSESSMENT
CLINICAL RESEARCH
MANAGEMENT & SUPPORT OFFICE
MIAMI

For questions or additional information, please contact:

Yolanda Davis
Director
Clinical Research Management & Support Office (CRMSO)

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🖥 research.miami.edu

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Open Forum Questions

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