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Research and Scholarship Administrative Update

August 2021

Agenda

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- Training Grant Data Resource
- COI Implementation Update
- Complion Process Update
- HSRO/IRB Training Update
- Research Navigator Update
- ORA Updates
 - OVPRS Welcomes Kimberly Croft
 - Proposal Deadline Policy & Exception Process
 - Charging Billing Rates on Grants
 - Subawards Using University Funds
 - Effort Policy Effort Reporting (complete prior to audit)
 - Reporting Unobligated Balance on RPPRS's
- Q&A

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Training Grant Data Resource

Eva Olivares

Manager, Research Support

What is Training Grant Data Resource?

- NIH Data Tables are required for T32 and other training grant applications, as well as progress reports
- The data tables are designed to enable consistent entry and review of data of training program faculty and scholars
- This resource will allow for a more consolidated and consistent way to obtain data for training grant data tables
- This initiative is under the leadership of the Vice Provost for Research + Scholarship, Dr. Erin Kobetz, in collaboration with the Miami CTSI, UM IT, the Graduate School and other institutional partners

Benefit

How will this resource benefit the research community?

- Reduce length of time it takes study teams to collect data
- Reduce administrative burden
- Improve accuracy and completeness of data provided to funding agencies

Goals

What are the goals?

Short-term Project Goals:

- Identify existing data sources and centrally capture data in one repository (UM data warehouse)
- Create streamlined process through which study teams can request available data from the resource
- Provide service for faculty and staff submitting these type of proposals
- Create process for capture and verification of data on an ongoing basis
- Disseminate T32 Proposal Guidelines document

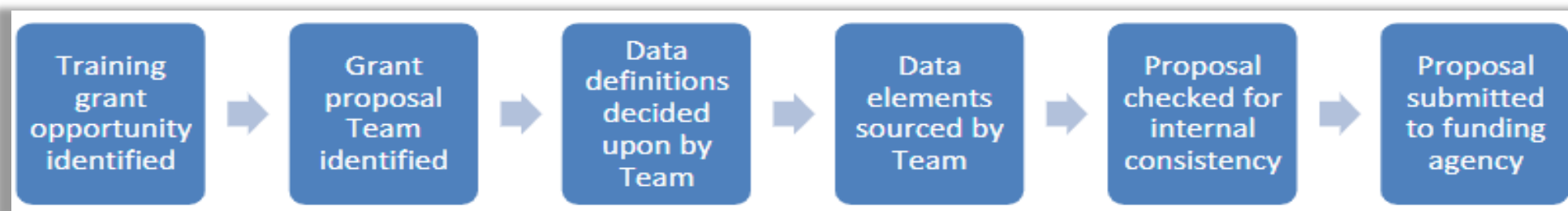
Long-term Project Goals:

- Enable an increase in the number of training grant submissions

Current Process

What is the current process to obtain data for training grant proposals?

The current process is through individual data sourcing, as well as individual interpretations of data elements and definitions.

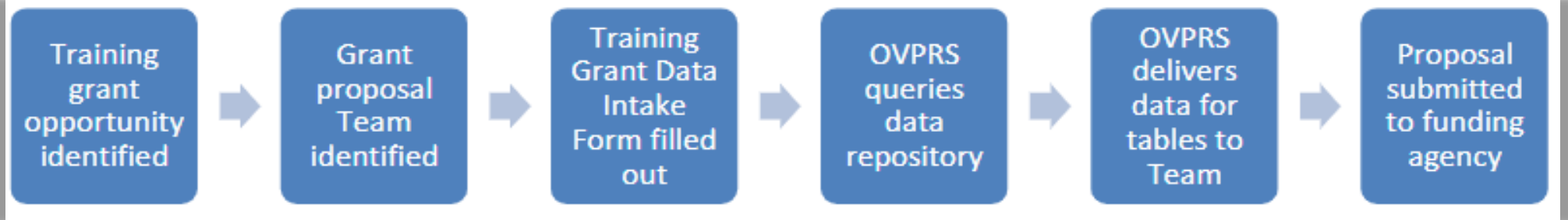


Challenges:

- Highly laborious
- Significant administrative burden
- Process leads to inconsistent and incomplete information across applications submitted from UM PIs
- Lengthy process (3+ months to collect data for tables)

New Process

What is the proposed new process?



Benefits:

- Reduced data variability
- Reduced administrative burden involved with individuals independently defining and sourcing data
- Provide proposal guidelines and data element definitions
- Establish process for annual updating and verification of data

Next Steps

- UM IT is working on developing the data warehouse for data tables
- T32 Proposal Development Guidelines document being finalized
 - Expected Launch: Fall 2021
- What should you expect?
 - Data for many of the NIH Data Tables will be provided
 - T32 Proposal Development Guideline document will be disseminated
 - Proposal Timeline (based on NIH and UM internal deadlines/best practices)
 - Data definitions document (clearly defined based on UM standards/best practices)

Additional Information

If you have any questions, or would like to learn more about this resource, please contact eolivares@med.miami.edu

Special thank you to our institutional partners:

ORA, Miami CTSI, UM IT, T32 Grant Administrators, Human Resources, IRSA, Faculty Affairs, Workday team, Libraries, Graduate School, MSOM Executive Dean for Research Office

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COI Implementation Update

Allen Mora

Executive Director, Research Intelligence & Capacity

Project Personnel



Governance

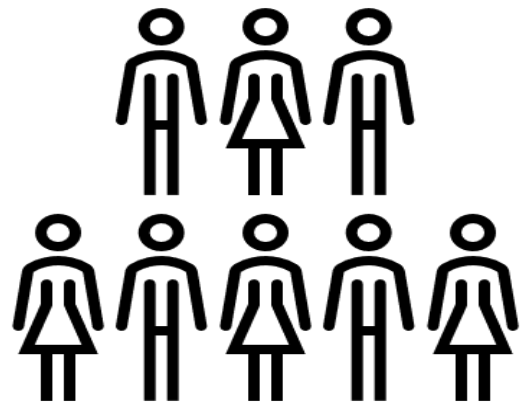
Erin Kobetz, Executive Sponsor
Frank Azuola, Executive IT Stakeholder
Blanca Malagon, Executive Sponsor/Program Manager



Project & Core Team

Allen Mora, Project Sponsor
Kristine Martinez, UM PM
Yoonsook Pack, Huron PM
Kanchan Sakhrani, Business Analyst/SME
Aymee Ortiz, Programmer/SME
Raquel Zamora, ORIM SME
Lory Hayes, DRM SME
Cristina Garcia, UHealth Compliance SME
Mariana Faustinelli, A&AS SME

Project Personnel (cont.)



Project Champions

Brian Doss, Psychology

Cynthia Levy, UMMG Hepatology

Belinda Quinta, MSOM Ophthalmology

Petra Caliste, MSOM Surgery

Kelly Padgett, MSOM HIHG

Kenneth Voss, College of A&S Dean's Office

Jerri Halgowich, MSOM Otolaryngology

Suhrud Rajguru, Biomedical Engineering

Betsy Arias, MSOM Miami Project to Cure Paralysis

Robyn O'Reilly, UMMG - Neurology

Progress Status Report

Current Project Phase: Iteration

- Final design requirements and specifications have been delivered for:
 - Disclosure Types
 - Disclosure Categories
 - Certification Types
 - Ancillary Reviews
 - Basic Settings
- From a development perspective, CPiP has been enabled to IBIS and both profile data as well as functional syncs have been set up and tested.

Progress Status Report (Cont.)

What's Next?

- Finalize Requirements & Future State Business Process Documentation
- Develop Staging Environment & Test Scripts
- Core Team & Project Team User Acceptance Testing Process
- Training
 - Huron Learning Lab
 - UM Training/Open Labs

Go Live: November 2021

Highlights

- **Branding & Communications**
 - The NEW! UDisclose
 - OVPRS Communications
 - Events Roundup
 - Week in review
 - Website Management
- **Truly Annual Disclosure Requirement**
- **Streamlined Training Approach**
- **Prior Approvals for External Work**
- **Expanded Population (New Policy)**

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Complion Process Update

Allen Mora

Executive Director, Research Intelligence & Capacity

Complion Regulatory eBinder Policy

[New policy](#) went into effect on June 1, 2021

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 - System Usage Fee Information

*****One-time fee of \$1250 per study***



For Industry studies:

- 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.

To date: 88 binders purchased, 26 binders activated

Complion – Process to Obtain Binders

1. Email resinfo@med.miami.edu to request study binders and include the following information:
 - For each study provide the PI First and Last name, Department/Division the eProst number (s), and Sponsor.
2. OVPRS finance will email an invoice to the requestor with the total amount.
3. Interdepartmental payment is to be completed via Workday.
4. The invoice can be shared with sponsors or kept internally for record.
5. Once payment is complete, Research IT will facilitate system access and training.
6. For any questions, please email resinfo@med.miami.edu

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HSRO/IRB Training Update

Kenia Viamonte

Director, Human Subject Research (HSRO)

&

Evelyne Bitai

Associate Director, Regulatory Affairs & Reliances

HSRO/IRB Training Update

Expanded Access to FDA Regulated Investigational Products (Compassionate use)

- “Emergency Use” means administering an investigational product to a human in a life-threatening situation in which no standard acceptable treatment is available, and in which there is insufficient time to obtain IRB approval.
 - The physician must report the emergency use to the IRB within 5 working days
 - Any subsequent use of the test article at the institution is subject to IRB review.
- “Expanded Access” means to use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient’s disease or condition

Emergency Use Checklist

- IND or IDE
- Discuss with IRB Chair, if time permits
- Report to HSRO within 5 working days
- Reports to FDA
- Submit Expanded Access protocol

Other Expanded Access

- IND or IDE
- Submit protocol showing information about IP, eligibility, follow-up
- Reports to FDA

HSRO/IRB Training Update

Genomic Data Sharing Certification

Expectation for NIH-funded research involving genetic, genomic and phenotypic data
IRB Review is Required

Process:

Submit a GWAS or GDS sharing request to the IRB via email

Include a copy of the consent form(s) or eProst number. The requirements differ for samples collected before January 2015.

Suggested Consent language:

The information from this study will be freely available in a public, unrestricted database that anyone can use. The public database will include information on hundreds of thousands of genetic variations in your DNA code, and your ethnic group and sex. The only health information included will be whether you had a disease or not.. This information will not include your name or other information that could be used to easily identify you. However, it is possible that people could use information from your genome and combine it with information from other sources to identify you, though we believe this event is unlikely. See <https://www.genome.gov/about-genomics/policy-issues/Informed-Consent-for-Genomics-Research/Special-Considerations-for-Genome-Research>

HSRO/IRB Training Update

Required eProst Training

- You will soon receive notice that you are assigned to complete a course in ULearn called **Basic Walkthrough of the eProst System**.
- The OVPRS is offering this course to help new users and to comply with the training requirements described in regulations.
- This computer-based course includes videos and a quiz.
- It is one of several pre-requisite training modules for eProst/IRB users designed for anyone needing access to the system.

Please note: If you do not complete all of the assigned modules by the end of the day, October 31, 2021, your access to eProst/IRB will be disabled. You will need to complete all assigned courses to reactivate your eProst/IRB user account.

HSRO/IRB Training Update

Short Form Process Reminders for Participants who do not Read/Understand English

- Use the Short Form to enroll a participant **only** when:
 - there is potential for direct benefit to the participant that is not available outside of the research; or
 - when the IRB directs you to obtain re-consent from a subject who does not read or understand English and the IRB-approved translated consent form is not available
- Document the above circumstances requiring the short form in the research record.
- Obtain IRB approval before using the Short Form Process and an IRB-approved translated short form. Consider obtaining approval with your initial review submission.
- If you use the Short Form Process for a clinical trial, you must obtain consent from the participant as soon as the translated version of the consent document is available.

Best practice:

Describe the Short Form Process clearly in your local protocol. Include the translated short forms in your IRB submission. Develop a reminder process to document the circumstances and ensure you obtain consent when the translated version is available.

Thank you

Best Practices / Guidance / General Information:

- Contact us at 305-243-3195 or hsro@miami.edu

Visit our webpage:

- www.hsro.miami.edu or www.eprost.med.miami.edu

We are committed to service excellence and
to supporting our HRPP partners.

We are always happy to help.
Thank you for your time!

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Research Navigator Update

Patty Atkinson

Research Navigator, Research Intelligence & Capacity



Research Navigator

Focus on **research**, not roadblocks

A new type of research support

Customer-friendly

Faculty-centric

Concierge-style service

Connects faculty to the right resources, right now

- ✓ Completed Needs Assessment
- ✓ Obtained Faculty & Staff Feedback
- ✓ Developed Services
- ✓ Piloted Successfully
- ✓ Launch Plans Underway
- ✓ Stay Tuned for Launch Date!
- ✓ Reach out at

Navigator@miami.edu

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ORA Updates

Laura Kozma

Associate Vice President, Research Administration

Welcome

Kimberly Croft

Executive Director, Research Accounting and Cost Analysis



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Proposal Deadline Policy

K. Brandon Strickland, J.D.

Executive Director, Research Administration

Proposal Deadline Policy & Exception Process

- Proposal Deadline Policy is now in full effect now
- FAQ in development
- Please remember SBIR and STTR must be submitted 5 days before the deadline
- Exception request
 - Submitted before routing
 - must be submitted to both your Dean and the Vice Post Research Scholarship and approved by both
 - Is not required if ORA return a proposal because of an error

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Charging Billing Rates on Grants

Lionel Vera

Director, Cost Analysis and Reconciliation

Interdepartmental Billing Risks:

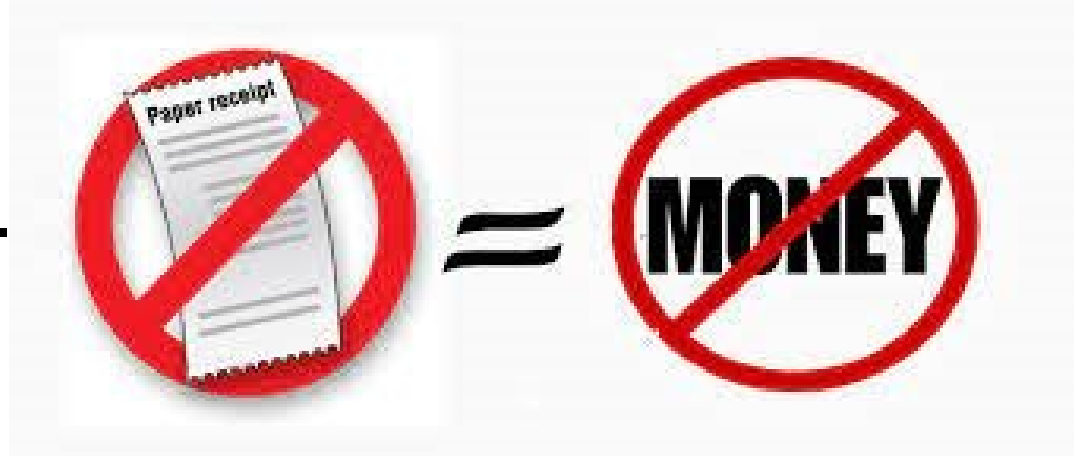
- Documenting actual costs
- Disguised F&A Costs
- Patient Care Costs



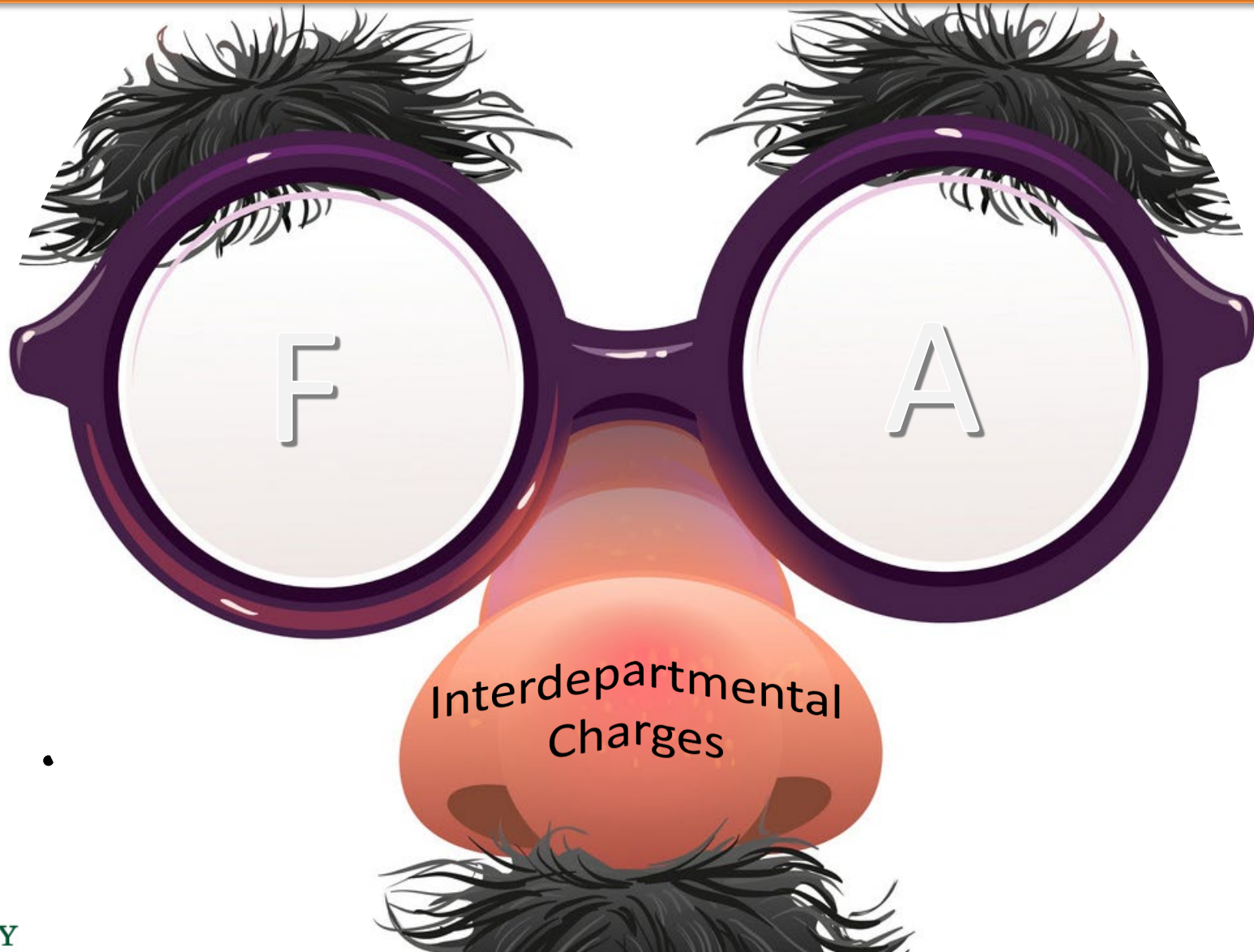
Federal Guidelines

1. Recover \leq actual cost to UM

2.



Charging Billing Rates on Grants



Research Patient Care Costs

NIH Grants Policy Statement:

The costs of routine and ancillary services provided by hospitals to individuals participating in research programs. The costs of these services normally are assigned to specific research projects through the development and application of research patient care rates or amounts (hereafter "rates"). Research patient care costs **do not include**: (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors, (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or **laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service**, (3) recruitment or retention fees or (4) the data management or statistical analysis of clinical research results.

https://grants.nih.gov/grants/policy/nihgps/html5/toc_test_417.htm

Research Patient Care Costs

- ☐ Rate \leq Medicare Allowable Rate
- ☐ Double billing professional fee as effort?
- ☐ No F&A:
 - ✓ SC08710 - Hospital In-Patient; SC08711 - Hospital Out-Patient

Examples:

- Radiology – MRI's
- Clinical Labs – Transplant
(Immunomonitoring & Histocompatibility)



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Subawards Using University Funds

Laura Kozma

Associate Vice President, Research Administration

Subawards Using University Funds

- In rare instances, a subaward to another entity may be needed on a UM funded project
- Reach out to ORA for assistance:
 - Approval for use of funds as a subaward required
 - ORA will assist with the agreement but will not manage the SPC/Purchase order, the project or funds



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Effort Policy

Laura Kozma

Associate Vice President, Research Administration

Effort 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 appointments:** No more than 95% of time on sponsored awards (or less based on other responsibilities)
 - Some research staff postdocs and other employees may be charged 100% to sponsored awards
- **9-month appointments:** No more than 2.5 months of summer salary on sponsored awards
 - Note that faculty may charge academic time to sponsored awards and departments are allowed to use this salary savings towards summer salary

Unallowable Activities When Paid from Sponsored Award

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

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Effort Reporting & Single Audit

Laura Kozma

Associate Vice President, Research Administration

Effort Reporting

- The University undergoes a single audit annually in accordance with Uniform Guidance
- This year UM has contracted with a new audit firm
- The auditors are requiring that effort and project cards to be **certified by September 10th**
- **Payroll costs may need to be removed from grant accounts if the card is not certified**
- **24% (612 cards) are still not certified!**

Key Dates

September 9th: Updated cards pending PAAs submitted by the deadline available in ECC for certification*

September 10th: ALL certifications MUST be completed

★ Note: ORA processed all PAAs received by the morning of 8/26 for the payroll cutoff deadline of 8/26 at noon

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Reporting Unobligated Balance on RPPRs

Edwin Bemmell

Executive Director, Research Administration

Reporting Unobligated Balance on RPPRs

RPPRs:

- Due annually
- Must include estimate of unobligated balance
- Workday shows unobligated (ie available) balance
- Only the department (not ORA) can estimate commitments not yet in WD that should be included
- Amount reported must be reasonably close, else risk of getting prammed

Open Forum - Questions

