Office of Research and Economic Development

Research Administration Meeting

April 16th 2019

AGENDA

Welcome and Introductions

- Pre-Award
- Post-Award
- Research Compliance

Welcoming Remarks

- Introduction of New Attendees
- Future University Wide Research Administrators Meeting for 2019
  - October meeting will be held MARC 430 with limited space and online
  - Monthly brown bag session will be scheduled. Dates and topics to be announced.
- Monthly Meetings
  - Monthly meetings of Dean's Office level and Pre-Eminent / Emerging Pre-Eminent Administrators continue
  - Please reach out to Regnier Jurado to ensure you are on the invite list.
- Slides will be posted on the Office of Research and Economic Development website after the meeting
- Please remember to register for the ORED Research-Admin listserv. Details at http://research.fiu.edu/communications/

Updates to Institutional Policy
DEADLINES FOR PROPOSAL SUBMISSIONS

The institution's policy for the submission of complete proposals together with their signed and fully routed electronic proposal routing approval form (ePRAFs) has been updated and is available for download at https://policies.fiu.edu/policy/267.

The policy has been updated to reflect the following key updates in procedures:

- If the proposal contains any subawards or external consultants then they need to be submitted to ORED with their signed and fully routed ePRAF at least eight (8) business days prior to the sponsor's deadline to allow for sufficient review of required subaward documentation. Proposals that do not contain proposed subawards or consultants remain with the existing five (5) business day deadline.

- ORED has eliminated the Proposal Deadline Exception Request process from the policy. A request for an exception of the Proposal Submission Deadline Policy is no longer needed when a proposal does not adhere to the eight (8) or five (5) business day deadline. Instead, complete proposals received by ORED in accordance with the business days prior to the sponsor/submission deadline date as specified in the policy will receive a full review and will have priority status.

- Proposals received by ORED with less than eight (8) or five (5) business days (depending on whether subawards and external consultants are proposed) will receive a limited review or no review depending on when it is received in ORED and the current workload of the assigned Pre-Award Proposal Coordinator. A proposal that is submitted without a full review may be withdrawn if it is determined at a later date that there were errors or omissions significant enough to justify the withdrawal.

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The following chart provides the level of review and risk(s) associated with the allotted time allowed for the ORED proposal review and submission process.

Risk Assessment for Proposal Review Time			
Risk Factors	**FULL REVIEW** **Complete proposal and fully routed ePRAF provided to ORED at least 8 or 5[1] full business days[2] before sponsor's proposal deadline**	**LIMITED REVIEW** **Complete proposal and fully routed ePRAF provided to ORED 3 - 4 full business days[2] before sponsor's proposal deadline**	**NO REVIEW** **Complete proposal and fully routed ePRAF provided to ORED 2 (or less) full business days[2] before sponsor's proposal deadline**
1. Risk of proposal rejection due to non-compliance with sponsor guidelines	Low	Medium	High
2. Risk of proposal rejection due to electronic system validation issues	Low	Medium	High
3. Risk of department/unit incurring financial burden due to budget errors or omissions	Low	Medium	High
4. Risk of proposal withdrawal by ORED after submission and/or rejection of award	Low	Medium	High

[1]If the proposal contains any subawards or external consultants then they need to be submitted to ORED at least eight (8) business days prior to the sponsor's deadline.

[2]A full business day is considered an official FIU workday between the hours of 8:30 a.m. to 5:00 p.m.

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When a proposal does not receive a full review due to a late submission to ORED of the complete proposal and fully routed ePRAF, a letter will be submitted to the Principal Investigator, with a copy to their department chair and associate research dean notifying them that a "Limited Review or No Review" was conducted due to failure in adhering to the Proposal Submission Deadline Policy.

The following components of our institutional proposal submission process continue to remain in place:

ORED needs to have received via the fully signed ePRAF the following items eight (8) business days prior to the sponsor's deadline for projects with subawards or external consultants or five (5) business days for projects that do not contain subawards or external consultants:

- 1. Budget & budget narrative
- 2. Draft of proposal
- 3. Routed ePRAF with college and departmental approvals completed
- 4. Non-Programmatic elements of the proposal (biosketches, facilities and resources, support forms etc...)
- 5. Subawardee Commitment Form and associated statement of work, budget and budget narrative from the proposed subawardee

- We will require the following items two business days before the sponsor's deadline:
- 1. Cost Share Form signed by all parties (if required)
- 2. Direct Charge Exemption Form signed by all parties (if required)
- 3. Finalized proposal

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Additionally, please note that all electronic submissions (i.e. grants.gov, NSF Fastlane, NASA NSPIRES, NIH Assist and other sponsor specific systems) will need to be submitted by ORED no later than Noon on the date that the application is due to the sponsor in order to have sufficient time to address any errors or warnings related to the electronic submission process.

This applies to all deadlines, even if the sponsor's deadline is after business hours (i.e. an 11:59pm deadline).

NIH Sexual Harassment in Science

NIH leadership released an important statement outlining actions NIH is taking to become part of the solution to address sexual harassment in science.

- If a principal investigator or other key personnel named on an NIH grant award is no longer able to fulfill their obligations to conduct research because they have been removed from the workplace because of sexual harassment concerns, NIH requires institutions to notify the agency of this change.

NIH expects all NIH-funded institutions to have disseminated and implemented policies and practices that:

- foster a harassment-free environment;
- maintain clear, unambiguous professional codes of conduct;
- ensure employees are fully aware and regularly reminded of applicable laws, regulations, policies, and codes of conduct;
- provide an accessible, effective, and easy process to report sexual harassment, and protection from retaliation; and
- respond promptly to allegations to ensure the immediate safety for all involved, investigate the allegations, and take appropriate sanctions.

Please see NIH's Anti-Sexual Harassment website for more information and resources.

NSF Important Notice Harassment

The National Science Foundation (NSF) does not tolerate sexual harassment, or any kind of harassment, within the agency, at grantee organizations, field sites, or anywhere NSF-funded science and education are conducted. The 2,000 American colleges, universities and other institutions that receive NSF funds are responsible for fully investigating complaints and for complying with federal non-discrimination law.

- New Award Requirements: NSF has developed a new award term and condition that will require grantee organizations to report findings of sexual harassment, or any other kind of harassment regarding a PI or co/PI or any other grant personnel.
- Harassment-Free Research Workplaces: NSF expects all awardee organizations to establish and maintain clear and unambiguous standards of behavior to ensure harassment-free workplaces wherever science is conducted, including notification pathways for all personnel, including students, on the primary and supplemental awards.
- Enhanced Web Resources: The NSF Office of Diversity and Inclusion (ODI) is tasked with seeking to ensure that NSF-funded programs and projects are free of discrimination.

This portal is where NSF will continue to add content related to ending harassment. To access the portal, please visit NSF.gov/harassment.

Changes to the R15 Academic Research Enhancement Award (AREA)

As of January 2019, NIH is shifting its approach to how we use the R15 activity code. While NIH will continue to provide R15 research enhancement opportunities for health professional and graduate schools, the name, AREA, will be reserved for grants to undergraduate-focused institutions that do not receive substantial funding from NIH.

R15 Changes in 2019

The R15 activity code was recently revised by the NIH to restrict eligibility to undergraduate-focused institutions that do not receive substantial amounts of funding from NIH.

"Substantial" funding is defined by the NIH as receiving research support from the NIH totaling more than $6 million per year (in both direct and F&A/indirect costs) in 4 of the last 7 fiscal years. FIU has consistently exceeded this amount for the last decade.

Based on these changes, FIU units no longer qualifies for the R15 AREA grant program.

To access this announcement, please visit https://grants.nih.gov/grants/funding/r15.htm

Fringe Benefit Rates
FY 2019 -2020

The Office of Financial Planning has updated the fringe benefit rates for the 2019-2020 fiscal year, therefore the fringe benefit rates used at proposal stage have been revised as follows:

Employee Group	Pooled Fringe Benefit Rate
COM Faculty	23.93%
Admin/Faculty (excluding COM Faculty)	34.01%
Staff	47.42%
Non Student OPS (other temporary)	4.29%
Graduate Student Assistants	8.79%

The internal budget sheet used at proposal stage will be revised to reflect these changes in the fringe benefit rates.

The revised rates will become effective for all proposals being routed via ePRAF on or after April 1, 2019 and will be charged to all active awards as of July 1st, 2019.

Updated Facilities and Administrative (F&A) Costs Rate Agreement

The University has executed a new Facilities and Administrative (F&A) Costs Rate Agreement (also known as the indirect cost rate agreement) with our cognizant federal agency, the Department of Health and Human Services (DHHS).

A copy of the agreement is available at http://research.fiu.edu/facts-figures/documents/rateProposal.pdf.

The updated F&A rates are as follows:

Rate Type	Rate
On Campus Research	47.50%
On Campus Other Sponsored Activities	35.00%
Off Campus Research and Other Sponsored Activities	26.00%
On Campus DOD Contracts or Subcontracts	50.00%
Off Campus DOD Contracts or Subcontracts	28.00%

The updated F&A rates are applicable to all proposals being submitted effective immediately.

UPDATED PRE-AWARD FORMS

- **Agreement Request Form**
  - HIPPA Compliance

    HIPAA Compliance (For a summary of Privacy Practices and HIPAA, see http://research.fiu.edu/irb/privacy-practices-and-hipaa):
    Does the proposed agreement seek to disclose Protected Health Information (PHI)? No ☐ Yes ☐
    Does the proposed agreement require a Business Associate Agreement? No ☐ Yes ☐
    If either of the above is answered yes, answer all questions in Data Use Agreements section below.

  - Data Use Agreement Section
    - Revised Questions
    - Approved IRB allows for sharing of data
    - Nepotism
  - Cost Share

- **Subaward / Amendment Request Form**
  - HIPAA
  - Data Collection Information
  - Clinical Trial
  - Nepotism

- **No Cost Extension Form**

- **Material Transfer Agreement Request Form**
  - Currently being revised

New Processes

➢Cost-Share on Non-Funded Agreements

- Cost-Share Form required
- Same rules apply
- Post-Award Manager will open a cost-share account
- Please indicate cost-share requirement on request form

➢ Budgets at Award Stage

- Post-Award Manager to assist with budget
- Pre-Award Representative will process award per usual process

Controllers Office Year End Processing Deadlines

http://finance.fiu.edu/controller/FYECalendar.html

Please make sure deadlines are met.

Travel Medicine Program and Clinic

Whether you are traveling for business or pleasure; visiting the family or going on a great adventure, the FIU Health Travel Medicine Program and Clinic can provide you with up-to-date advice and information for a safe and healthy trip. Call 305-FIU-DOCS (348-3627) to make your appointment with our travel medicine experts, Dorothy Contiguglia-Akcan, MD, MPH, MS and Aileen Marty, M.D., FACP.

Pre-travel Assessment

- Vaccinations, immunizations, health counseling, resources, and prescriptions for travel medications customized according to destination, itinerary, planned activities, and medical history

Post-travel care

- Evaluation and treatment for any travel-acquired health problem

When purchasing components that are being used to construct a capital asset, use an OCO account code and include the following language in the requisition of the item(s) and reference the asset tag number if already assigned.

“These items are being used to construct/fabricate a (describe asset being built). Related to asset tag no. 1234567”

Certified Research Administrator (CRA)
Study session for exam November 2019
Commence August 2019

- Sessions are once a week for 1 ½ hours for 10 weeks
- Organized around the CRA Body of Knowledge
- Designed to assist in targeting study areas to prepare for the CRA exam
  - 250 multiple choice questions – testing time 4 hours
  - Passing 70% or 175 correct multiple choice questions
- Eligibility requirements for the exam
  - Bachelor's Degree and 3 years experience
  - Associates Degree and 5 years experience
  - No degree and 6 years experience with additional approval
- Email Donna.Kiley@fiu.edu if interested in joining the study session in March 2019

SRA INTERNATIONAL | SOCIETY OF RESEARCH ADMINISTRATORS INTERNATIONAL

- **New Laboratory Safety Committee**
  - Evaluates and identifies potential hazards in the laboratory environment
  - Makes recommendations to ORED and EH&S on policies, procedures, trainings, and corrective actions
  - Enhances and promotes laboratory safety at FIU

- **Upcoming Training Workshop**
  - Preparing for an IACUC Inspection
  - When: May 7, 2019
  - Further details: http://research.fiu.edu/rcr/workshops

- **Upcoming AAALAC Re-Accreditation**
  - Site visit will occur sometime in Fall 2019 semester (Sept or Oct)
  - ORI will send out email reminders with useful preparation tips

- **HIPAA Authorization Updates**
  - External HIPAA Authorization Forms
    - No longer need to be attached (when obtaining PHI from non-FIU HIPAA covered entities)
    - Only need to be attached when obtaining PHI from an FIU covered entity (e.g., CCF, HWCOM, etc.)
  - New FIU HIPAA Authorization Form template on website

- **Revised Common Rule Updates**
  - Became effective on January 21, 2019
    - http://research.fiu.edu/irb/revised-common-rule/
  - All new IRB protocols and renewals need to use new Consent Form templates (available online)
  - Posting of Consent Forms online for HHS-funded clinical trials
    - http://research.fiu.edu/irb/clinical-trials
  - NIJ and FDA are not under the Revised Common Rule

- **Device Studies**
  - A “Medical Device” is a device that is intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.
  - FDA regulated under following scenarios:
    - Determining safety or effectiveness of a device;
    - Using a medical device not legally distributed;
    - Studying an FDA approved device for new indication, new patient population, device enhancements, or modifications;
    - Data will be shared with the FDA; or
    - Humanitarian Use Device
  - New option on IRB Approval Form to select “Non-Medical Device”.
    - Use this option when using a device that is not intended to have any impact on a disease or health condition.

Closing Remarks

- Questions
- Adjournment
- Don’t forget to sign the sign-in sheet