Office of Research and Economic Development
Quarterly Research Administration Meeting

October 27th, 2015
AGENDA

- Welcome and Introductions
- Pre Award Update
- Post Award Update
- Research Information Systems
- Research Integrity
• Welcoming Remarks

• Introduction of New Attendees

• Future Quarterly Research Administrators Meeting for 2016
  • Thursday, January 28th 2016
  • Wednesday, April 27th 2016
  • Tuesday, October 25th 2016
  • All meetings are from 10:00 am – 12:00 pm in the MARC Pavilion

• Slides will be posted on the Office of Research and Economic Development website after meeting
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Pre Award Update

- Introduction of Pre-Award Team

- NSF Update
  - PAPPG changes for proposals submitted, or due, on or after January 25, 2016.
  - ORED will be releasing a detailed memo with changes, however key items to note include:
    - Enforcement of 5 p.m. submitter’s local time across all NSF funding opportunities;
    - Implementation of NSF’s Public Access Policy;
    - Submission of proposal certifications by the Authorized Organizational Representative (AOR) concurrently with proposal submission;
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Pre Award Update

- NSF Update Continued

- NSF’s implementation of the US Government Policy for Institutional Oversight of Life Sciences on Dual Use Research of Concern;

- Provision of Collaborators and Other Affiliations information as a new single-copy document, instead of as part of the Biographical Sketch;

- Submission of Biographical Sketches and Current and Pending Support separately for each senior personnel;

- Electronic signature and submission of notifications and requests by the AOR only;

- Revision of timeframe for submission of final project reports, project outcomes reports and financial closure of awards to 120 days after the award end date;
NIH Update

Changes to Policies, Instructions and Forms for 2016 Grant Applications

The planned changes focus on the following areas:
- Rigor and transparency in research
- Vertebrate animals
- Inclusion reporting
- Data safety monitoring
- Research training
- Appendices
- Font requirements
- Biosketch clarifications

Changes will be implemented in two phases
- Phase 1: Implements a subset of the policy changes using existing (FORMS-C) forms and updated instructions and will impact due dates on or after January 25, 2016.
- Phase 2: Completes the implementation with the introduction of new (FORMS-D) forms and instructions and will impact due dates on or after May 25, 2016.
NIH Update – Phase I Changes

Rigor and Transparency

NIH is changing application requirements and review language to enhance reproducibility of research findings through increased scientific rigor and transparency. These changes will take effect for most research grant applications (including small business and complex research grant applications), but will not impact institutional training and individual fellowship applications until Phase II.

Changes include:
- Updates to application guide instructions for preparing the research strategy attachment
- Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment (uploaded in Other Attachments section of R&R Other Project Information form)
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications
NIH Update – Phase I Changes - Continued

Vertebrate Animals

NIH is removing redundancy with Institutional Animal Care and Use Committee review while meeting the requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Changes include:
- Updated guidance on criteria to be addressed (description of procedures; justifications; minimization of pain and distress; and euthanasia)
- A description of veterinary care is no longer required
- Justification for the number of animals has been eliminated
- A description and justification of the method of euthanasia is required only if the method is not consistent with AVMA Guidelines for the Euthanasia of Animals
NIH Update - Phase I Changes - Continued

- **Definition of Child**
  
  NIH is redefining the age of a child for the purposes of NIH's inclusion policy to individuals under 18 years old instead of under 21 years old.

- **Research Training**
  
  NIH is updating requirements and instructions for several attachments on the PHS 398 Research Training Program Plan form to reflect recent policy guidance and reduce applicant burden.

  Changes include:
  - "Recruitment and Retention Plan to Enhance Diversity" - applicants will be asked to focus on recruitment
NIH Update - Phase I Changes - Continued

Research Training

Changes include:

- "Human Subjects" - applicants must describe how the institution will ensure that trainees only participate in exempt human subjects research or non-exempt human subjects research that has IRB approval; no longer necessary to provide a list of potential grants trainees may work on and associated IRB information

- "Vertebrate Animals" - applicants must describe how the institution will ensure that trainees only participate in vertebrate animal research that has IACUC approval; no longer necessary to provide a list of potential grants trainees may work on and associated IACUC information

- "Progress Report" - requirement to report on publications that arose from work conducted by the trainee while supported by the training grant will be moved to the Just-in-Time process
NIH Update - Continued

Phase II Changes include:

- Extending Phase 1 changes related to Rigor and Transparency to include institutional training and individual fellowship applications.

- Extending Phase 1 changes related to Vertebrate Animals to include institutional training and individual fellowship applications.

Inclusion Forms

- Adding an optional PHS Inclusion Enrollment Report form to FORMS-D application packages.

- The new form, with additional study descriptors, will replace the optional Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms found in FORMS-C application packages.
NIH Update – Phase II Changes - Continued

Data Safety Monitoring Plans

Adding a new “Data Safety Monitoring Plan” to the following forms in FORMS-D application packages:
- PHS 398 Research Plan
- PHS 398 Career Development Supplemental Form
- PHS Fellowship Supplemental Form
- PHS 398 Research Training Program Plan

This new attachment must be included with all applications involving clinical trials.

Although the requirement of a data and safety monitoring plan for clinical trials is not new, the use of a separate attachment to collect this information will emphasize its importance and facilitate systematic enforcement of its presence.
NIH Update – Phase II Changes - Continued

- Research Training

NIH is changing the research training data table format.

Changes include:
- Reducing the number of tables from 12 to 8
- Minimizing the reporting of individual-level information
- Extending the tracking of trainee outcomes from 10 to 15 years

NIH’s xTRACT system to help applicants prepare the new tables will be available October 16, 2015.
NIH Update – Phase II Changes - Continued

New PHS Assignment Request Form

Adding an optional PHS Assignment Request Form to FORMS-D application packages to provide a consistent way to collect application referral information, including:

- Awarding component (NIH institute) assignment preference
- Study Section preference
- List of potential reviewers in conflict, and why
- List of scientific expertise needed to review the application

New Font Guidelines

- Font size: must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%)

- Type density: must be no more than 15 characters per linear inch (including characters and spaces)
NIH Update – Phase II Changes - Continued

New Font Guidelines - Continued

- Line spacing: must be no more than six lines per vertical inch

- Text Color: must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable as long as it is legible)

- The following fonts are recommended, although other fonts are acceptable if they meet the above requirements.
  - Arial
  - Garamond
  - Georgia
  - Helvetica
  - Palatino Linotype
  - Times New Roman
  - Verdana

- Since some PDF converters may reduce font size, it is important to confirm that the final PDF document complies with the font requirements.
NIH Update – Phase II Changes - Continued

Biosketch Clarifications

- Clarifications include:
  - Indicating that a URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography
  - Allowing publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement and the contributions to science sections
  - Explicitly stating that graphics, figures and tables are not allowed

Additional details regarding all Phase I and Phase II changes are available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-004.html
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Pre Award Update

- Export Controls Updates
  - **EUD Equipment Form**
    - End-User Declaration Form being requested by equipment manufacturers to be signed by the institution
    - Form should not be signed by PIs or Research Administrators
    - Form should be sent to Nelson Perez, Export Control Officer at the University Compliance Office
  - **Shipping Equipment Internationally**
    - Any shipping of equipment to foreign countries should be coordinated with the Export Control Officer.
  - **Export Control Review at Award Time**
    - Reminder that at award stage all awards are reviewed by ORED for compliance with export control terms and conditions.
    - If Export Controls Training is determined to be appropriate then the award funds cannot be released until the CITI based export control training is taken.
Other Pre-Award Updates

- Jessica Lunsford Act Requirements / Background Level II checks
  - Florida law requires that personnel must undergo and pass a criminal background check (meeting Level 2 background screening requirements) if they:
    - are permitted access on school grounds when students are present or
    - have direct contact with students or
    - have access to or control of school funds.

- If ePRAF is marked as “yes” ORED requires the project PI and all project personnel to complete forms developed by ORED to certify their compliance with the background screening requirements.

- The completed forms must be provided to ORED before the award funds will be released to the PI for commencement of the project;

- Any new personnel hired throughout the life of the project must comply with this requirement

- The background screening process is required every five years.
Other Pre-Award Updates

National Compliance Week
- FIU is participating in a national Compliance and Ethics Week celebration, November 2-6.

Wednesday, November 4
- Lunch and Movie: 12:00 – 1:30 in ZEB-120
  - Game of Pawns is a short film produced by the FBI. The movie is about a young American student that is caught selling information to the Chinese government. FBI agents will answer questions and share their insights.
- Ethics and Compliance Carnival: 3:00-5:00, GC Pit
  - There will be games, prizes, popcorn and cotton candy

During Compliance and Ethics Week, you can visit https://compliance.fiu.edu/ to play compliance games and watch informative videos about the importance of Compliance.
Other Pre-Award Updates

Updated ePRAF Questions
- Question # 6 on the ePRAF has been updated to read:

“Human Subjects: Is IRB approval necessary for the work on this project? (refer to the "Determining if IRB Review is Needed" at http://research.fiu.edu/irb/pages/determine-irb-review.html to determine if your project requires IRB approval). If yes then please note that approval will need to be in place before award can be released. Please note if your research will involve any interaction with vulnerable populations (these groups, as outlined in 45 CFR 46.111(b) are children, wards of the state, prisoners, pregnant women and fetuses, persons who are mentally disabled or otherwise cognitively impaired, and economically or educationally disadvantaged persons) then please specify in the comment box.”
Other Pre-Award Updates

Updated ePRAF Questions
- Question # 8 on the ePRAF will be updated to read:
  - “Recombinant or Synthetic Nucleic Acid (i.e., transgenic, targeted mutant, etc): Is IBC approval necessary for the work on this project? (refer to the IBC's webpage to http://research.fiu.edu/ibc/index.html to determine if your project requires IBC approval). If yes, please note that approval will need to be in place before award can be released.”

MTA Process Reminder
- Please note that all MTAs related to research need to go through ORED for review and execution.
- An agreement request form is required for each MTA
- All applicable Research Compliance approvals are required (i.e. IRB/IACUC/IBC/EH&S etc...)
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Pre Award Update

- Uniform Guidance Updates
  - Research Terms and Conditions
    - Companion document to the Uniform Guidance to provide clarity for select provisions consistent with government wide policies
  - Apply to an award when included as part of the award or when incorporated by references
  - USDA/NIFA, NIST/NOAA, DHS, DOE, FAA, EPA, NASA, NIH, NSF

- Key Items:
  - Fixed price subaward prior approval requirement is waived
  - Administrative / Clerical costs prior approval are not waived

- Expected to become active by October 2016
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Pre Award Update

- **Uniform Guidance Updates - Continued**
  - **Procurement Status**
    - OMB has granted an additional one year extension for the procurement requirements in the Uniform Guidance

  - Policy “Only Allowable Direct Costs may be Charged on Federally Sponsored Project Proposals” has been updated (available at https://policies.fiu.edu/policy/260)

  - “Florida International University has delayed implementation of the Uniform Guidance Procurement standards as specified in 2 CFR 200.317 through 200.326 until July 1, 2017 in accordance with the two-year grace period provided by the Office of Management and Budget (OMB) in the Federal Register notice dated September 10, 2015. In the interim, Florida International University’s existing procurement policies and procedures and applicable OMB Circulars will continue to apply.”

  - Expectation continues to be that IHEs will be able to convince OMB to not enact the most burdensome of the requirements
\textbf{Uniform Guidance Updates - Continued}

\begin{itemize}
  \item \textbf{Subawards}
    \begin{itemize}
      \item Processes and policies have been updated as a result of the Uniform Guidance that impact procedures at proposal, award and post award stages
    \end{itemize}

  \item \textbf{Impacts at Proposal Stage}
    \begin{itemize}
      \item Commitment Form is required
      \item 10\% MTDC De Minimis Rate
        \begin{itemize}
          \item Any non-federal entity that has never received a negotiated indirect cost rate may opt to use the 10\%
        \end{itemize}
    \end{itemize}

    \begin{itemize}
      \item DUNS# \footnotesize{(http://www.dnb.com/get-a-duns-number.html)}
    \end{itemize}

  \item \textbf{Impacts at Award Stage}
    \begin{itemize}
      \item Risk Analysis is required for all subrecipients and to be done by Pre-Award.
    \end{itemize}
\end{itemize}
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Pre Award Update

- Uniform Guidance Updates - Continued

- Impacts at Award Stage continued...

  - Updated FIU Template will now contain the following required information:

    - Federal Award Identifier, Federal Award Date, total amount of federal award, CFDA Title, Identification of R&D (Research & Development) award

    - Subrecipient DUNS# and associated Subrecipient name

    - Inclusion of 10% de Minimis if applicable

    - Fixed Price Subawards require Sponsor approval
      - Maximum limit $150,000

- Impacts at Award Stage
  - Updated invoicing process through Post-Award
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*Research Metrics Update*

- **Research Expenditures**
- **Economic Impact**
  - (Jobs created / Students supported)
**New Subaward Process**

- **If subrecipient falls under the Uniform Guidance (Universities)**
  - Invoice is sent to PI
  - PI will review and approve for appropriateness of cost & work performed
  - PI will approve, create receipt in PS, & forward invoice to Accounts Payable to pay
New Subaward Process (continued)

- If subrecipient DOES NOT fall under the Uniform Guidance (Private for Profit, Foreign)
  - Invoice is sent to subinv@fiu.edu
  - Post Award will confirm
    - Available budget
    - Certification & documentation per agreement
    - Forward to PI with approval form
  - PI will
    - Review and approve for appropriateness of cost & work performed
    - Complete the approval form
    - Approve, create receipt in PS, & forward invoice & approval form to Accounts Payable to pay
- **New Subaward Process (continued)**
  - If work is not being performed satisfactorily
    - PI should communicate with Post Award and return the approval form describing the performance deficiencies and a plan of action to remedy the situation when applicable.
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Post Award Update

- New Forms
  - Purchase of Electronic Devices on Federal Awards
    - Help determine if the device is an allowable expense to the federal project
  - Direct Charge Exemption Form
    - Was recently updated, general information is the same
  - Both are available in the Research website under Proposal Preparation Forms
Project Organizational Chart

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Post Award Update

- **Project Financial Report updates**
  - Payroll tab
    - transfers now include the name of the employee
  - Report Notes
    - Importance of reviewing reports
    - Clarification of amounts
      - Project Summary (based on ‘as of date’ displayed in the report header)
      - Detail Tabs (based on the date the report is run)
Useful Crosswalk

NIGP Category Code and Research Budgetary Account Crosswalk

- Includes
  - S / P Level account codes & descriptions
  - Expense G/L account codes & descriptions
  - NIGP Categories & descriptions
- Can be downloaded in excel or PDF from our Research website [http://research.fiu.edu/award-management/](http://research.fiu.edu/award-management/)
How a Project Manager can elect an alternate (Proxy)

- If project manager will be temporarily unavailable, they can select an alternate user to receive their approvals (workflow)

- Navigate in your PantherSoft main menu to:
  - My System Profile

- The General Profile Information page should open

- Populate the following fields under ‘Alternate User’:
  - Alternate User ID
  - From Date
  - To Date

- Save
• **ecrt Update**
  
  • **ecrt 5.0 Upgrade Status**
    • Rolled out v5.0 in June 2015 for Spring Certification

  • **Spring Certification**
    • We reached 100% Certification faster than any other prior semester

  • **Training**
    • Training Guides, Videos and How-To’s located on our website at
      http://research.fiu.edu/effort/pages/training.html
ecrt Update

Changes and Enhancements
- An update to the login screen has been made. The username label has been updated to read Panther ID in order to clarify what credentials you should use to access ecrt.
- As a result of feedback, we have become aware of some system lag time. UTS and the ecrt vendor are currently working in conjunction to reduce lag time and improve performance.

Summer 2015 Certification Status

Feedback
- As always, we welcome your feedback. Please contact ecrt@fiu.edu with any feedback or questions you may have.
Training/Workshops

- New Workshops
  - Obtaining IRB Approval Workshop
  - Managing IRB Approval Workshop
  - IACUC: Animal Ethics Workshop
  - ORI Overview Workshop

- Coming Soon
  - IRB Ethics Workshop
  - IACUC: Preparing for a Site Visit Workshop

- New Training
  - Online CITI – Working with the IACUC (Field Studies)
Training/Workshops (cont.)

- Workshops are announced via:
  - Email listserv,
  - Univmail,
  - ORED Newsletter &
  - ORED Website

- Is there a particular workshop you would like?

- Contact Research Integrity at ori@fiu.edu
 QA/QI Updates

IRB QA/QI

- IRB QA/QI has been deployed
- IRB Website provides valuable resources on the QA/QI process

Coming Soon – IACUC QA/QI

- Semiannual Inspections
- Website: Best Practices
- Workshop: Preparing for Site Visits
IBC Website Updates

http://research.fiu.edu/ibc/index.html

Obtaining Initial FIU IBC Approval

The following steps are provided to assist investigators with submitting applications to the FIU IBC for review and approval.

Step 1: Determine if You Need IBC Review
IBC approval is required for all research involving Recombinant or Synthetic Nucleic Acid molecules.

Definition of Recombinant or Synthetic Nucleic Acid Molecules
Does My Work Require IBC Approval?

Step 2: Complete the CITI Online IBC Training Course
All research personnel that will be engaged in conducting research with recombinant or Synthetic Nucleic Acid are required to complete the CITI Online "Biotechnology & Biosafety" Course.

Instructions to Sign Up for CITI Online IBC Training

Step 3: Review the Guidelines and Policies
The investigator is required to follow guidelines set forth by the NIH and the IBC in conducting research with recombinant or Synthetic Nucleic Acid.

Access IBC Regulations, Policies & Procedures

Step 4: Submit an Application
FIU IBC applications need to be submitted through the online TOPAZ Electronic Protocol Application System.

Investigators should complete one of the following forms:
IBC Website Updates

- http://research.fiu.edu/ibc/pages/required-approval.html
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Closing Remarks / Adjournment

- Closing Remarks
  - Questions
  - Adjournment