Hot Topics in Research Administration Program

November 8, 2013

Planning Committee:
Andrew Bean
Cookie Bryant-Gawthrop
Jackie Butram
Amanda Hamaker
Jessica Lawrence
Beth Siple
Mike Szczepanski

Program Sponsored by:
Mike Ludwig
Sponsored Program
Business Services

Chris Martin
Business Services

Howie Zelaznik
Office of the Vice President for Research
Welcome
Beth Siple, Assistant Director of Financial Affairs Agriculture Sponsored Programs

Industrial Contracting and OMB Circular Update
Mike Ludwig, Director, Sponsored Program Services

- Changes in Industry Contract options
- Recap and highlight of OMB items that have occurred since March

Research Incentive Fund Changes
Jeff Bolin, Associate Vice President for Research

- Background and reasons for review or change
- Process and principles
- Key findings from the review
- The new system

Regulatory Hot Topics
Cookie Bryant-Gawthrop, Director of Research Regulatory Compliance

- Identifying Regulatory Items
- Grant to protocol review process
- Impact of Export Controls
Industrial Contracting – New Contracting Options – STEW 310

Information related to new contracting options available to faculty who engage in industry-sponsored research.

Coordinator: Amanda Hamaker, Assistant Director of Pre-Award, SPS
Facilitator: Jeff Kanable, Assistant Director of Contracting, SPS

Basics of Export Controls – STEW 214D

Introduce the impact of export control regulations and related sanctions focusing on application of these concepts in a university setting.

Coordinator/Facilitator: Cookie Bryant-Gawthrop, Director of Research Regulatory Compliance, OVPR
Research Compliance at Purdue – STEW 202

Panel discussion to share findings and recommendations identified from financial grant management reviews and recent external audits.

Coordinator: Mike Szczepanski, Director of Research Quality Assurance, OVPR
Facilitators: Mike Szczepanski, Director of Research Quality Assurance, OVPR
Tom Wright, Sr. Operations Manager, OVPR
Randy Bryant, Quality Assurance Specialist, Financial Management, OVPR

Federal Agency Updates – STEW 314

Discussion of recent Federal Sponsor updates over the past year focusing on Pre-Award and Post-Award updates and changes.

Coordinator: Jessica Lawrence, Assistant Director of Post-Award, SPS
Facilitator: Kim Gascho, Pre-Award Center Manager COE, SPS
Susan Corwin, Post-Award Sr. Account Manager, SPS
Megan Sweet, Post-Award Sr. Account Manager, SPS
Up next......

Mike Ludwig, Director, Sponsored Program Services

Industrial Contracting and OMB Circular Update
Industrial Contracting – New Contract Options

Project Type:

1. Basic/Fundamental Research
2. Publishable Applied Research
3. Industry-focused Applied Research
4. Testing Services
Industrial Contracting – Why the change?

• Purdue will maintain its position as a leader in industry-funded research

• Provide faculty flexibility in selecting contract terms which fit the project

• Enhance Purdue relationships with industry
Industrial Contracting – Key Differences

- Purdue faculty choose which option fits the scope of work

- Faculty-led decision *may* allow Sponsor:
  - Pre-paid, exclusive license to Purdue-owned IP
  - Ownership of project IP

- SPS, OVPR, and OTC to provide consultative assistance to help faculty select the best option

- Faculty advisory committee will serve as a resource in making key management decisions
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<th>TYPE OF INDUSTRIAL PROJECT</th>
<th>PUBLICATION</th>
<th>INTELLECTUAL PROPERTY</th>
<th>F&amp;A Rate</th>
<th>IP Fee</th>
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| Basic/Fundamental Research| 30 day review by sponsor for proprietary or patentable information | Sponsor receives a NERF license  
Sponsor has first option to a royalty bearing license | 54% | N/A |
| Publishable Applied Research | 30 day review by sponsor for proprietary or patentable information | New Project IP dominated by either sponsor BIP or PRF BIP  
If technology is licensed to sponsor by PRF, sponsor receives an exclusive license to new IP by amending existing license agreement. No additional fees are charged.  
If technology is not connected to Purdue or PRF, sponsor will receive a 5 year royalty free exclusive license to new IP. After 5 years the license would be extended on mutually agreeable royalty bearing terms. | 64.75% | 0% |
| Industry-focused Applied Research | No publication without approval by sponsor | Purdue assigns ownership of new IP to the sponsor | 64.75% | 10% |
| Testing | Deliverable data is sponsor confidential information | No IP should be created | 36% | N/A |
Restricted Project Approval Form

Special approval is required when either Applied Research option is used.

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<tr>
<th>Purdue University</th>
<th>Restricted Project Approval Form</th>
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<tr>
<td><strong>This form is for internal use only and should not be forwarded to the sponsor.</strong></td>
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<td><strong>GENERAL INFORMATION</strong></td>
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<td>PI Name</td>
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- Please attach any description of the research objective that you have supplied to the potential Sponsor.
- Please list in detail the Sponsor-owned data, inventions, copyrights, and materials that will be used on the project.

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<th><strong>INTELLECTUAL PROPERTY</strong></th>
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<td>(Copyrightable works, research data and tangible research materials, and inventions and discoveries)</td>
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Note: All Purdue employees are required to file an invention disclosure on any inventions or software generated by this research. (http://www.purdue.edu/policies/academic-research-affiliates.html)
OMB published the ‘Proposed OMB Uniform Guidance’

Combines 8 existing OMB circulars (e.g., A-21, A-110, A-133) into one comprehensive and streamlined circular A-81.

Also being referred to as the “omnicircular,” and “supercircular.”

An example of a few changes mentioned at the March Hot Topics program were:

- Limits on the Negotiated F&A rate require approval by Agency head and OMB (A-110)
- Salaries of Administrative or Clerical staff allowable as a Direct Charge when integral to the project (A-21)
- Eliminates Effort Reporting Requirement
June 2, 2013  Over 300 comments submitted to OMB during the comment period

Comments were submitted by Purdue University, COGR (105 page letter), AAU

Purdue’s comments can be found at:
http://tinyurl.com/Nov8Topics

COGR’s comments can be found at:
http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=14436

June – Oct  OMB is reviewing and evaluating the comments and responding to suggestions made
OMB Circular Update


Coalition includes 10 organizations (AAU, APLU, COGR, NACUBO & others)

• Requests a meeting with OMB & COFAR to review issues & concerns
• Have a number of ideas for genuine grant reform
• Provide coalition perspective of the systemic issues associated with federal grants management and the true reforms we seek

Concerns

• How will it be implemented - must be adopted and implemented by approximately 26 federal funding agencies
• Let’s avoid a chaos of different requirements.
OMB Circular Update

Jan 2014  OMB hopes to publish final guidance

2014  What to anticipate in 2014?

Once the guidance is published, we can then begin addressing the implementation and impact on current and future awards
Up next......

Jeff Bolin, Associate Vice President for Research

Research Incentive Fund Changes
Changes To The Research Incentive Fund Distribution

I. Background
II. Reasons for Review or Change
III. Process and Principles
IV. Key Findings from the Review
V. The New System
R.I. Fund: Background

• Established in FY90 as a monetary research incentive to academic units and faculty

• Programs of this type are often funded from F&A recovery and labeled “F&A Return” programs
  – Typically they return a small fraction of total F&A to academic units/faculty except in RCM systems

• Changes in base funding over time
  – FY97 – ‘01 fixed at $800K
  – FY02 – ‘04 increases in proportion to F&A yield
  – FY05 – ’12 fixed at $3.2M
R.I. Fund: Background

- FY06 – 10: incremental increases in F&A return were redirected from the R.I. Fund to capital projects and R&R
  - F&A yield up by 60%; R.I. Fund share down by 40%
  - Discovery Park Centers except Birck were eligible to receive R.I. Fund allocations (double credit)

- FY11 and FY12
  - FY06 – 10 plan expired but not replaced
  - R.I. Fund base remains fixed at $3.2M
  - D.P. Centers dropped from R.I. Fund allocation
Reasons For Review/Change

• FY06 – 10 plan expired but return to FY05 plan was not fully realized

• An incentive plan that doesn’t respond to success may be ineffective

• Perception: some peers deliver more F&A to units
  – Some top institutions hold all F&A centrally

• Pres. Córdova approved $1M increase for FY13

• The allocation process (how much to each unit) was also “dusty” and deserved review
Process For Review/Change

- Working group formed and charged to review Purdue’s system and others’ systems and provide recommendations to V.P.R.

**Some of the Principles:**

- R.I. Fund policies and processes should promote enhanced disciplinary and interdisciplinary sponsored program activity
- Reasonable folk should view the system as fair, understandable, and transparent
- Outcomes should not create extra burdens for faculty, administration, or support staff
- If changes occur, attempt to minimize disruption
Key Findings From The Review

• Existing system tied the incentive to F&A rates – viewed as misguided by the working group
  – Full F&A recovery was a criterion for inclusion
  – But faculty pursue funding without regard to F&A rate; some activities are only funded at reduced rates

• Existing system had elements that were inequitable
  – U.S.D.A. awards were included despite F&A rates lower than other sponsors
  – Meaning of “F&A rate” varies among sponsors

• Existing system used mismatched inclusion and distribution metrics
  – Inclusion determined by F&A rate
  – Distribution determined by total costs
Eligibility Criteria In The New System

- Eligibility to receive R.I. Fund $$ is still determined on an individual account basis
- The Primary Rule: Accounts are eligible if they incur expenses in support of sponsored programs at the West Lafayette campus
  - Full F&A recovery criterion removed
  - Special U.S.D.A. inclusion issue obviated – same criteria apply to all accounts
  - Subcontract expenses in excess of the first $25K per contract are excluded as before
R.I. Fund Distribution In The New System

• Primary allocations are still from the O.V.P.R. to the College (or equivalent unit)

• The College Allocation is the sum of the allocations calculated from the expenditures of eligible accounts of the unit using the prior year’s expenditures

• The allocation for each account:

\[
\text{Allocation} = \frac{\text{Modified expenditures for the account}}{\text{Modified expenditures for all accounts}} \times \text{R.I. Fund Budget}
\]

  – “Modified expenditures” subtracts unrecovered F&A

• The College must distribute at least 25% of the Unit allocation to the investigators
Up next......

Cookie Bryant-Gawthrop,
Director of Research Regulatory Compliance

Research Regulatory Compliance and Export Controls
Research Regulatory Compliance Staff within OVPR

- Perform and monitor the grant to protocol review process
- Monitor and manage sponsor requirements for training in the Responsible Conduct of Research (RCR)
- Manage research subject to Export Controls
Regulatory Acronyms

- IBC Institutional **Biosafety** Committee
  - rDNA, unfixed human blood
- IRB Institutional Review Board
  - Human subjects, surveys
- P(I)ACUC Purdue (Institutional) Animal Care and Use Committee
  - Vertebrate Animals
- Export Control Related
  - EAR, ITAR, OFAC
- RCR Responsible Conduct of Research
How Are Regulatory Items Identified?

- PI provides information during proposal submission
- Sponsor asks for information prior to funding a proposal
- SPS Pre-award or Contracting review may identify a regulatory item
- SPS Post-award notes any issues that might be unresolved
Campus Committees

• An Institutional Review Board (IRB/HRPP) works with research staff to identify how human participants are managed in research studies.

• An Institutional Animal Care and Use Committee (IACUC) works with research staff to affirm that vertebrate animal research is conducted within required parameters.
Approval Timelines

- IRB (humans) protocols are reviewed and renewed on at least an annual basis
  - Can be shorter
  - Decided by the committee/office
- PACUC and IBC protocols are reviewed and renewed at least every three years.
- Any time in between renewals, the PI can choose to terminate or amend the protocol.
Grant to Protocol Review Process

**GRANT/AWARD**

Proposal submitted

Sponsor (NIH, NSF, I/F, etc).

Sponsor funds activity

**PROTOCOL**

Protocol application describes specific elements of research with humans/animals/ rDNA

Campus Committee (IRB, IACUC, IBC)

We review and document that these two items are congruent

Committee provides determination
Certain federal sponsors require RCR training

Requirements differ between agencies

Consists of online training course and may include discussion based learning (seminar, course, etc.)

OVPR staff notify affected investigators and monitor training status
Export Controls

• U.S. laws that regulate the export of strategically important products, software, services, and technical data to foreign persons and foreign countries for reasons of foreign policy and national security.

• Apply to ALL activities – not just sponsored research.
Principal Export Control Regimes

- International Traffic in Arms Regulations (ITAR; 22 CFR 120 et.seq.)
  - Dept. of State, Div. of Defense Trade Controls
  - Control access to military technologies
  - U.S. Munitions List

- Export Administration Regulations (EAR; 15 CFR 730 et.seq.)
  - Dept. of Commerce, Bureau of Industry and Security
  - Control access to “Dual-Use” technologies (primary civilian use)
  - Commerce Control List

- Country Specific Sanctions
  - U.S. Dept. of Treasury, Office of Foreign Assets Control (OFAC)
Impact of Export Controls

- Export controls may impact your activities …
  - If your research:
    - Has a specific military purpose
    - Involves dual use technology
    - Involves confidential or proprietary information
    - Involves encryption technology
    - Requires sponsor approval before publication
    - Utilizes technology or equipment on the Commerce Control List
  - If you:
    - Travel to international meetings or study sites and
      - Carry technology and/or data when you travel
      - Visit countries subject to U.S. embargoes administered by OFAC
    - Interact with citizens of countries subject to embargoes administered by the OFAC
    - Possess controlled technology and host foreign visitors and/or collaborate with international scientists
Tips and Tricks

- If you believe that there is a reason for regulatory review on an award, contact our office.

- Memorize and properly use committee acronyms (IRB= humans, IACUC=animals, IBC=biosafety)

- Get help with regulatory items. Allow us to assist as soon as possible. Please do not assume!
Information Resides in Regulatory Tab in SAP
Information Resides in Regulatory Tab in SAP
Information Resides in Regulatory Tab in SAP
We are Here to help with...

- Sponsor-specific human/animal/rDNA/RCR/export control requirements
- Citations to regulations affecting research
- Connecting Sponsored funding to Regulatory Protocols
- Developing strategies to assist research staff fulfill regulatory requirements
If you need assistance ...

• Research Regulatory Compliance
  – Grant to Protocol Review/RCR Training:
    • Aurora Cruz-Torres; Ianthe “Cookie” Bryant-Gawthrop, (Prof. Howard Zelaznik-Leads team)
      – 494-6840, vprregulatory@purdue.edu
  – Export Controls:
    • Michael Reckowsky; Steven Riedel; Ianthe “Cookie” Bryant-Gawthrop, (Mike Ludwig-Leads team)
      – 494-6840, exportcontrols@purdue.edu
Thank you,

Questions?

General Session presentation will be located at http://www.purdue.edu/business/sps/