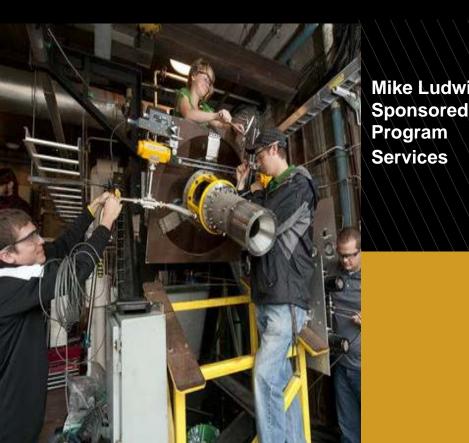
Hot Topics in Research Administration Program





Mike Ludwig

Program Sponsored by:

Chris Martin Business Services Business Management

Howie Zelaznik Office of the Vice President for Research

November 8, 2013

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



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 Hot Topics

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



Agenda - Breakout Sessions

➤ 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



Agenda – Breakout Sessions

➤ 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



Hot Topics in Research Administration Program

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

 PUR

Industrial Contracting – IP Term Summary (Decision Guide)

Mike Ludwig

TYPE OF INDUSTRIAL PROJECT	PUBLICATION	INTELLECTUAL PROPERTY	F&A Rate	IP Fee
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.	64.75%	0%
		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%	5% per field
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.

UNIVERSI	REQUI	RESTRICTED PROJECT APPR RED FOR USE OF APPLIED RESEARC	
Thi	s form is for internal use only a	and should not be forwarded to the sp	oonsor.
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(Copyrightal		CTUAL PROPERTY gible research materials, and inventions	and discoveries)
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Feb 1, 2013 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

<u>June – Oct</u> OMB is reviewing and evaluating the comments and responding to suggestions made



Sept 3, 2013 Letter from Coalition in Support of Innovative Grants Reform to OMB & COFAR

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.



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



Hot Topics in Research Administration Program

Up next.....

Jeff Bolin, Associate Vice President for Research

Research Incentive Fund Changes



Changes To The Research Incentive Fund Distribution

- 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



Research Incentive Fund Changes

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:
- $Allocation = \frac{Modified \ expenditures \ for \ the \ account}{Modified \ expenditures \ for \ \textbf{all} \ accounts} \times R.I. \ Fund \ Budget$
 - "Modified expenditures" subtracts unrecovered F&A
- The College must distribute at least 25% of the Unit allocation to the investigators

Hot Topics in Research Administration Program

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 <u>Biosafety</u> 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.

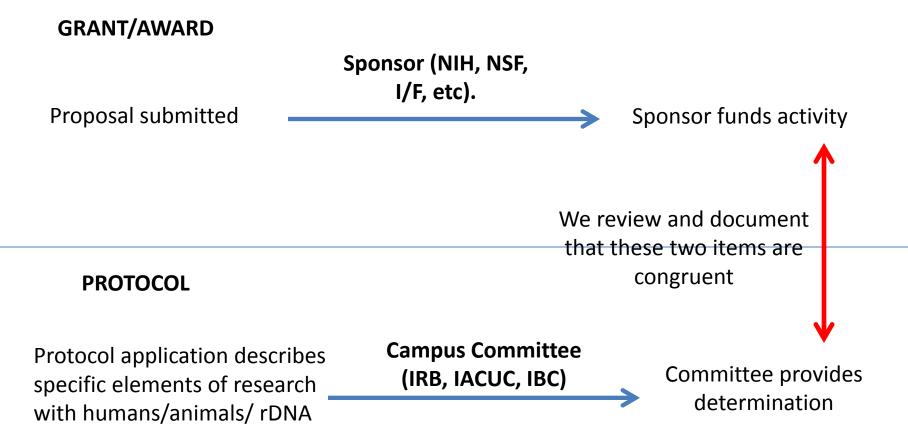


Approval Timelines

- 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





Responsible Conduct of Research (RCR) Training

- 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!

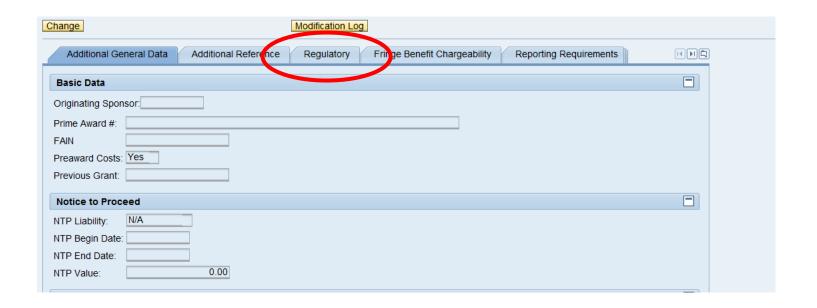


Information Resides in Regulatory Tab in SAP

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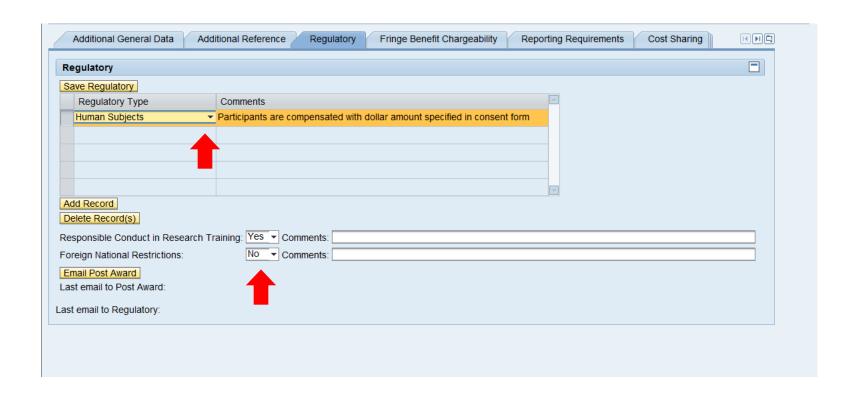


Information Resides in Regulatory Tab in SAP





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; lanthe "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, <u>exportcontrols@purdue.edu</u>



HOT TOPICS IN RESEARCH ADMINISTRATION PROGRAM



Thank you,

Questions?

