

2010 BRINGING ADMINISTRATORS TOGETHER CONFERENCE

Advanced Topics in Research Compliance: Avoiding the Pitfalls

UIC UNIVERSITY OF ILLINOIS
AT CHICAGO

Succeeding in Challenging Times

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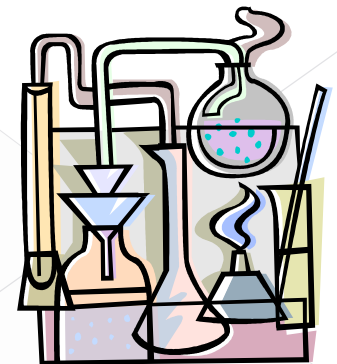
The knowledge you should walk away with today...



- ⦿ Understand what research compliance is as it relates to certain pre- and post-award activities
- ⦿ Be able to identify possible compliance pitfalls
- ⦿ Further insight into research compliance through Case Study Discussions

What is research compliance?

- ◎ Compliance is undertaking activities or establishing practices or policies in accordance with the requirements or expectations of an external authority
- ◎ Internal Controls are established in order to meet the external authorities policies & procedures and to protect the faculty and the University



Examples of Research Compliance Pitfalls

◎ Pre-Award research compliance issues include:

- ❖ Human Subjects
- ❖ Animal Subjects
- ❖ Bio-Safety
- ❖ Radiation
- ❖ IRB approval
- ❖ Mandatory training (human subject, responsible research conduct (NSF), K-award training)
- Hazardous Materials
- Export Control
- Potential Conflicts of Interest
- Other support
- IACUC approval

◎ Post-Award research compliance issues include:

- Effort Reporting
- Cost Allocation & Transfers
- Sub-Recipient Monitoring
- Handling Large Unobligated Balances
- Cost Share Tracking
- Accelerated Expenditures

What Governs What We Do

Aware of OMB Circular A-21 Cost Principles

- Establishes principles for determining costs applicable to grants, contracts, and other agreements
- Direct Costs
- Selected Items of cost
 - Allowable/unallowable costs
 - Time and effort reporting

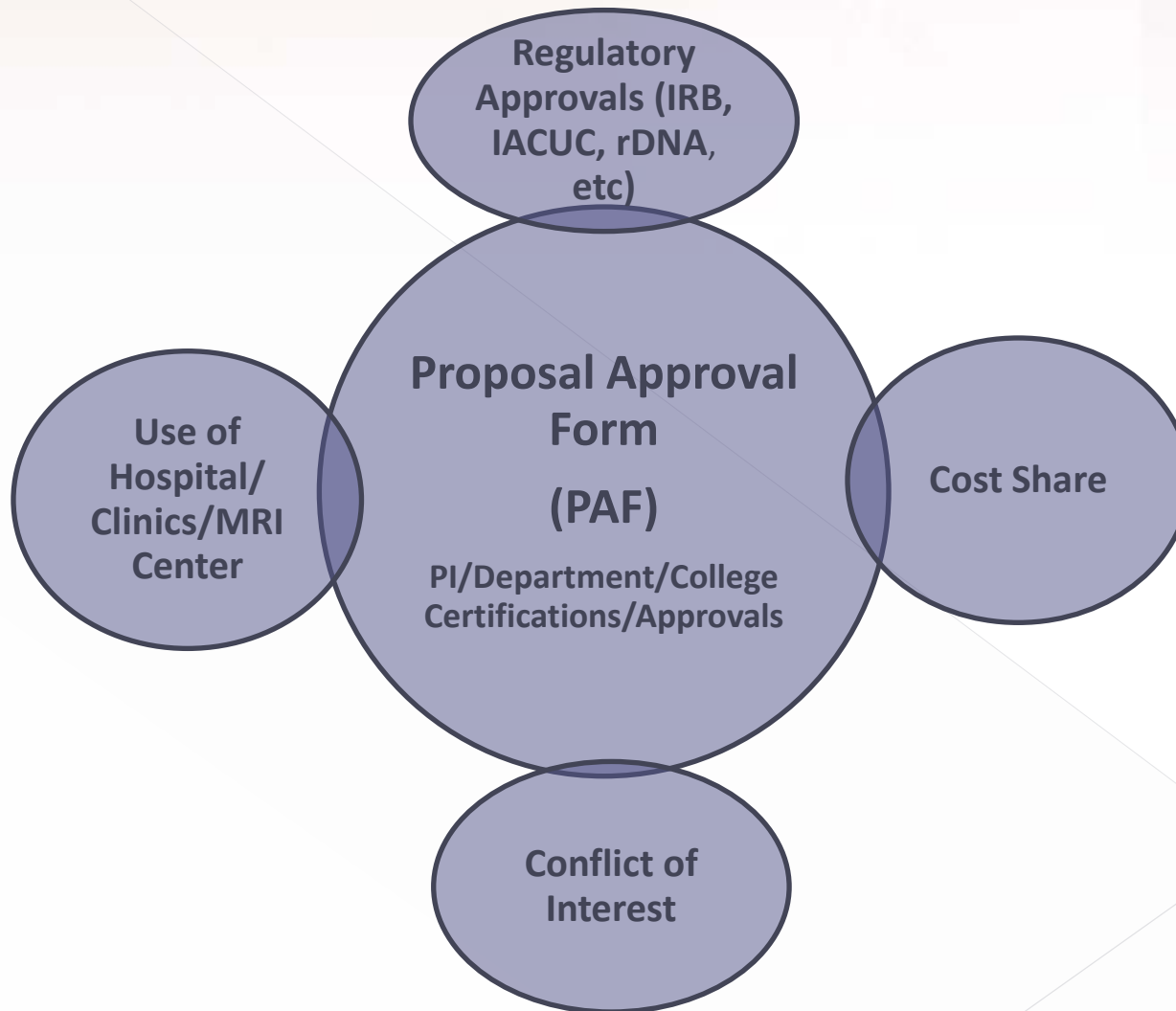
Aware of OMB Circular A-110 Administrative Standards

- Pre-award requirements
- Post Award requirements
 - Financial management systems standards
 - Property Standards
 - Procurement standards
 - Reports & records
- After-the-Award requirements

Aware of OMB Circular A-133 Audit Requirements

- In general, A-133 requires a State government, local government, or non-profit organization (including Institutions of Higher Education) that expends \$500,000 or more per year under Federal grants, cooperative agreements, and/or procurement contracts to have an annual audit by a public accountant or a Federal, State, or local government audit organizations.

Pre-Award compliance related issues are captured on the Proposal Approval Form (PAF)....



Each signature on the PAF is a certification of...

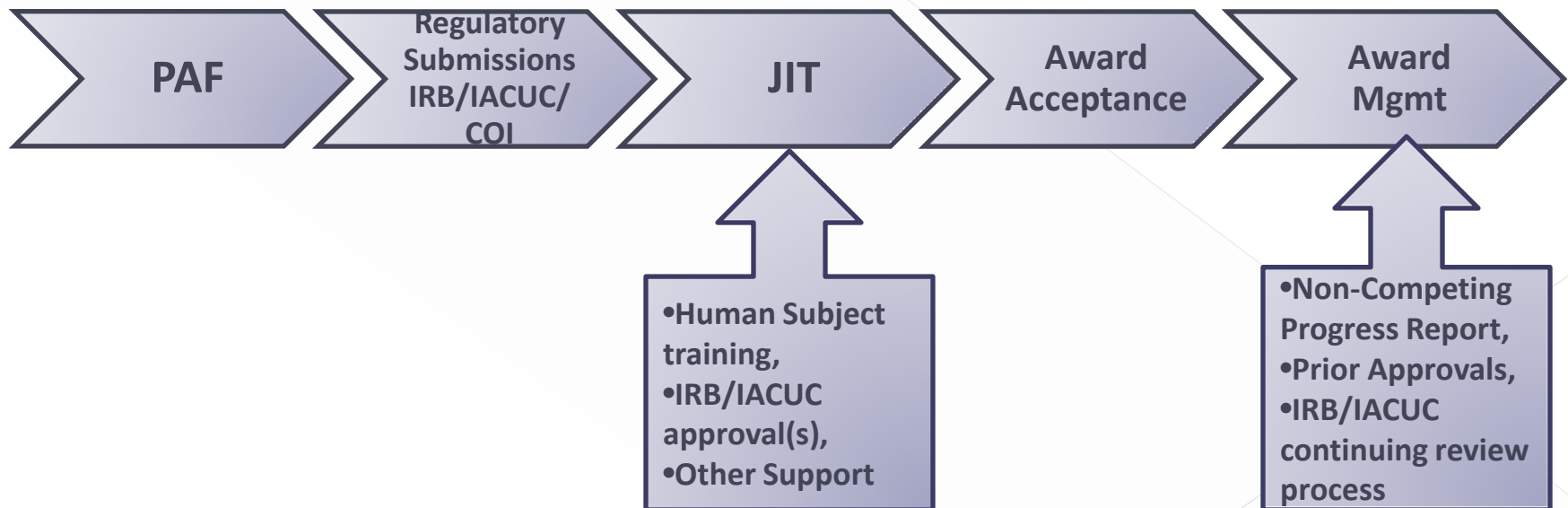
The **Principal Investigator(s)** that he/she accepts responsibility to carry out commitments as outlined in the proposal and in accordance with University and Sponsor guidelines, and the information submitted within the application is true, complete and accurate to the best of the PI's knowledge.

The **Department Chair** that the proposed project is consistent with department goals, is not in conflict with assigned duties, and commits departmental resources where outlined in the proposal.

The **Dean** that the proposal is consistent with the college goals and commits college resources where outlined in the proposal.

The **ORS (Authorized Institutional Representative)** that the information contained within the proposal is true complete and accurate

Points of Entry for Administrative Compliance Related Issues through the life cycle of an award



What is the importance of the Proposal Approval Form (PAF) ?

- Submission of proposal to ORS along with internal supporting documents, the Proposal Approval Form (PAF) is **the initial “documentation” phase of the compliance effort** here at UIC.
- Goal of gathering said documentation is to establish that the PLAN was in compliance with the appropriate guidelines at that point in time.

Remember to submit applicable institutional regulatory applications!

- ⦿ Working with respective institutional regulatory offices to secure appropriate approvals for those compliance related issues as identified on the PAF and sponsor application
- ⦿ Examples include: IRB, IACUC, Mandatory institutional and/or federally required training (Human subject training, Responsible Research Conduct, K-Award Training and Conflict of Interest Statement of Explanation and Management (COI-SEAM))

Be aware of Just-In-Time (JIT) requirements for NIH proposal...

- ◎ NIH grants policy allows the submission of certain elements of a competing application to be deferred for certain programs and award mechanisms.
- ◎ These elements, that can be submitted Just-in-Time by the applicant when requested by NIH, generally include:
 - ✓ [Other Support](#) - According to the NIH, other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, and/ or institutional awards. Training awards, prizes, or gifts are not included.
 - ✓ [IRB Approval](#) - Certification of Institutional Review Board (IRB) Approval
 - ✓ [IACUC Approval](#) - Verification of Institutional Animal Care & Use Committee (IACUC) Approval when applicable
 - ✓ [Human Subject Training Approval](#) - Evidence of compliance with the education in the protection of human subjects requirement for all key personnel

Are you ready to comply with all terms & conditions the award?

- ◎ Review and adhere to Notice of Award terms and conditions, paying close attention to special terms. (i.e.; restrictive terms)
 - › Identify outstanding compliance issues (i.e.; mandatory training, IRB and/or IACUC approvals, conflict of interest)
 - › Understand the fiduciary responsibility and spend the funds in a reasonable and responsible manner

Compliance is throughout the award management phase...

- ◎ Prior Approval Requests
- ◎ Timely and accurate submission of Annual Progress Reports.
Specific areas of concern:
 - › Accurate responses to SNAP questions, specifically unobligated balance greater than 25%
 - › Accurate listing of ALL personnel effort on Personnel Report
- ◎ If applicable, Continuing Review of IRB and/or IACUC approval.

Selected Pre-award Administrative Compliance Case Studies

- ◎ Case Study #1– Other Support
- ◎ Case Study #2– IRB approval
- ◎ Case Study #3– Annual Progress Report/
Handling of Unobligated Balances

Pre-award Case Study #1- Other Support

DEFINITION:

- ◎ According to the NIH, other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, and/ or institutional awards. Training awards, prizes, or gifts are not included.
- ◎ Applicants must submit complete and up-to-date other support information for key personnel before an award is made. Pursuant to NIH's "just-in-time" procedures, other support information is submitted upon the request of NIH staff when the application is under consideration for funding. Once an award is funded, grantees must report any changes in other support for key personnel as part of the annual progress report to NIH.

Case Study 1- Other Support

- Dr. Silver submits NIH grant and receives email from NIH requesting JIT information which included updated other support documentation for all key personnel.

- 1) one of his co-investigators' active effort exceeded 100%
- 2) another key personnel supplied him with other support information that he used for a previous submission a year ago.

Is this appropriate?

Issues Related to Case Study 1 – Other Support

- ⦿ **Other support not complete and up-to-date**
- ⦿ **Other support only includes support from Federal Sources**
- ⦿ **Other support indicates budgetary, commitment or scientific overlap**
- ⦿ **Other support does not list support where key personnel are spending time but not receiving salary support**
- ⦿ **Clinical trial awards not listed as other support**
- ⦿ **Other support does not include effort during no cost extension period.**

Pre-award Case Study #2- IRB Approval

DEFINITION:

- ① University's that perform research on human subjects are required to obtain the review and approval of the university's Institutional Review Board (IRB)
- ① The IRB approves the protocol, which is the outline or plan for use of an experimental procedure or experimental treatment. Review and approval must include all protocols involving humans, including externally and internally funded research
- ① HHS Regulations are codified at 45 CFR Part 46
- ① FDA Regulations are codified at 21CFR Part 50,56 (applicable for drugs, biologics and medical devices)

Case Study 2– IRB Approval

- ◎ Dr. Grant submits new R01 application to NIH and was assigned NIH Grant number 1R01HL12345-01.
 - > This application include human subject activities and therefore Dr. Grant submitted the appropriate IRB protocol/application to OPRS and secured IRB approval. Ultimately that grant was not funded.

- ◎ He then decides to resubmit a revised application (resubmission) to NIH which was assigned NIH grant number R01HL12345-01-A1. He receives email notification from NIH to submit JIT information which included IRB approval.

Is it appropriate for Dr. Grant to use the IRB approval from initial application submission?

Issues related to Case Study 2 – IRB Approval

- ⦿ Research conducted without IRB Review and/or Approval
- ⦿ Failure of IRB to review HHS Grant applications
- ⦿ Failure to conduct continuing review at least once per year.
- ⦿ Changes to research initiated without IRB review and approval.

Case Study #3

Annual Progress Report

DEFINITION:

- ⦿ Periodic progress reports are normally required by granting agency. These reports are used to assist the agency in determining future funding.

- ⦿ The NIH in their annual report require response to specific issues. **Two areas of concern are:**
 - › Accurate responses to SNAP questions, specifically unobligated balance greater than 25%
 - › Accurate Personnel Report - Listing of ALL personnel involved in the project

How do you determine the unobligated balance?

- Per PHS2590 instruction:

Unoblig. Bal = Total amount available for carryover

Current year's **total approved budget**

(**Total approved budget** = current year award authorization + carryover from prior year)

	<u>Year 1</u>	<u>Year 2</u>	<u>Year 2 Unobligated Calculation</u>
Budget	100,000	100,000	120,000
Expense	<u>80,000</u>	<u>80,000</u>	<u>80,000</u>
Balance	20,000	20,000	40,000
Carryover	20%	20%	33%
			(\$40,000/\$120,000)

Case Study #3

Annual Progress Report

- ◎ PI is submitting NIH eSNAP report for year 3.
- ◎ He prepares progress report summary and asks the business manager to prepare other components of the report (i.e, respond to snap questions, personnel report) based on year 2 progress report
- ◎ Is this appropriate?

Issues related to Case Study #3

- ⦿ Responses to SNAP questions must be based on year 3 activities
- ⦿ Effort reported on personnel report should be consistent with salary charged, effort expended, and captured in the University Effort Reporting System
- ⦿ Other related regulatory requirements (i.e, IRB, IACUC) should be reviewed

What does R. A. A. C. stand for?

What does *reasonable* mean?

Cost is considered reasonable to a specific grant if:

- ◎ The cost is recognized as necessary for the performance of the sponsored project and NOT the operation of the Institution
- ◎ Due prudence was used in considering the responsibilities to the University, it's employees & students, the Federal Gov't & the public at large
- ◎ The incurrence of the cost is consistent with established University policies & procedures applicable to the work of the institution, including sponsored agreements

What does *allocable* mean?

A cost is allocable to a specific grant if:

- ⦿ It is incurred solely in order to advance work under the grant
- ⦿ If it benefits both the grant and other work of the institution
- ⦿ If it is necessary to the overall operation of the organization
- ⦿ And it is deemed assignable, at least in part, to the grant

What does *allowable* mean?

A cost is allowable if it is reasonable, allocable, and conforms to the cost principle and the sponsored agreement And is not prohibited by law or regulation

Conformance with limitations and exclusions as contained in the terms & conditions of award including cost principles –varies by type of activity, type of recipient, and other characteristics of individual awards.

What does *consistently applied* mean?

Grantees must be ***consistent*** in assigning costs to cost objectives. Although costs may be charged as either direct costs or F&A costs, depending on their identifiable benefit to a particular project or program, they must be treated ***consistently*** for all work of the organization under similar circumstances, ***regardless of the source of funding***, so as to avoid duplicate charges.

Selected Post Award Administrative Case Studies

- ❖ Case Study # 4 –Reasonable Cost
- ❖ Case Study # 5 –Allowable Cost
- ❖ Case Study # 6 –Sub-Recipient Monitoring

Case Study # 4

Reasonable Cost

- ⦿ The PI purchased a laptop, but we are questioning the allowability.
- ⦿ It is a NSF grant which the budget justification requests funding for statistical software, but no mention of a new computer to run the software.
- ⦿ Is the laptop allowable on a federally sponsored project given A-21 guidelines concerning general office equipment vs. special purpose equipment?

PI's Explanation for Laptop Expenditure

- ❑ The computer purchase cited was for a SONY laptop to be able to conduct analyses with a faster computer than what I had at the time as a desktop through the Institution.
- ❑ The laptop is without clutter of other programs except the statistical software programs I needed.
- ❑ I also needed the freedom to conduct analyses at home and on the road.
- ❑ Since this is a secondary data analysis project, this was a completely justifiable expense.

Further questions to consider for the laptop inquiry

- Will the laptop be exclusively used for this grant?
- Can a portion of the cost be charged to this grant?
- Is the laptop a specialized device with enhanced hardware capabilities and software utilizations that are uniquely required by the project?
- What is the institutional policy?
- Will more, less, or the same effort be conducted on the analysis?
- Would you allow since with expanded authorities you can re-budget?

Case Study # 5

Allowable Cost

You are asked by a PI to stop at an office supply store on your way to work and pick up a few items. The PI also asked you to get some donuts for a lab meeting that morning. When you arrive at work, the PI tells you that all of the items should be charged to the grant.

Your Departmental Administrator tells you that these purchases must come from Departmental funds. Why?

Issues related to case study # 5

- ⦿ If the supplies are not specifically allocable to the grant, they are considered general office supplies and should not be charged as a direct cost.
- ⦿ Entertainment costs, such as food, are unallowable.
- ⦿ Meals are allowable when
 - > (1) they are provided by a conference grant (for scientific meetings supported by the conference grant),
 - > (2) they are provided to subjects or patients under study provided that such charges are not duplicated in participant's per diem or subsistence allowance, and
 - > (3) such costs are specifically approved as part of the project activity in the NGA.

More issues related to Case Study # 5

- ◎ Meals may be an allowable cost if they are provided in conjunction with a meeting when the primary purpose is to disseminate technical information
- ◎ An Institution must also have a written and enforced policy in place that addresses:
 - * Consistent charging of meal costs
 - * Defines what constitutes a meeting for disseminating technical information
 - * Specifies when meals are allowable for such meetings
 - * Establishes limitations and other controls on this cost
- ◎ Recurring business meetings, such as staff meetings are generally not considered meetings to disseminate technical information

Case Study # 6

Sub-recipient monitoring

As a grant administrator, what are your responsibilities to monitor your sub-awardees?

Guidelines for Sub-Recipient Monitoring

- * Review sub-recipients A-133 audit reports for compliance issues
- * Review financial & performance reports submitted by the sub-recipient
- * Perform site visits to review records & observe operations
- * Check public websites for relevant information

Monitoring Basics & Resources

- ⦿ Periodically compare actual expenses with budget
- ⦿ Actual expenses are accurate, i.e. reasonable, allocable, allowable, & consistently charged
- ⦿ Request back-up ledger documentation to accompany invoices
- ⦿ Mischarges are corrected within a timely fashion (cost transfers within 90 days & not done in mass quantity)
- ⦿ Prior approvals are obtained when required
- ⦿ Sub-recipient is not debarred (www.epls.gov); check out the excluded parties list

Who is responsible for compliance?



QUESTIONS



FUTURE TRAINING OPPORTUNITY

As we build for more training and education activities, we would like to hear from you.

- Topics related to sponsored project administration
- Format of training (webinar, on-line or in-person training, etc)

Use the “Other Comments” box of Workshop Evaluation form to provide your input.

THANK YOU!