




Common Compliance Pitfalls:
a discussion based on case studies

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This Division was established on August 28, 2001 and is responsible for managing internal and external compliance activities, both proactive and for-cause.

Internal Compliance Activities

- Grants Management Professional Certification Program
- Management Controls Compliance Model
- Audit oversight
- Provide direction and advice to NIH grants staff and recipient institutions on compliance issues

External Compliance Activities

- Institutional compliance process
 - Technical assistance
 - Corrective action process
 - Settlement process
- Outreach
 - Educational seminars
 - National and regional meetings
 - NIH Regional Seminars
- Proactive Compliance Site Visits
- Targeted Site Reviews (FCOI)

Compliance is.....

- The effective management of public funds to maximize research outcomes
- The avoidance of fraud, institutional mismanagement, and poor management of Federal funds

What are grantees responsible for.....

- Safeguarding all assets
- Spending funds in accordance with the authorized purpose
- Developing and implementing systems to ensure proper stewardship of funds
 - Financial management systems
 - Procurement systems
 - Time & effort reporting systems
 - Monitoring activities
 - Adherence to terms & conditions of award

Summary of Applicable Regulations			
Grantee Type	Admin Requirements	Cost Principles	Audit Requirements
State & Local Governments	A-102 (45 CFR Pt92)	A-87	A-133
Colleges & Universities	A-110 (45CFR Pt74)	A-21	
Non-Profits		A-122	
Hospitals		45 CFR Pt 74 App E	
For-Profits		FAR 31.2 (48 CFR)	45 CFR Part 74.26
Foreign	45 CFR Pt 74 or Pt 92	As stated above for your grantee type	NIH GPS use 45 CFR Part 74.26


And grantees must comply with.....

- Institutional Policies
 - Organizational Structure
 - Purchasing
 - Accounting/Budgetary Controls
 - Time and Effort Reporting
 - Travel
 - Consulting
 - Property Management
 - Ethics/Conflict of Interest



Compliance Pitfalls

- Unallowable costs
- Misallocation of costs
- Excessive cost transfers
- Inaccurate effort reporting
- Incomplete other support
- Inadequate subrecipient monitoring
- Accelerated expenditures
- Large unobligated balances
- Delinquent closeout reporting




Case Studies

Case Study 1...


A University employee transfers funds from one account to another and annotates the cost transfer "to correct an accounting error."

Internal Audit takes exception. Why?



Case Study 2...

Dr. Micron has a U01 in the -03 year with some unexpected equipment needs. He notices a large amount of unobligated funds from the -02 year. Can he use these funds to purchase the equipment?



Case Study 2 (Part 2!)...

Moving forward a few years, Dr. Micron's grant is now in its final year and is not being renewed. There is an unobligated balance of \$100,000. Dr. Micron decides to request a no-cost extension so he can have additional time to complete his research. Is this appropriate?



Case Study 3...



You heard that an employee who works at the University of Woe (UW) was charged with theft by submitting false vouchers. This concerns you because this person is the administrator for a subcontract that supports the research of a PI in your lab.

Your supervisor advises you to stay out of it, it's none of your business. What should you do?

Case Study 4...

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?



Case Study 5...

Dr. Award, the PI, is asked to provide other support in response to a "Just-In-Time" request (application is being considered for funding).

Dr. Award has several NIH grants (including a training grant), funding from a pharmaceutical company, and institutional gift funds.

What should Dr. Award include as other support?



Case Study 6...

A PI is very excited about her research plan and wants to increase her chances of receiving funding. She asks you to submit identical applications to both the National Institutes of Health and the Centers for Disease Control and Prevention. The approach seems logical, but is it permissible?



Case Study 7...

You recently learned that a PI did not disclose on his proposal sign-off form that he was debarred for defaulting on his college loan. Unfortunately, you determined that this situation has gone unreported for a period of three years and during that time the PI's salary has been paid by NIH grant funds. Now what?





Case Study 8...

You were recently informed that a foreign sub-recipient has not completed an A-133 audit. You contact the Canadian university and are assured that they are in compliance with Canadian regulations and they do not have to comply with U.S. regulations. Is this correct?

Case Study 9...



The Co-Investigator on an NIH grant receives a new NIH award on which he is PI. As a result, he needs to reduce his effort on the existing grant from the initial approved level of 50% to 40%. Does the grantee institution need to obtain NIH prior approval for this change?

What if the PI has similar circumstances and wants to reduce his effort? Is NIH prior approval required?

Case Study 10...

Dr. Miller purchases a much needed piece of specialized equipment for her research on hypertension. When preparing the purchase request, she realizes that the only account with enough money is her grant for research on sleep disorders. Because both grants are funded by NIH, she charges the equipment to the sleep disorder grant. Is this appropriate?



Case Study 11...

Dr. Wellbe, the Director of the Clinical Center, will be collaborating (contributing scientific expertise) on the project but will not be committing any effort.

Should Dr. Wellbe be identified as a "key personnel" or as an "Other Significant Contributor?"



Case Study 11 (Part 2)...

In July 2004, Dr. Wellbe was listed on the grant application as a "key personnel", due to her role in the project and the former definition. Dr. Wellbe is contributing her scientific expertise to this project but is not committing any effort to this project.

Should Dr. Wellbe be listed on the PHS 2590 personnel report in this year's progress report?



Case Study 12

- Mr. Administrator has received a call from his foreign subrecipient asking what costs can be covered and paid from the awarded 8% F&A costs?

Case study Issues and Responses

Issues Related to Case Study 1

- If it was an accounting error, the transfer must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organization official.
- Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.
- All charges to grants must be reasonable, allowable, allocable, and consistent.

Issues Related to Case Study 2

- Review the Notice of Grant Award (NGA) for specified carryover authority.
 - P50, P60, P30, Us, Ts, non-Fast Track R43s and R41s, clinical trials (regardless of mechanism), and awards to individuals are routinely excluded from the automatic carryover of unobligated balances. Carryover of unobligated balances for these awards normally requires prior approval from the NIH awarding office **unless** that requirement is waived by a term or condition of the NGA.
 - Specific awards may be excluded from use of carryover through a special term or condition in the NGA.
- Cost principles – purchases paid for with grant funds must be allocable to that award.

Issues Related to Case Study 2 (Part 2!)

The grantee may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original expiration date shown in the NGA if:

- no additional funds are required,
- the project's originally approved scope will not change, **and any one of the following applies:**
 - Additional time beyond the established expiration date is required to ensure adequate completion of the originally approved project.
 - Continuity of NIH grant support is required while a competing continuation application is under review.
 - The extension is necessary to permit an orderly phase-out of a project that will not receive continued support.

More Issues Related to Case Study 2 (Part 2!)

Remember that:

- The fact that funds remain at the expiration of the grant is not, in itself, sufficient justification for an extension without additional funds.
- Grantees registered in the NIH Commons can extend their grant up to the day before it expires, but only if all requirements are met.
- If the grantee is not registered in the NIH Commons, the NIH awarding office must be notified in writing of the extension 10 days before the expiration date of the project period.

NOTE: Any additional extension beyond the one-time extension of up to 12 months requires NIH prior approval.

Issues Related for Case Study 3

As grantee, your institution is legally responsible and accountable to NIH for the appropriate use of funds provided and for the performance of the grant-supported project or activity. This includes the grant-supported activities of consortium (subcontract) participants.

How to Report Concerns Related to NIH Grants

Consider contacting:

- Your institution (e.g., Office of Sponsored Research)
- The NIH grants management office that funded the grant
http://grants.nih.gov/grants/stafflist_gmos.htm
- The Division of Grants Compliance and Oversight, OPERA, OER
GrantsCompliance@nih.gov

Or make a formal allegation by contacting the:

- NIH Office of Management Assessment at (301) 496-5586
- DHHS Office of Inspector General at HTips@os.dhhs.gov

Issues Related to Case Study 4

- 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 to the grant account.
- Entertainment costs, such as food, are unallowable.

More Issues Related to Case Study 4

- 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 allowances, if any; and (3) such costs are specifically approved as part of the project activity in the NGA.

More Issues Related to Case Study 4

- With the June 9, 2004 revision of A-21, 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 the following:
 - Ensures consistent charging of meal costs
 - Defines what constitutes a meeting for the dissemination of technical information
 - Specifies when meals are allowable for such meetings
 - Establishes limitations and other controls on this cost

More Issues Related to Case Study 4

REMEMBER:

Recurring business meetings, such as staff meetings, are generally not considered meetings to disseminate technical information.

Issues Related to Case Study 5

Other support includes **all** financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. **Other support does not include training awards, prizes, or gifts.**

Issues Related to Case Study 6

- Submission of identical applications to different agencies within the PHS or to different Institutes/Centers within the NIH are not allowed. Essentially identical applications will not be reviewed except for an:
 - Application for an Independent Scientist Award (K02) proposing essentially identical research in an application for an individual research project; and
 - Individual research project identical to a subproject that is part of a program project (P01) or other P-series grants, such as P30 or P50.

Issues Related to Case Study 7

- Immediately report the situation to your Office of Sponsored Research and to each NIH funding component.
- Individuals debarred from eligibility cannot be paid from NIH grant funds and such charges are unallowable.

Additional Information Related to Case Study 7

Q: What is the Excluded Parties Lists System (EPLS)?

A: EPLS is the electronic version of the Lists of Parties Excluded from Federal Procurement and Nonprocurement Programs (Lists), which identifies those parties excluded throughout the U.S. Government (unless otherwise noted) from receiving Federal contracts or certain subcontracts and from certain types of Federal financial and nonfinancial assistance and benefits.

<http://epls.arnet.gov/>

Frequently asked questions:

<http://epls.arnet.gov/FAQEPLS.html#1>

Issues Related to Case Study 8

- **Foreign recipients** of NIH grant funds are subject to the **same** audit requirements as **for-profit organizations**. These requirements are specified in 45 CFR 74.26(d) and in the NIH Grants Policy Statement "Grants to For-Profit Organizations." In **summary**, these requirements apply if, during its fiscal year, the organization expends a total of \$500,000 or more under one or more HHS awards – and at least one award is an HHS grant (for fiscal years ending after 12/31/2003).
- Audit options include:
 - A financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the "Yellow Book"), of all the HHS awards; or
 - An audit that meets the requirements of OMB Circular A-133.

Issues Related to Case Study 9

- Grantees are required to notify the NIH Grants Management Officer in writing if the PI or key personnel **specifically named in the NGA** will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, **or reduce time devoted to the project by 25 percent or more from the level that was approved at the time of award.**
- NIH must approve any alternate arrangement proposed by the grantee, including any replacement of the PI or key personnel **named in the NGA.**

Issues Related to Case Study 9 cont'd

The requirement to obtain NIH prior approval for a change in status pertains only to **the PI and those key personnel NIH named in the NGA** regardless of whether the applicant organization designates others as key personnel for its own purposes.

Reduced Effort Calculations

- The PI's effort on grant A is 50% and it needs to be reduced to 40%. Does this require NIH prior approval?
 - No, because the requested reduction of 10% effort does not meet the 25% prior approval threshold ($.25 \times 50 = 12.5$)
- The PI's effort on grant A is 25% and it needs to be reduced to 10%. Does this require NIH prior approval?
 - Yes, because the requested reduction of 15% effort meets the 25% prior approval threshold ($.25 \times 25 = 6.25$)

Issues Related to Case Study 10

The cost principles address four tests to determine allowability of costs:

- **Allocability**

A cost is allocable to a specific grant, if it is incurred solely in order to advance work under the grant; and is deemed assignable, at least in part, to the grant.

- Reasonableness

A cost may be considered reasonable if the nature of the goods or services acquired reflect the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made.

Issues Related to Case Study 10 cont'd

- Consistency
Grantees must be consistent in assigning costs. 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.
- Conformance
Conformance with limitations and exclusions as contained in the terms and conditions of award—varies by type of activity, type of recipient, and other variables of individual awards.

Issues Related to Case Study 11

- Dr Wellbe is **NOT** devoting measurable effort to the project.
- Dr. Wellbe is considered as an "Other Significant Contributor" (no effort).
- Submit biographical sketch but no "other support" required.

Issues Related to Case Study 11 (Part 2)

- Dr Wellbe is **NOT** devoting measurable effort to the project.
- Dr. Wellbe is not considered as "key personnel" under the new definition.
- Dr. Wellbe is considered as an "Other Significant Contributor."
- Only "key personnel" are listed in the personnel report.

Definitions Related to Case Study 11


Change in Definition of "Key Personnel" and New Definition for "Other Significant Contributors"

- NIH GPS (12/03) defines "Key Personnel" as "...individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested..."
- PHS 398 (9/04), defines - "Other Significant Contributors" as "...individuals who have committed to contribute to the scientific development or execution of the project but are **not** committing any specified measurable effort to the projects..."
- Former definition of "Key Personnel": "Individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not they receive compensation from the grant supporting that project. The principal investigator and collaborators are included in this category."

Issues Related to Case Study 12

- NIH provides limited F&A costs to foreign entities.
- NIH provides 8 percent of total direct costs less equipment to foreign institutions and international organizations **to support the costs of compliance with NIH requirements including, but not limited to**, protection of human subjects, animal welfare, research misconduct and invention reporting.
- NIH will not support the acquisition of, or provide for depreciation on, any capital expenditures, or support the normal, general operations of foreign and international organizations.

So... what do Grantees need to comply with?



So...What do Grantees Need to Comply with?

Code of Federal Regulations (CFR)

- 42 CFR Part 52 – Grants for Research Projects
http://www.access.gpo.gov/nara/cfr/waisidx_03/42cfr52_03.html
- 45 CFR Parts 74 and 92 – Public Welfare, Administrative Requirements (74) http://www.access.gpo.gov/nara/cfr/waisidx_04/45cfr74_04.html (92) http://www.access.gpo.gov/nara/cfr/waisidx_04/45cfr92_04.html
- 45 CFR Part 46 – Public Welfare, Protection of Human Subjects
http://www.access.gpo.gov/nara/cfr/waisidx_04/45cfr46_04.html




So...What do Grantees Need to Comply with?

OMB Circulars - <http://www.whitehouse.gov/ombcirculars/>

Administrative Requirements or Standards:

- **A-102:** Uniform Administrative Requirements for Grants and Cooperative Agreements awarded to State and Local Governments and Indian Tribes
- **A-110:** Uniform Administrative Requirements for Grants and Agreements awarded to Universities, Hospitals, and Other Non-Profit Organizations

These include pre-award and post-award requirements



So...What do Grantees Need to Comply with?

Cost Principles: Applicable OMB Circulars and CFRs

- **A-21:** Cost Principles for Educational Institutions
- **A-87:** Cost Principles for State and Local Governments and Indian Tribes
- **A-122:** Cost Principles for Non-Profit Organizations
- **45 CFR Part 74, Appendix E:** Principles for Determining Costs Applicable to Hospitals
- **48 CFR Subpart 31.2 (Federal Acquisition Regulation)** Applicable to For-profit organizations

So...What do Grantees Need to Comply with?

Audit Requirements: Applicable OMB Circular and CFR

- **A-133:** Audits of States, Local Governments, and Non-Profit Organizations
- **45 CFR Part 74.26:** Audits of For-Profit and Foreign Organizations

So...What do Grantees Need to Comply with?

- NIH Grants Policy Statement
http://odoerdb2.od.nih.gov/gmac/nihgps_2003/index.htm
- Notice of Grant Award
- NIH Guide to Grants and Contracts (for new requirements)
<http://grants.nih.gov/grants/guide/index.html>

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Questions?

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