



Common Compliance Pitfalls and Strategies for Success

Diane Dean, Director

John Burke, Assistant Grants Compliance Officer

Division of Grants Compliance and Oversight
Office of Policy for Extramural Research Administration, OER
National Institutes of Health, DHHS

Las Vegas, NV NIH Regional Seminar June 2009



Division of Grants Compliance and Oversight

Joe Ellis
Director, OPERA

Diane Dean
Director, Division of Grants
Compliance and Oversight

John Burke, Mary Fran Deutsch,
and Kathy Hancock
Assistant Grants Compliance Officers

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

Compliance is.....

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

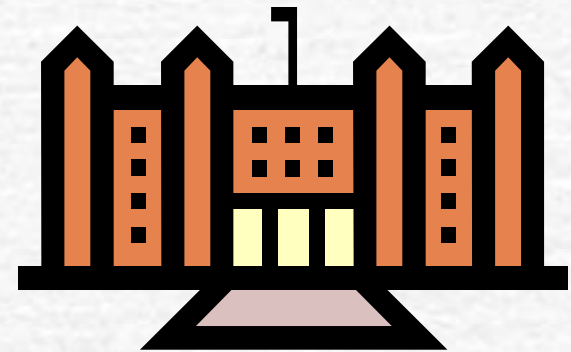
What are grantees responsible for.....

- 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

Grantee Compliance Requirements

Institutional Policies

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



Federal Compliance Requirements

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

Federal Compliance Requirements

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 / 2 CFR Part 215 formerly at 45 CFR Part 74:** Uniform Administrative Requirements for Grants and Agreements awarded to Universities, Hospitals, and Other Non-Profit Organizations

These include pre-award and post-award requirements



OFFICE OF
MANAGEMENT AND BUDGET



Federal Compliance Requirements

Cost Principles: Applicable OMB Circulars and CFRs

- **A-21 (2 CFR Part 220):** Cost Principles for Educational Institutions
- **A-87 (2 CFR Part 225):** Cost Principles for State and Local Governments and Indian Tribes
- **A-122 (2 CFR Part 230):** 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

Federal Compliance Requirements

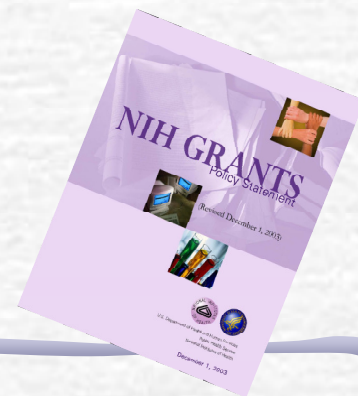
Audit Requirements: Applicable OMB Circular and CFR

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

Federal Compliance Requirements

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

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



Compliance Pitfalls

- Unallowable costs
- Misallocation of costs
- Excessive cost transfers
- Inaccurate effort reporting
- Incomplete other support
- Inadequate subrecipient monitoring
- Administrative & Clerical costs
- Noncompliance with Assurances and special terms and conditions of award
- Delinquent closeout reporting





Case Studies with References

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?



References for 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 consistently applied.

Case Study 2...

Dr. Micron has a U01 in the -03 year with some unexpected equipment needs. Dr. Micron notices a large amount of unobligated funds from the -02 year.

Can these funds be used to purchase the equipment?



References for Case Study 2

- Review the Notice of Award (NoA) Letter 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 NoA.
 - Specific awards may be excluded from use of carryover through a special term or condition in the NoA.
- Cost principles – purchases paid for with grant funds must be allocable to that award.

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 to complete the research.

Is this appropriate?



References for 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 NoA 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 renewal (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 References for Case Study 2

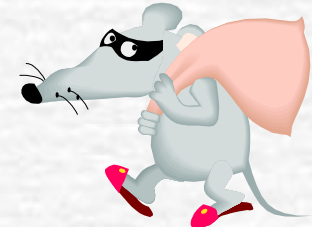
(Part 2!)

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 can extend a grant through the eRA Commons three months prior to the expiration date.
- Extensions may be done up to the day before the grant expires, but only if all requirements are met.

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

Case Study 3...



As a grant administrator, you continue to see recurring charges that appear to be personal in nature. You continue to ask for clarification and/or justification of the charges but you haven't received a response in over six months.

Your inclination is to continue to question the costs but you aren't getting answers. What should you do?

References for Case Study 3

As a grantee, your institution is legally responsible and accountable to the 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 - Case Study 3

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

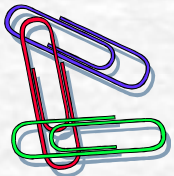
Or make a formal allegation by contacting the:

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

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?



References for 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 References for 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 NoA.

More References for Case Study 4


- With the May 10, 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 References for Case Study 4

REMEMBER:

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



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 her other support?



References for 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.**

Case Study 5

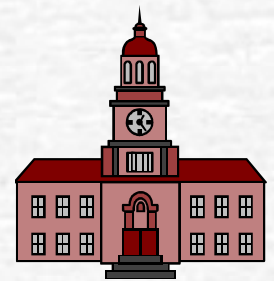
How to Report Other Support

- No Form page (sample page provided)
- Include information on active & pending support for Senior/Key personnel (excludes consultants and Other Significant Contributors)
- Provide the level of **actual effort in person months (even if unsalaried)** for the current budget period. Person months should be classified as academic, calendar and/or summer. For pending projects, indicate the effort in person months as proposed. If appointment is divided into academic and summer, indicate the proportion of each devoted to the project.

For additional information see Frequently Asked Questions:
http://grants.nih.gov/grants/policy/person_months_faqs.htm
and SF 424 instructions, Part III, Section 1.8 Other Support at
http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerA.doc#_Toc216166015

Case Study 6...

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?



References for Case Study 6

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

Additional Information Related to Case Study 6

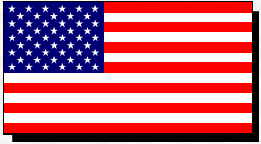
Q: What is the Excluded Parties Lists System (EPLS)?

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.gov/>

Frequently asked questions:

<http://www.epls.gov/epls/jsp/FAQ.jsp>



Case Study 7...

You were recently informed that a foreign sub-recipient had not completed its annual audit. You contact the foreign university and are assured that they are in compliance with their country's regulations and they do not have to comply with U.S. requirements.

Is this correct?

References for Case Study 7

- **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.
- 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.

Case Study 8...



A project leader on an NIH-funded program project grant (a P01 award) submitted a research (R01) grant application to NIH. The R01 application is selected for funding. Because the individual plans to spend 12 person months (100% effort) on the R01 project, the individual withdraws from the currently-funded P01 project.

1. Does the grantee institution need to obtain NIH prior approval for a change in status of a Project Leader on a P01 award?
2. What if the P01 PD/PI wants to withdraw from the project? Is NIH prior approval required?

References for Case Study 8

- Grantees are required to notify the NIH Grants Management Officer in writing if the PD/PI or Senior/Key personnel **specifically named in the NoA** will either
 - 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 PD/PI or Senior/Key personnel **named in the NoA** (refer to Section IV of the terms of award).

References for Case Study 8 cont'd

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

Case Study 9...

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?



References for Case Study 9

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 to advance work under the grant; benefits both the grant and other work of the institution, in proportions that can be approximated through use of reasonable methods; or is necessary to the overall operation of the institution and is deemed assignable 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.

References for Case Study 9 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.

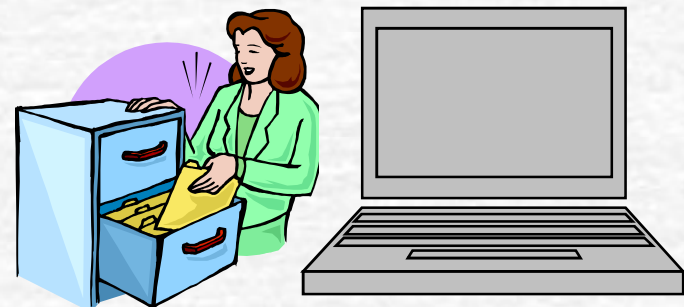
- Conformance (Allowable)

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.

Case Study 10...

Dr. Admins from the University of Education submits a research grant application that seeks support for a half-time secretary, two laptops and a blackberry.

Are these types of costs appropriate for a traditional "R01" grant application?



References for Case Study 10

- Generally, these cost items are not allowed as direct costs on grants for educational institutions.
- A-21, Exhibit C, provides examples and guidance where direct charging of administrative or clerical staff salaries may be appropriate.
- Check with your institutional policy before including these types of costs in grant proposal budgets.

References for Case Study 10 cont'd

- When requested in the budget, NIH considers these costs on a case by case basis.
- NIH considers the justification of 'general use' business items (e.g. laptops) to determine if they are needed for a special research purpose. General office use is not sufficient justification.
- Post award rebudgeting actions must also meet institutional and A-21 requirements.

Questions?

Diane Dean

diane.dean@nih.gov

301-435-0949

John Burke

john.burke3@nih.gov

301-451-4351

GrantsCompliance@nih.gov



Common Compliance Pitfalls and Strategies for Success
Excerpts from NIH Grants Policy Statement (Revised 12/03),
SF424 Research and Research Related (R&R) Version 2 instructions (12/08),
PHS 398 Application Instructions (11/07)

Case Study 1:

Issue 1: Cost Transfers

Excerpt from NIH GPS:

Cost Transfers, Overruns, and Accelerated and Delayed Expenditures (Pages 83 - 84) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600120

Issue 2: Cost Principles – 4 tests

Excerpt from NIH GPS:

The Cost Principles (Pages 79 - 80) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600117

Case Study 2:

Issue: Carryover of Unobligated Balances

Excerpt from NIH GPS:

Carryover of Unobligated Balances from One Budget Period to Another Within an Approved Project Period (Pages 103 - 104) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600128

Case Study 2 – Part 2:

Issue: Extension of Final Budget Period

Excerpt from NIH GPS:

Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds (Page 104) or

http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600128

Case Study 3:

Issue: Role and Responsibilities of grantee participants

Excerpt from NIH GPS: Authorized Organizational Official (now referred to as Authorized Organizational Representative) and Principal Investigator (now referred to as Project Director/Principal Investigator) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part3.htm#_Toc54600044

Case Study 4:

Issue 1: Facilities and Administrative Costs

Excerpt from NIH GPS:

Direct Costs and Facilities and Administrative Costs (Page 81) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600118

Issue 2: Entertainment Costs/Meetings and Conferences (meals)

Excerpt from NIH GPS:

Allowability of Costs/Activities - Selected Items of Cost (Pages 86 and 91) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm#_Toc54600125

Excerpt from A-21 (see J. 17 and J.32):

http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html#j

Excerpt from A-122 (see Attachment B #s 14 and 29)

http://www.whitehouse.gov/omb/circulars/a122/a122_2004.html#attb

Case Study 5:

Issue: Other Support

Excerpt from NIH GPS:

Definition of Terms - Other Support (Page 12) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part2.htm#_Toc54600040

Case Study 5, continued:

See also:

Excerpt from NIH GPS:

Just-in-Time Procedures (Pages 32 – 33) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part4.htm#_Toc54600057

Excerpts from the SF424 (R&R) and PHS 398 application: Part III, Policy, Assurances, Definitions. See Other Support Information or

http://grants.nih.gov/grants/funding/phs398/phs398.doc#_Toc224516079

http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerA.doc#_Toc216166015

Case Study 6:

Issue: Using Federal Grant Funds to Pay a Debarred Individual

Excerpt from NIH GPS:

Debarment and Suspension (Pages 46 - 47) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part4.htm#_Toc54600066

Case Study 7:

Issue: Foreign Sub-Recipient A-133 Audit Requirements

Excerpt from NIH GPS:

Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components, Administrative Requirements, Audit (Page 232) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part12.htm#_Toc54600269

See also:

Grants to For-Profit Organizations, Administrative Requirements, Audit (Page 239) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part13.htm#_grants_to_for-profit_organizations

Case Study 8:

Issue: Change in Key Personnel Named in the Notice of Award (NoA)

Excerpt from NIH GPS:

Administrative Requirements, Changes in Project and Budget, Prior Approval Requirements – Change in Status, Including Absence, of Principal Investigator and Other Key Personnel (Pages 105 and 107) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part7.htm#_Toc54600129

Case Study 9:

Issue: Cost Principles – 4 tests

Excerpt from NIH GPS:

The Cost Principles (Pages 79 - 80) or

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part5.htm#_Toc54600117

Case Study 10:

Issue: Allowability of charging administrative costs as direct costs to NIH grants

Excerpts from the cost principles OMB Circular A-21 (J. 18 and Exhibit C)

http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html#j and

<http://www.whitehouse.gov/omb/circulars/a021/a021.html#exc>