



Common Compliance Pitfalls and Strategies for Success



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Office of Policy for Extramural Research Administration, OER
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Compliance is.....

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



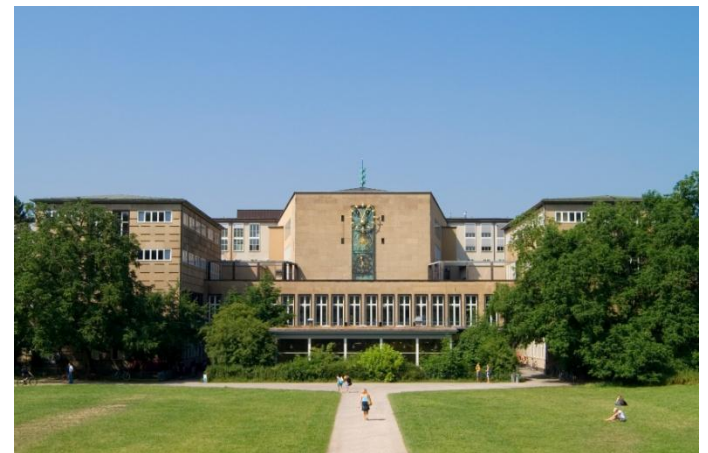
Recipient's Responsibilities

- **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**
 - **Payroll Distribution systems**
 - **Monitoring activities**
 - **Adherence to terms & conditions of award**

Compliance Requirements

Institutional Policies

- **Organizational Structure**
- **Purchasing**
- **Accounting/Budgetary Controls**
- **Payroll Distribution**
- **Travel**
- **Consulting**
- **Property Management**
- **Ethics/Conflict of Interest**



HHS Regulations

- **45 CFR Part 75 – Public Welfare, Uniform Administrative Requirements, Cost Principles and Audit Requirements for HHS Awards**
 - **Effective for all HHS awards made on or after December 26, 2014**
 - **<http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75&rgn=div5>**

Compliance Requirements

Administrative Requirements or Standards:

- 45 CFR Part 75 - Subpart C – Pre-Federal Award Requirements and Contents of Federal Awards (§ 75.200 – § 75.218)
- 45 CFR Part 75 - Subpart D – Post Federal Award Requirements (§ 75.300 – § 75.391)
 - Standards for Financial and Program Management
 - Property Standards
 - Procurement Standards
 - Performance and Financial Monitoring and Reporting
 - Subrecipient Monitoring and Management
 - Record Retention and Access
 - Remedies and Noncompliance
 - Closeout
 - Post-Closeout Adjustments and Continuing Responsibilities
 - Collection and Amounts Due



Compliance Requirements

Cost Principles:

- **45 CFR Part 75, Subpart E (§ 75.400- § 75.477)**
 - **Institutions of Higher Education (IHE), State, Local Governments and Indian Tribes, and Non-profit Organizations**
- **45 CFR Part 75, Appendix IX**
 - **Hospitals**
- **48 CFR Subpart 31.2 (Federal Acquisition Regulation)**
 - **For-Profit Institutions**

Compliance Requirements

Audit Requirements:

- **45 CFR 75.501: Institutions of Higher Education, States and Local Governments, and Non-Profit Organizations, including Non-Profit Hospitals**
- **45 CFR 75.501(h) through (k): For-Profit Organizations, including For-Profit Hospitals**
- **NIH Grants Policy Statement: Foreign Organizations must follow the same requirements as For-Profit Organizations**

Audit Requirements

All NIH grant recipients that expend \$750,000 or more within a year in Federal awards are subject to an audit requirement.

- For-Profit and Foreign Organization audit requirement:

- Expend \$750,000 under one or more HHS awards (as a direct recipient and/or consortium participant)



AUDIT

- Audits are due within the earlier of 30 days after receipt of the auditor's report(s) or 9 months after the end of the recipient's audit period.
- Recipients delinquent in submitting audits risk the imposition of sanctions and potential loss of Federal funds.

Summary of Audit Requirements

Recipient Type	Source of Audit Requirement	Where to Submit Audit Reports
State & Local Governments	45 CFR 75.501	Federal Audit Clearinghouse (See contact information in NIH GPS Part III)
Institutions of Higher Education	45 CFR 75.501	Federal Audit Clearinghouse (See contact information in NIH GPS Part III)
Non-Profits (including non-profit hospitals)	45 CFR 75.501	Federal Audit Clearinghouse (See contact information in NIH GPS Part III)
For-Profits (including for-profit hospitals)	45 CFR 75.501(h) through 75.501(k) and 45 CFR 75.215	National External Audit Review Center (See contact information in NIH GPS Part III)
Foreign Organizations	<u>NIH Grants Policy Statement</u> (same as For-Profits)	National External Audit Review Center (same as For-Profits, see contact information in NIH GPS Part III)

Summary of Federal Requirement References

Recipient Type	Administrative Requirements	Cost Principles	Audit Requirements
State & Local Governments and Indian Tribes	45 CFR Part 75, Subpart C – Pre-Federal Award Requirements and Contents of Federal Awards §75.200-§75.217 AND 45 CFR Part 75, Subpart D – Post Federal Award Requirements §75.300-§75.391	45 CFR Part 75, Subpart E See also §75.416 and §75.417	45 CFR Part 75, Subpart F at §75.501
Institutions of Higher Education		45 CFR Part 75, Subpart E See also §75.418 and §75.419	
Non-Profits		45 CFR Part 75, Subpart E	
Hospitals		45 CFR Part 75, Appendix IX	45 CFR Part 75, Subpart F at §75.501 (h)-(k) and §75.216
For-Profits		FAR 31.2 (48 CFR Subpart 31.2)	
Foreign Organizations			Same as above depending on type of institution

Compliance Requirements

- **NIH Grants Policy Statement (GPS) 2018**

- Including any addenda in effect as of the beginning date of the budget period

<https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>

- **Notice of Award (NoA)**

- **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**
- **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 expenses 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

- **Errors should be corrected within 90 days of when the error was discovered.**
- **Transfers must be supported by:**
 - **Documentation that fully explains how the error occurred**
 - **Certification of the correctness of the new charge (by a responsible organizational 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.....

You are asked by a PI to stop at an office supply store on your way to work and pick up a few items (pens, envelopes and paperclips). 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 2

- **If the office 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 2

- **Meals are allowable on a research grant when:**
 1. **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;**
 2. **such costs are an integral and necessary part of a meeting or conference (i.e., a working meal where business is transacted), and**
 3. **such costs are specifically approved as part of the project activity, consistent with the terms of award.**

More References for Case Study 2

- **An institution should 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 to meet the test of reasonableness**

More References for Case Study 2

REMEMBER:

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

Case Study 3....

Dr. Admins from the University of Education submits a research grant application that seeks salaries of administrative and clerical staff, two laptops and a smartphone.

Are these types of costs generally appropriate for an “R01” grant application?



References for Case Study 3

Salaries of administrative and clerical staff:

- Direct charging of these costs should normally be treated as indirect (F&A) costs.
- NIH GPS 8.1.1.5 provides that direct charging of these costs may be appropriate only if all of the following conditions are met:
 1. Administrative or clerical services are integral to a project or activity
 2. Individuals involved can be specifically identified with the project or activity
 3. Such costs are explicitly included in the budget, and
 4. The costs are not also recovered as indirect costs
- Such charges must also meet the criteria for allowable costs as described in NIH GPS 7.2.

References for Case Study 3 cont'd

Salaries of administrative and clerical staff:

NIH's implementation of Uniform Regulation

- NIH prior approval is *not* required to rebudget funds for salaries of administrative and clerical staff if conditions provided in NIH GPS 8.1.1.5 are met.
- NIH prior approval *required* when:
 - additional funds are requested for such a position or
 - the incurrence of such costs constitutes a change in scope
- For Modular grants, these costs must be included in the Personnel Justification. Provide:
 - the person's name, percent effort and role.
 - justification documenting how they will meet all four requirements in NIH GPS 8.1.1.5

References for Case Study 3 cont'd

Computing Devices are defined in NIH GPS 1.2

“...machines used to acquire, store, analyze, process, and publish data and other information electronically, including accessories (or “peripherals”) for printing, transmitting and receiving or storing electronic information.”

References for Case Study 3 cont'd

Materials and Supplies Costs, including Costs of Computing Devices:

- (a) Costs incurred for materials, supplies, and fabricated parts necessary to carry out a Federal award are allowable.
- (b) Purchased materials and supplies must be charged at their actual prices, net of applicable credits. Withdrawals from general stores or stockrooms must be charged at their actual net cost under any recognized method of pricing inventory withdrawals, consistently applied. Incoming transportation charges are a proper part of materials and supplies costs.
- (c) Materials and supplies used for the performance of a Federal award may be charged as direct costs. *In the specific case of computing devices, charging as direct costs is allowable for devices that are essential and allocable, but not solely dedicated, to the performance of a Federal award.*
- (d) Where federally-donated or furnished materials are used in performing the Federal award, such materials will be used without charge.

More References for Case Study 3

- **Check with your institutional policy before including these types of costs in grant proposal budgets.**
- **Post award rebudgeting actions must also meet institutional, 45 CFR 75 requirements and NIH Grants Policy Statement requirements.**

Case Study 4.....

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 recipient 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 4

- **Recipients 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 recipient, including any replacement of the PD/PI or Senior/Key personnel named in the NoA.**

References for Case Study 4 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 key personnel for its own purposes.**
- **NIH prior approval is also required when there is a change:**
 - **From multiple PD/PIs to a single PD/PI**
 - **From a single PD/PI to multiple PD/PIs**
 - **In the number or makeup of the PD/PIs on a multiple PD/PI award**

Case Study 5....

Dr. Miller purchases a much needed piece of specialized, scientific 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 5

The NIH Grants Policy Statement addresses 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 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.

References for Case Study 5 cont'd

- **Consistency**

Recipients 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 like circumstances, regardless of the source of funding.**

- **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 specific requirements of individual awards.**

Case Study 6....

You recently learned that a post-doc working on an NIH grant had not disclosed that he was debarred for defaulting on his student loan. Unfortunately, you determined that this situation has gone unreported for a period of three years and during that time his 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.**

References for Case Study 6 cont'd

- **As of November 26, 2003, Debarment and Suspension is implemented as a term and condition of award**
 - **2 CFR Part 376 (HHS regulations that implement the government-wide debarment and suspension system guidance)**
 - **2 CFR Part 180 (OMB guidelines on government-wide debarment and suspension (nonprocurement))**

References for Case Study 6 cont'd

- **Prior to drawdown of funds for each grant award, recipients must report to the NIH funding IC if the recipient or any of its principals:**
 - **Are presently excluded or disqualified;**
 - **Have been convicted within the preceding three years of any of the offenses listed in 2 CFR 180.800(a) or had a civil judgment for one of those offenses within that time period;**
 - **Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses listed in 2 CFR 180.800(a); or**
 - **Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.**

References for Case Study 6 cont'd

- **Recipients must also immediately report to the NIH funding IC if at any time during the project period, including periods of no-cost extension, they discover:**
 - **That they failed to disclose information prior to the drawdown of funds, or**
 - **Due to changed circumstances, the recipient or any of its principals for the grant now meet the reporting criteria**

References for Case Study 6 cont'd

- **“Lower tier” transactions (consortia, subcontracts, consultants, collaborators, and contractors that require the provision of goods or services that will equal or exceed \$25,000) are also subject to the regulations.**

References for Case Study 6 cont'd

For lower tier transactions, recipients must:

- **Verify that the person is not excluded or disqualified prior to entering into a lower tier covered transaction.**
- **Require participants to:**
 - **Comply with the HHS Debarment and Suspension regulations as a condition of participation in the transaction, and**
 - **Pass the requirement to comply with regulations to each person involved in the covered transaction at the next lower tier**

References for Case Study 6 cont'd

- **Lower tier participants and contractors under grants (where the contract requires the provision of goods or services that will equal or exceed \$25,000) must report to the recipient if it or any participants are presently excluded or disqualified.**

More Information Related to Case Study 6

Q: What is the System for Award Management (SAM)?

A: The System for Award Management (SAM) is the Official U.S. Government system that consolidated the capabilities of CCR/FedReg, ORCA, and EPLS.

Q: What is the purpose of the Exclusions portion of Performance Information in SAM?

A: SAM provides a single, comprehensive list of individuals and firms excluded by federal government agencies from receiving federal contracts or federally-approved subcontracts and from certain types of federal financial and nonfinancial assistance and benefits.

The system is used to keep agencies aware of administrative, as well as, statutory exclusions taken throughout the Federal Government.

<https://www.sam.gov/>

General Information:

HHS Debarment Regulation (2 CFR Part 376)

- Implements the government-wide debarment and suspension system guidance (2 CFR Part 180)

Questions?

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Related Excerpts from NIH Grants Policy Statement etc.

- **Case Study 1:**

Issue: Cost Transfers

**NIH Grants Policy Statement (GPS) 2017: Chapter 7.5
Cost Transfers, Overruns, and Accelerated and
Delayed Expenditures.**

Related Excerpts from NIH Grants Policy Statement etc.

- **Case Study 2:**

- Issue 1: Cost of Office supplies**

45 CFR Part 75 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. See §75.413 (a) Direct Costs and Appendix III B.6.b.(2) Departmental Administration Expenses:

- http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&ty=HTML&h=L&r=PART&n=pt45.1.75#se45.1.75_1413
- http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&ty=HTML&h=L&r=PART&n=pt45.1.75#ap45.1.75_1521.iii

Related Excerpts from NIH Grants Policy Statement etc.

- **Case Study 2 (continued):**

Issue 2: Cost of Meals

45 CFR Part 75 - Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. See §75.432 Conferences and §75.438 Entertainment Costs:

- http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&ty=HTML&h=L&r=P&ART&n=pt45.1.75#se45.1.75_1432 and
- http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&ty=HTML&h=L&r=P&ART&n=pt45.1.75#se45.1.75_1438

NIH GPS 2017 – 7.9.1. Selected Items of Costs - Meals

Related Excerpts from NIH Grants Policy Statement etc.

- **Case Study 3:**

Issue: Allowability of charging administrative and clerical staff salaries, materials and supplies, including the costs computing devices as a direct cost to NIH grants.

45 CFR Part 75 - Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. See §75.413 (c) (1)-(4) and 75.453(c):

- http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75&rgn=div5#se45.1.75_1413
- http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&ty=HTML&h=L&r=PART&n=pt45.1.75#se45.1.75_1453

Related Excerpts from NIH Grants Policy Statement etc.

- **Case Study 3 continued:**

Issue: Allowability of charging administrative and clerical staff salaries, materials and supplies, including costs of computing devices as a direct cost to NIH awards:

NIH GPS 2017: Section 7.9.1. Selected Items of Costs – Materials and Supplies Costs, including Costs of Computing Devices

NIH GPS 2017: Section 8.1.1.5 Direct Charging Salaries of Administrative and Clerical Staff

Related Excerpts from NIH Grants Policy Statement etc.

- **Case Study 4:**

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

NIH GPS 2017: Chapter 8.1.2.6 Administrative Requirements, Changes in Project and Budget, Prior Approval Requirements – Change in Status, Including Absence, of PD/PI and Other Senior/Key Personnel.

Related Excerpts from NIH Grants Policy Statement etc.

- **Case Study 5:**

Issue: NIH GPS – 4 Tests to Determine Allowability of Costs

NIH GPS 2017: Chapter 7.2 The Cost Principles.

- **Case Study 6:**

Issue: Using Federal Grant Funds to Pay a Debarred Individual

NIH GPS 2017: Chapter 4.1.6 Debarment and Suspension