



Lessons Learned for Grants Management of Time and Effort and Financial Conflicts of Interest:

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Division of Program Integrity

OMA, OD, NIH



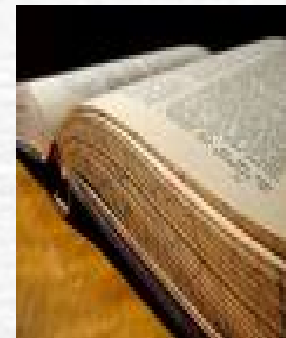
- Provides centralized review capability to promote program integrity
- Evaluates allegations of waste, fraud, and mismanagement
- Reviews issues referred to NIH by the OIG
- Serves as liaison with OIG investigations and other law enforcement



DPI Review Process



- DPI uses the Generally Accepted Government Auditing Standards as guidelines
- DPI consults with:
 - Grants management officials (GMO)
 - Scientific officials
 - Policy officials (OER)



Allegations DPI Does not Review



- **Scientific misconduct:** HHS Office of Research Integrity
- **Human subject issues:** HHS Office for Human Research Protections
- **Animal welfare issues:** NIH Office of Laboratory Animal Welfare
- **Criminal activities:** HHS Office of Inspector General
- **Personnel issues:** at grantee institutions
- **Discrimination or harassment:** Equal Employment Opportunity Commission
- **Contractor and subcontractor disputes**

Types of DPI Reports

- Administrative Closure Memo
- Management Advisory Memo
- Final Advisory Report
 - Issued after Draft Report for comments
 - Recommendations for management to:
 - ✓ disallow and recover costs
 - ✓ ensure compliance with federal policies and requirements
 - ✓ establish management controls



Sources of Allegations and Types of Issues Found



Sources of Allegations

80% from NIH staff, employees of other organizations, or the public
20% from the Office of Inspector General Hotline

Types of Issues Found (sample of cases)

Misspent funds	67	Closely related research	3
Alleged fraud	15	Cost transfers	3
Time & effort	22	Equipment & supplies	4
Cost allocation	20	Conflicts of interest	6
Contract problems	18		



Grantee 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
 - ✓ Time and effort reporting systems
 - ✓ Monitoring activities
 - ✓ Adherence to terms & conditions of award
- Eliminating, reducing, and managing conflicts of interest

Grantee Requirements



Institutional policies

- Organizational structure
- Purchasing
- Accounting/budgetary controls
- Time and effort reporting
- Travel
- Consulting
- Property management
- Ethics/conflicts of interest



Compliance Pitfalls

- Unapproved, undocumented, unsupported, or unjustified charges or cost transfers
- Unallowable costs
- Misallocation of costs
- Untimely or excessive cost transfers
- Inaccurate effort reporting
- Incomplete other support
- Inadequate subrecipient monitoring
- Administrative and clerical costs as direct costs
- Noncompliance with assurances and special terms and conditions of award
- Conflicts of interest



Indications of Potential Problems



- Significant rebudgeting or cost transfers
- Accelerated expenditures
- Large \$ carry over
- Letters of complaint
- Late or missing Progress Reports
- Unusual \$ draw downs
- Change in key personnel
- Change in scope



Some Examples - Costs



The PI wants to purchase equipment and other items for grant A. The only account with enough money is grant B. Both grants are funded by NIH. The PI charges the purchases for Grant A to Grant B.

The PI asks staff to go to a store and pick up some personal items and grant-related items using a grantee purchase card. The PI tells staff to charge everything to the grant.

A PI charges NIH grants for staff who perform preliminary studies to prepare new applications for federal and non-federal grants.

The PI transfers funds from one account to another and annotates the cost transfer "to correct an accounting error."

More Examples - Costs



Reporting to NIH: The grantee institution does not report funding from a pharmaceutical company to NIH.

Budgetary or scientific overlap: The PI obtains funding for similar research from multiple federal agencies but does not notify NIH.

Debarment: The university does not disclose debarment to NIH and continues to pay the PI's salary from the NIH grant .

Prior approval: The grantee institution does not obtain prior approval before the PI reduces effort on the grant.

Conflicts of Interest (COI)



- Responsibilities of researchers:
 - Follow institutional policies
 - Comply with federal laws and regulations
 - Submit and update financial interest disclosure reports
- Responsibility of grantee institution when COI is found:
 - Promptly notify the NIH awarding component of corrective actions taken or planned

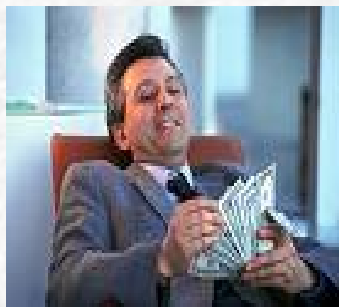


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Some Examples - COI



A PI was in charge of a university lab and was also the owner of a private business. Both entities received NIH grant funds. The PI then had his lab contract work to his private business.



A university department chairman failed to report payments from drug companies. This led NIH to freeze a five-year grant worth \$9.3m and forced the PI to step down as department chair. The university created an office to oversee issues concerning conflicts of interest.

Some *Qui Tam* Cases



Report on _____

Volume 2, Number 7 • July 2005

RESEARCH COMPLIANCE

News and Analysis for Colleges, Universities and Teaching Hospitals

College Settles Fraud Claim for \$4.3M; Charges Focus on Poor Distribution of Funds

Weill Medical College of Cornell University has agreed to pay \$4.3 million to resolve civil charges that it defrauded the government in the way it spent money from two National Institutes of Health (NIH) grants. The charges, which were initiated in a whistleblower lawsuit, focus on the operation of the Children's Clinical Research Center from 1995 through 2003. The allegations target the way the college administered two National Center for Research Resources (NCRR) general clinical research center grants, which provide support for investigators performing research supported by other NIH grants. Weill is affiliated with New York Presbyterian Hospital, which provided some services under the grants. The settlement, however, does not include the hospital.



Department of Justice

FOR IMMEDIATE RELEASE
THURSDAY, MAY 26, 2005
WWW.USDOJ.GOV

CIV
(202) 514-2007
TDD (202) 514-1888

PARENT ORGANIZATION OF MAYO CLINIC PAYS U.S. \$6.5 MILLION TO SETTLE GRANT FRAUD INVESTIGATION

WASHINGTON, D.C. - The Mayo Foundation, parent organization of the Mayo Clinic, has paid the United States \$6.5 million to resolve allegations that it charged the government under federal grants for research costs unrelated to the research projects sponsored by those grants, the Justice Department and the United States Attorney from Minnesota announced today.

More *Qui Tam* Cases



Department of Justice

FOR IMMEDIATE RELEASE
THURSDAY, FEBRUARY 6, 2003
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NORTHWESTERN UNIVERSITY WILL PAY \$5.5 MILLION TO RESOLVE FALSE CLAIMS ACT AND COMMON LAW ALLEGATIONS

WASHINGTON, D.C. — Northwestern University will pay the United States \$5.5 million to settle allegations that the school violated the False Claims Act with regard to claims in connection with federally-sponsored medical research grants, the Justice Department announced today. The government alleged that Northwestern misled the United States into paying more money than the Chicago-area school was lawfully entitled to receive.

The Justice Department received analytical support in this case from the National Institute of Health's Division of Program Integrity in Rockville, Maryland

JHU, Bayview Settle Federal Lawsuit for \$2.6 Million

Whistle-Blower Told U.S. Grant Work Was Overbilled
by Jonathan Bor
Baltimore Sun Staff

February 27, 2004

The Johns Hopkins University and one of its teaching hospitals have agreed to pay more than \$2.6 million to settle a federal lawsuit alleging that they overbilled the National Institutes of Health for addiction research and other projects.

How to Report Your Concerns



To the grantee institution:

- Internal audit
- Compliance officer
- Legal office



To NIH:

- The NIH chief grants management officer
http://grants.nih.gov/grants/stafflist_gmos.htm
- DPI (301) 496-5586 <http://oma.od.nih.gov/pi/dpi.html>

To the Office of Inspector General:

- HHS OIG (administrative or criminal issues):
HTips@os.dhhs.gov

Questions?

