HOT TOPICS IN COMPLIANCE

Office of Research Services
Brown Bag
November 30, 2006
Ann Saputelli
Director, Compliance Monitoring
Office of Research Compliance and Integrity

Frank Tresnan
Director, University & Penn Medicine Audit
Office of Audit, Compliance & Privacy
Service Objectives

- Assess and help ensure compliance with:
  - OMB Circulars
  - Other Federal regulations
  - University policies
  - Sponsor policies

- Provide feedback to PIs and BAs

- Contribute to education and training
Significant Risks of Non-Compliance

- **Risks to the University:**
  - Damage to Penn’s reputation
  - Loss of funding/shutdown of research operations
  - Loss of NIH line of credit draw down privileges
  - Fines and penalties
  - Susceptibility to False Claims Act Allegations

- **Individual Risks:**
  - Loss of PI status
  - Debarment and suspension
  - Possible criminal and civil charges
Non-Compliance Fines and Penalties

- New York University Medical Center - $15M (inflated research grant costs)
- Thomas Jefferson University - $12M (over-billing and unallowable items)
- Florida International University - $11.5M (incomplete effort reporting records)
- Yale University - $5.6M (medical over-billing)
Recent Settlements
(From *Wall Street Journal* Aug. 16, 2005)

**Busy Docket**
Recent settlements between medical institutions and the U.S. Department of Justice over alleged misuse of federal grant money:

<table>
<thead>
<tr>
<th>INSTITUTION</th>
<th>SETTLEMENT DATE</th>
<th>ALLEGED MISCONDUCT</th>
<th>SETTLEMENT AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mayo Clinic</td>
<td>May 2005</td>
<td>Government was charged for research unrelated to the NIH grants it received</td>
<td>$6.5 million</td>
</tr>
<tr>
<td>University of Alabama at Birmingham</td>
<td>April 2005</td>
<td>Research work overstated; Medicare billed for research funded elsewhere</td>
<td>$3.4 million</td>
</tr>
<tr>
<td>Harvard University</td>
<td>June 2004</td>
<td>Government was billed for salaries and expenses unrelated to federal grants</td>
<td>$2.4 million</td>
</tr>
<tr>
<td>Johns Hopkins University</td>
<td>February 2004</td>
<td>Faculty time and effort devoted to NIH grants was overstated</td>
<td>$2.6 million</td>
</tr>
<tr>
<td>Northwestern University</td>
<td>February 2003</td>
<td>Researchers spent less time on NIH-sponsored projects than they reported</td>
<td>$5.5 million</td>
</tr>
</tbody>
</table>
Current Federal Audit Workplan Topics

- Effort Reporting
- Administrative & Clerical Salaries
- Cost Transfers
- Sub-Award Monitoring
- Compensation of Graduate Students
- Conflicts of Interest
- Monitoring Research Grants
Cost Transfers

- Effective grant management and good internal controls eliminate the need for excessive cost transfers, which can indicate inefficient management practices.

- Cost transfers must be
  - **Timely** – within 90 days of the month end in which the transaction appeared on the fund
  - **Documented** – fully explaining the circumstances under which the error occurred and the justification for transferring the costs to the receiving fund
  - **Authorized** – certified by the PI and BA
Cost Transfers: OIG Audit Outcomes

- Roger Williams Hospital - $53,655
- Yale - $151,252
- U of Mass - $71,972 of total payback
  $281,993
- Boston U - $11,234
Cost Transfers: UPenn Solutions

- According to Financial Policy 2113, cost transfer and payroll reallocations must be:
  - Proper and allowable costs
  - Supported by adequate documentation fully explaining how the error occurred
  - Certified by the PI and BA
  - Performed in a timely manner
Common Cost Transfer Issues

- Transfers lack adequate supporting documentation or are not documented at all
- No documented PI or BA approval
- No justification for new fund source
- Not performed in a timely manner
- Improper handling of pre-award costs
- Unallowable transfers - relieve overdrafts
- Lack of adherence to internal policies
Effort Reporting

- **What is Effort Reporting?**
  - Required by OMB Circular A-21
  - The process of planning, distributing, and certifying that payroll costs charged to sponsored projects reasonably represent actual proportions of total effort devoted to those projects

- **How is Effort Certification accomplished?**
  - By certifying 100% of all University activities that comprise an individual’s institutional base salary
Effort Reporting: OIG Audit Outcomes

- Yale – $101,228 unauthorized, cover overruns
- Northeastern – $ 65,286 unsupported
- UPenn – $27,121 questionable and unsupported salary
  - NSF auditors concluded with 95% confidence that $2.9M didn’t benefit NSF awards
Effort Reporting: UPenn Solutions

- NEW electronic effort reporting system
- Financial Policy 2114
- Time cards memo - Standardized Time Report Form for Temporary Hourly Employees, 9/28/05
Effort Reporting: Common Issues

- Appropriate Certifier/Verifiable Means
- Timeliness of Reallocations
- Salary Cap Calculation Errors
- Temp Effort Certification
- Late Certification
Sub-award Monitoring

- Core elements of compliance:
  - Routine receipt of Technical Performance Reports
  - Routine review of expenses to budgets
  - Review of A-133 reports filed by sub-recipients and any audit findings
  - Review of corrective actions cited by sub-recipients in response to their audit findings
  - On-site visits and audits (only as necessary)
Sub-award Monitoring: OIG Audit Outcomes

- Univ. of Massachusetts Medical School - $249,525

*Did not have adequate procedures for monitoring sub-recipients*
Sub-award Monitoring: UPenn Solutions

- Financial Policy 2131 – Compliance with Sub-recipient Standards of OMB Circular A-133
  - ORS Responsibilities:
    1. Advise subs of requirements imposed by Federal laws, regulations, and the provisions of contracts, grants or collaborative agreements as well as requirements imposed by the University
    2. Obtain and review sub-recipient A-133 outcomes
  - PI Responsibilities:
    1. Monitor activities of subs to ensure funds are being used for authorized purposes and that performance goals are achieved
    2. Review and approval all technical and financial reports including invoices
Sub-award Monitoring: Common Issues

- No PI approval of invoices
- Lack of proactive monitoring
- Failure to obtain/review/maintain technical reports
- Failure to involve ORS in a timely manner
- No verifiable means to support PO manager’s receipt of invoices
Direct vs. Indirect Costs

- **Indirect (F&A) Costs**
  - Costs incurred for common or joint objectives
  - Not readily or specifically identified with a particular sponsored project
  - Includes costs for buildings, equipment, interest expense, utilities, operations, maintenance, administration, and library
Direct vs. Indirect Costs: OIG Audit Outcomes

- Frequent disallowances of OIG do not specify types of unallowable expenditures as F&A
- Likelihood of unsupported expenditures as F&A is high
Direct vs. Indirect Costs: UPenn Solutions

- Financial Policies:
  - 2108 Cost Accounting Standards
  - 2110 Federal Direct Cost Expenditures

- Sponsored Project Manual

- Newsletter

- Educational Forums
Direct vs. Indirect Costs: Common issues

- Grant is not a “Major Project”
- Administrative/clerical salaries
- Books/subscriptions
- Office Supplies
- PennNet, Telephone, Postage
- Printer toner, paper
Graduate Students

- Reasonable compensation equivalent to PGY1 postdoctoral scientist
- NRSA stipend and other budgetary levels - policy notices NOT-OD-06-026
Graduate Students: OIG Audit Outcomes

- Joe Barton and Ed Whitfield letter to HHS-OIG 9-20-2005
- 1994 audit of graduate student compensation at selected University System – $5.7 million
- On OIG 2007 workplan
Graduate Students: UPenn Solutions

- Review of policies and procedures
- Add to future workplan for audit
- SOM – Graduate Studies Office which regulates compensation and charging NIH funds
Conflict of Interest

- **Financial:**
  - Stock or other investments, ownership of companies, royalties

- **Obligations:**
  - Board membership, trusteeship, consulting or contracting arrangements, employment, professional associations

- **Relationships:**
  - Family, friends, mentors, collaborators, advisors
Conflict of Interest

- Personal financial interests/research COI - core elements of compliance:
  - Disclosure is required for investigators and others
  - Designated individual(s) to review disclosures and resolve issues
  - Enforcement mechanisms and sanctions
  - Notification to responsible agency
  - Maintenance of records for at least 3 years post project
Conflict of Interest: OIG Audit Outcomes

- OIG Investigations could result in:
  - Criminal prosecution
  - Payment of restitution
  - Debarment
  - Divestiture of questioned assets
  - Modification or declination of proposals
  - Modification of research plans
Conflict of Interest: UPenn Solutions

- HR Policy 005: Conflict of Interest
- Faculty & Academic Administrators Handbook – II.E.10 – Conflict of Interest Policy for Faculty Members
- Financial Disclosure Policy for Research & Sponsored Projects: [http://www.upenn.edu/almanac/v47/n21/ORdisclosure.html](http://www.upenn.edu/almanac/v47/n21/ORdisclosure.html)
- Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials: [http://www.upenn.edu/almanac/v49/n32/OR-clinicaltrials.html](http://www.upenn.edu/almanac/v49/n32/OR-clinicaltrials.html)
Conflict of Interest: UPenn Solutions

- New web system to assist in recording financial interest of faculty and staff
- Future enhancements to record financial interest in database annually
- Future education sessions
PI Approval

- Policy memo - Authorization and Approval of Sponsored Projects Transactions 7/10/2006
  http://www.upenn.edu/researchservices/memoranda.html
Other Risks?

- Lack of supporting documentation
- Customary F&A
- Last minute spending
- Over and under-spending
- Uncaptured cost sharing
- Late reporting