



# Duke University and Health System Research Compliance Seminar

**Compliance Environment**  
June 19, 2006

Experience. **Redefined.**<sup>™</sup>

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# Overview of Research Compliance Environment

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## Trends related to research compliance at universities include:

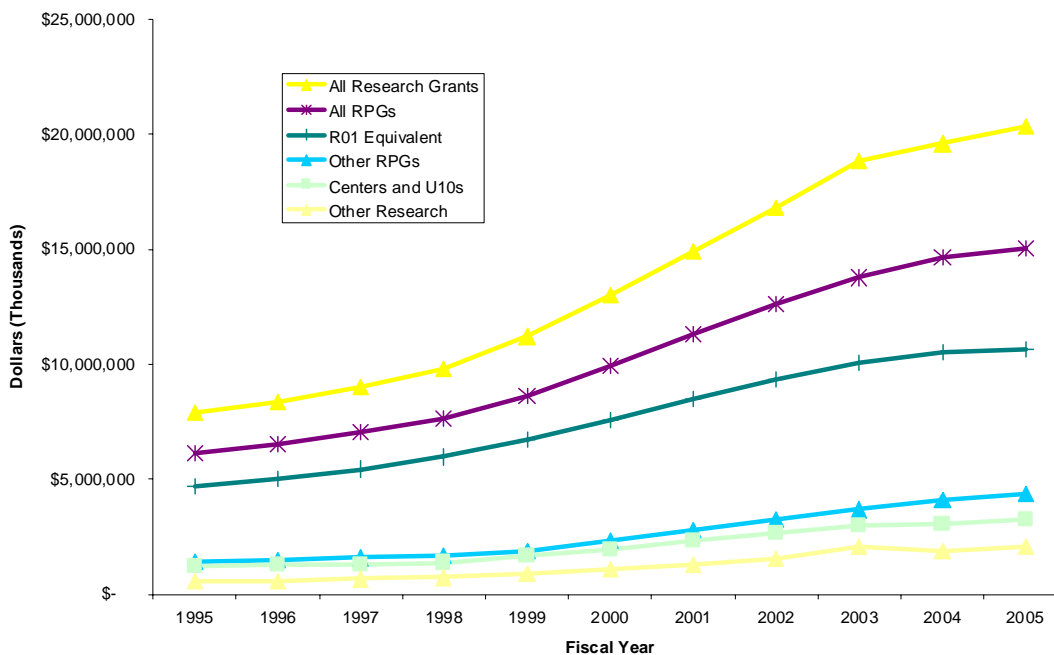
- ◆ **Rapid growth of sponsored research funding.**
  - **Congress has fulfilled a commitment to significantly increase federally funded research.**
  - **NIH funding doubled between 1998 and 2002.**
  - **With increased funding comes increased scrutiny by regulators.**
  - **Institutions experiencing rapid growth often lag in the development of an appropriate infrastructure to support the research growth.**

# Overview of Research Compliance Environment

Trends related to research compliance at universities include:

◆ Rapid growth of sponsored research funding

1A. Distribution of Extramural NIH Research Funds for Selected Grant Awards  
Fiscal Years 1995-2005



# Overview of Research Compliance Environment

## Trends related to research compliance at universities include:

- ◆ **Scrutiny by regulators is increasing. OIG's semi-annual report (4/01/04 through 9/30/2004) for Health and Human Services noted the following:**
  - **Since 1996, financial penalties resulting from audits of sponsored research have increased from \$237 million to \$1.9 billion.**
  - **Since 1996, the number of annual criminal convictions of individuals or entities that engaged in improper compliance activities has nearly quadrupled, to 533 in FY2004.**

# Overview of Research Compliance Environment

## Areas of current compliance emphasis:

### Fiscal

- ◆ Cost Transfers
- ◆ Clinical Trial Billing
- ◆ Award monitoring
- ◆ Cost sharing
- ◆ Direct charging practices
- ◆ Effort reporting
- ◆ NIH salary cap
- ◆ Pre-authorized spending authority
- ◆ Program income
- ◆ Recharge centers
- ◆ Unallowable costs

### Research

- ◆ Animal subject protections (IACUC)
- ◆ Human subject protections (IRB)
- ◆ Conflicts of interest
- ◆ Environmental health & safety
- ◆ Invention disclosure & reporting
- ◆ Scientific overlap
- ◆ Scientific misconduct
- ◆ Other support

# Overview of Research Compliance Environment

**Complexity is found in research and fiscal areas and in the diversity of constituents:**

## Research & Fiscal Areas

- ◆ Genomics
- ◆ Stem cell research
- ◆ Clinical trials
- ◆ Technology transfer
- ◆ Faculty owned start-ups
- ◆ University equity interests
- ◆ Conflict of interest
- ◆ International collaborations
- ◆ Interdisciplinary Research
- ◆ Subcontracts
- ◆ Human subject protections
- ◆ Electronic payment
- ◆ Grants.gov
- ◆ Cost accounting standards
- ◆ OMB circular A-21

## Constituents

- ◆ Investigators, research assistants, staff, technicians
- ◆ Students, grad students, parents of students
- ◆ Board members, taxpayers
- ◆ Federal agencies, external auditors
- ◆ Suppliers, donors, corporate sponsors, investors
- ◆ Human subjects, advocacy groups (PETA, etc.)
- ◆ University administration, college and departmental administration

# Overview of Research Compliance Environment

**Trends related to research compliance at universities include:**

◆ **False Claims Act/Qui Tam:**

- **Allows an individual who knows about a person or entity who is submitting false claims to bring a suit on behalf of the government**
- **The individual may receive a portion (15-30%) of the damages recovered as a result of the suit**

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# Government's Focus

# Government's Focus: DHHS OIG 2005 Workplan

## NIH Focus Areas:

### ◆ University Administrative and Clerical Salaries

- We will determine whether colleges and universities have appropriately charged administrative and clerical salaries to federally sponsored grants and cooperative agreements. OMB Circular A-21 provides that such costs should usually be treated as indirect costs. However, direct charging of these costs may be appropriate when the nature of the work performed under a particular project requires extensive administrative or clerical support.

### ◆ Recharge Centers

- We will determine whether colleges and universities have complied with Federal cost principles. A previous OIG review of recharge centers found that 11 of 12 universities did not maintain adequate accounting systems and records. Weaknesses resulted in duplicate or unallowable costs in billing rates, use of recharge center funds for unrelated purposes, and accumulated surplus fund balances.

### ◆ Level of Commitment

- We will determine whether major research universities committed more than 100 percent of principal investigators' effort when applying for National Institutes of Health (NIH) grants and, if so, whether the resulting grant awards were inflated. The NIH funds grant proposals on a cost-reimbursable basis and considers the investigator's role in deciding whether to fund the proposal. If a university promises more of the proposed investigator's time than is available, the NIH funds intended to pay for salary could possibly be used for costs not included in the proposal and the research quality could be affected.

# Government's Focus: DHHS OIG 2005 Workplan

## NIH Focus Areas:

### ◆ Safeguards Over Controlled Substances at NIH

- We will evaluate control procedures for pharmaceuticals used in NIH intramural clinical settings, with emphasis on safeguards over controlled substances. Using criteria established by FDA, the Drug Enforcement Administration, and NIH, we will evaluate the practices used to purchase, inventory, dispense, and administer pharmaceuticals. Weaknesses in these practices could result in the misappropriation of costly pharmaceutical products, especially controlled substances.

### ◆ Royalty Income From Intramural Inventions

- We will determine whether NIH collects the royalty income earned from new technologies developed by Federal employees in its research laboratories. NIH has a statutory mandate to ensure that such promising new technologies are transferred to the private sector for commercialization. Typically, NIH seeks patent protection for these inventions and enters into a royalty-bearing licensing agreement with private entities to use or commercialize the technology. This technology transfer licensing program generates over \$52 million a year in NIH revenue. Our review will determine whether NIH ensures that it receives royalty income on all products to which it is entitled, the royalties are calculated correctly, and payments are received in a timely manner.

# Government's Focus: DHHS OIG 2005 Workplan

## NIH Focus Areas:

### ◆ Employee Conflicts of Interest at NIH

- We will describe how NIH addresses issues related to employee conflicts of interest. Federal employees must adhere to both government wide and program-specific ethical standards, which include provisions on conflict of interest. The provisions require that employees disclose all conflicts of interest, which are then screened for severity and handled accordingly. A recent investigation raised questions about employee conflicts of interest at NIH and cited several cases in which senior-level NIH officials responsible for overseeing millions of dollars in research grants concurrently had private business relationships with organizations that had business pending before their divisions. We will compare NIH's policies and practices for employee conflict of interest to those of other Federal agencies, both within and outside of the Department, as well as private organizations to assess their relative rigor and comprehensiveness.

### ◆ Superfund Financial Activities for Fiscal Year 2004

- As required by Superfund legislation, we will conduct this annual financial audit of payments, obligations, reimbursements, and other uses of Superfund monies by the National Institute of Environmental Health Sciences. The institute's Superfund activities, carried out by its own staff and through cooperative agreements, include training for people engaged in hazardous waste activities and studying the effects of exposure to specific chemicals. During FY 2003, agency obligations and disbursements of Superfund resources amounted to \$85.7 million and \$81.3 million, respectively.

# Government's Focus: DHHS OIG 2005 Workplan

## Cross-Cutting Public Health Activities:

### ◆ Implementation of Select Agent Regulations by University Laboratories

- Following our first series of reviews, which identified a pattern of weakness in select agent security, we will assess the security of additional university laboratories that have select agents. At each university, we will determine whether (1) laboratories have adequate physical security to prevent unauthorized entry to areas with select agents, (2) adequate inventory controls have been implemented to keep track of select agents, (3) CDC regulations on possessing and transferring select agents are followed, and (4) the institution forwards the names of persons handling select agents to the Attorney General's office for a background search. These additional reviews are important because new legal requirements have been imposed on institutions having select agents since our initial reviews. Further, for selected universities reviewed during FY 2003, we will assess the corrective actions taken in response to our recommendations.

### ◆ Review of Adverse Event Reports by Institutional Review Boards

- We will assess how institutional review boards (IRBs) use adverse event reports as a tool to protect human subjects. Adverse event reports can serve as a key tool to protect human subjects by helping IRBs understand the potential risks associated with ongoing studies. Federal regulations require clinical investigators to report to IRBs "any unanticipated problems involving risks to human subjects or others." The OIG's previous work surfaced concerns with IRBs' use of adverse event reports. We intend to assess the extent to which IRBs receive useful information in adverse event reports, have adequate processes for reviewing adverse event reports, and factor adverse event reports into their decisions to recommend changes to a clinical trial.

# Government's Focus: DHHS OIG 2005 Workplan

## Cross-Cutting Public Health Activities:

### ◆ Privacy of Medical Records

- We will conduct an early assessment of colleges' and universities' policies and procedures for protecting the privacy of medical records of persons participating in NIH-funded clinical trials and other research. In response to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandate, HHS developed the first Federal privacy standards to protect patients' medical records. These new standards, which were effective in April 2003, provide patients with access to their medical records and more control over how their personal health information is used and disclosed. The HHS Office for Civil Rights (OCR) oversees and enforces the standards at colleges and universities that are covered universities. We will seek advice from OCR to ensure that the universities we select for review are covered by the HIPAA privacy rule.

### ◆ Time and Effort Reporting Compliance Through Single Audits

- We will determine how and to what extent single audits assess and document colleges' and universities' compliance with time and effort reporting requirements of OMB Circular A-21. The single audit process, required by OMB Circular A-133, represents the Federal Government's primary internal control over costs claimed under Federal projects. The annual OMB Circular A-133 Compliance Supplement directs auditors of research and development programs to test the time and effort reporting system to support the distribution of salaries and wages. However, the extent to which the single audits currently assess time and effort reporting systems is largely unknown.

# Government's Focus: DHHS OIG 2006 Workplan

## NIH Focus Areas:

### ◆ Pharmacy Inventory Controls

- We will evaluate inventory control procedures for pharmaceuticals used in National Institutes of Health (NIH) intramural clinical settings, with emphasis on safeguards over controlled substances. Using criteria established by FDA, the Drug Enforcement Administration, and NIH, we will evaluate the practices used to purchase, inventory, dispense, and administer pharmaceuticals. Weaknesses in these practices could result in the misappropriation of costly pharmaceutical products, especially controlled substances.

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# Government's Focus: DHHS OIG 2006 Workplan

## NIH Focus Areas:

### ◆ NIH Monitoring of Extramural Conflicts of Interest

- We will examine how NIH monitors extramural grantees for potential conflicts of interest. Under 42 CFR Part 50, institutions must certify that they maintain a "written, enforced policy" on conflicting interests. Under the regulations, institutions must also report to NIH the existence of any conflicting interests and assure that the interest has been "managed, reduced, or eliminated." The inspection will focus on the effectiveness of NIH's oversight, whether conflicts of interest have affected Federal and public interests, and whether the definition of "significant financial interest" effectively protects researchers from perceived conflicts of interest. Conflicts of interest in the scientific community pose especially serious risks to clinical trial subjects and consumers, where a risk of bias can affect the quality of treatment decisions.

### ◆ Level of Commitment

- We will determine whether major research universities committed more than 100 percent of principal investigator's effort when applying for NIH grants and, if so, whether the resulting grant awards were inflated. NIH funds grant proposals on a cost-reimbursable basis, and considers the investigator's role in deciding whether to fund the proposal. If a university promises more of the proposed investigator's time than is available, the NIH funds intended to pay for salary could possibly be used for costs not included in the proposal, and the research quality could be affected.

### ◆ Subrecipient Costs and Monitoring

- We will determine whether college and universities are complying with applicable Federal regulations to monitor subrecipient costs. OMB Circulars A-110 and A-133 require that grantees monitor subawards and ensure subrecipients have met audit requirements. Grantee monitoring should take place during and after the award, and should include site visits, review of performance and financial reports, and development of risk assessments based on relevant factors to ensure a proper level of monitoring. Our reviews at three institutions show that grantees are not adequately complying with Federal requirements.

# Government's Focus: DHHS OIG 2006 Workplan

## NIH Focus Areas:

### ◆ University Administrative and Clerical Salaries

- We will determine whether colleges and universities have appropriately charged administrative and clerical salaries to federally sponsored grants and cooperative agreements. OMB Circular A-21 provides that such costs should usually be treated as indirect costs. However, direct charging of these costs may be appropriate when the nature of the work performed under a particular project requires extensive administrative or clerical support.

### ◆ Cost Transfers

- We will determine the allowability of cost transfers at NIH grantees. We will assess if the transfers are supported by documentation that fully explains how errors occurred and if responsible grantee officials certify the correctness of the new charges. On-site visits by NIH during fiscal years 2000 through 2002 found that cost transfer policies and procedures tend to be nonexistent, incorrect, or confusing. Prior OIG work also found that cost transfers were unallowable and/or not appropriately documented. The potential effect of unreasonable, unallocable, or unallowable cost transfers is substantial considering the value of NIH grant funds awarded each year is approaching \$20 billion and increasing.

# Government's Focus: NSF Management Challenges for 2006

## Award Administration Challenges:

### ◆ Post-Award Administration Policies

- During the past year, NSF has made progress toward strengthening its post-award monitoring of grantee institutions, but has not yet established an effective program for monitoring high-risk institutions.

### ◆ Management of Large Infrastructure Projects

- NSF's management of large science infrastructure projects has been listed as a management challenge since two OIG audits conducted several years ago found weaknesses in their financial management.

### ◆ Cost Sharing

- While federal guidelines require that cost-shared expenses be accounted for in a manner consistent with federal expenditures, our audit work has revealed that in practice many awardees do not adequately document or substantiate the value of cost shared expenditures, raising questions about whether required contributions are actually being made.

# Government's Focus: NSF Management Challenges for 2006

## Award Administration Challenges:

### ◆ Promoting Integrity

- The research community is again debating whether integrity in research is eroding as science enters the 21st century. A recent survey found that one third of NIH-supported researchers surveyed acknowledge engaging in activities that are best described as questionable research practices. The authors concluded that the “range of questionable practices . . . are striking in their breadth and prevalence.” We have observed the types of practices these scientists admitted to during our investigations and concluded they are not unique to NIH-supported researchers. They can reasonably be expected to be practiced by scientists supported by other federal agencies. Separate from the more serious behaviors defined as research misconduct (falsification, fabrication, and plagiarism) these questionable practices damage the integrity of science and erode the trust one scientist places in another, which can in turn undermine the reliance NSF’s merit review system places in the quality of the proposals it receives.... Such perceptions have significant potential for harm to the research enterprise, and thus present a management challenge to NSF to seek new opportunities and means to ensure integrity within the research community and within the pipeline of students NSF is charged with educating.

# Government's Focus: DHHS OIG Compliance Program Guidance

## Guidelines on setting up compliance programs:

- ◆ **In November 2005, the DHHS OIG issued a proposed set of guidelines for setting up research compliance programs**
  - The guidance they provided with regard to the elements of effective compliance programs was fairly consistent with previous government guidance.
  - However, the tone of the guidance appeared less flexible to many in the research community as the guidance included specific recommendations for some of the elements.
  - Based on COGR agenda for June 2006, this DHHS OIG guidance will be withdrawn.
- ◆ **Guidance Included Insight Into Key Risk Areas Identified by OIG**
  - Time and effort reporting
  - Proper allocation of charges to Federal awards
  - Reporting of financial support from other areas

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# Recent Settlements / Audits

## Recent Settlements/Audits: Summary

Institution	Headline	Source	Date
George Washington University	<i>Ex-GWU Professor Charged in \$600,000 Theft</i>	<i>The Washington Post</i>	October 13, 2004
University of California – Irvine	<i>Cancer Funds Misspent, UCI Auditors Say</i>	<i>The Los Angeles Times</i>	September 29, 2004
East Carolina University	<i>OIG Disallows \$500,000 in Costs, Challenges Additional \$1.7 Million</i>	<i>Report on Research Compliance</i>	September, 2004
University of Southern California	<i>USC Told to Repay Funds for Program</i>	<i>The Los Angeles Times</i>	July 31, 2004
Harvard University	<i>Harvard Agrees to Pay \$2.4-Million More to Settle Allegations of Overcharging the NIH</i>	<i>The Chronicle of Higher Education</i>	June 21, 2004
University of Washington	<i>U. Of Washington Affiliates to Pay \$35 Million to Settle Medicare Overbilling Case</i>	<i>The Chronicle of Higher Education</i>	June 1, 2004
University of Alabama – Birmingham	<i>Federal Regulators Again Push U. of Alabama-Birmingham to Improve Human-Subjects Protections</i>	<i>The Chronicle of Higher Education</i>	April 13, 2004

## Recent Settlements/Audits: Summary

Institution	Headline	Source	Date
Florida A&M University	<i>FAMU may lose research money</i>	<i>The Tallahassee Democrat</i>	May 5, 2005
George Washington University	<i>GWU Will Pay U.S. For Scholar's Theft</i>	<i>The Washington Post</i>	April 20, 2005
University of Alabama at Birmingham	<i>U. of Alabama at Birmingham Will Pay \$3.4-Million to Settle Accusations That It Overbilled Federal Agencies</i>	<i>The Chronicle of Higher Education</i>	April 15, 2005
University of South Dakota	<i>NSF Recommends More Grants Management Staffing</i>	<i>Report on Research Compliance</i>	April 8, 2005
University of Vermont	<i>Former Scientist at U. of Vermont Plead Guilty to Vast Research Fraud</i>	<i>The Chronicle of Higher Education</i>	March 18, 2005
Florida International University	<i>Florida International U. Agrees to \$11.5-Million Settlement With Government Over Grants Accounting</i>	<i>The Chronicle of Higher Education</i>	February 15, 2005
Northeastern University	<i>OIG Audit Finds Inappropriate Cost Allocations</i>	<i>Report on Research Compliance</i>	February 10, 2005

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## Recent Settlements/Audits: Summary

Institution	Headline	Source	Date
San Diego State University	<i>Audit: NSF Inspector General Disallows Overload Compensation</i>	<i>Report on Research Compliance</i>	April 9, 2004
Florida International University	<i>FIU Probes Accounting Matter</i>	<i>The Miami Herald</i>	March 16, 2004
Johns Hopkins University	<i>Johns Hopkins U. Settles Federal Charges of Overbilling on Research Grants</i>	<i>The Chronicle of Higher Education</i>	March 1, 2004
University of California	<i>U. of California Agrees to Pay \$3.9-Million for Inappropriate Charges at Livermore Lab</i>	<i>The Chronicle of Higher Education</i>	February 9, 2004
Northwestern University	<i>Northwestern U. Pays Federal Fine for Rules Violations in Animal Research</i>	<i>The Chronicle of Higher Education</i>	January 7, 2004
University of Connecticut	<i>UConn Scientist Resigns, Agrees to Pay \$100,000 Penalty</i>	<i>The Chronicle of Higher Education</i>	December 8, 2003
Florida A&M University	<i>State to Investigate Florida A&amp;M's Finances</i>	<i>The Chronicle of Higher Education</i>	December 1, 2003

# Recent Settlements/Audits: Detailed Cases

## Effort Reporting:

### ◆ Northwestern University

- Key elements of the complaint
  - Included physician salary components from faculty practice in the base in applications, while excluding some clinical activities when calculating effort
  - Insufficient tracking of effort vs. proposed effort
  - Faculty did not meet K award effort commitments of 75%
- \$5.5 million settlement to the government, plus attorneys fees for the relator
- No admission of wrongdoing on the part of NWU

### ◆ Johns Hopkins University

- Key elements of the complaint
  - Medical center misled U.S. into paying more money on research grants than it was entitled to receive.
  - JHU violated False Claims Act by overstating the percentage of effort that researchers were able to devote, and the percentage of effort that personnel actually worked in applications for research grants sponsored by NIH and other federal agencies.
- Settlement of \$2.6 million

# Recent Settlements/Audits: Detailed Cases

## Cost Transfers:

### ◆ Mayo Clinic

- Settlement of \$6.5 million in 2005 partially related to cost transfers
- Allegations of over-expenditures
- Investigation indicated improper cost transfers and accounting system unable to monitor and manage charges on grants

### ◆ Florida International University

- Settlement of \$11.5 million in 2005 partially related to cost transfers
- Major findings related to cost transfers including:
  - Incomplete cost transfer documentation
  - Using grants as “clearing accounts”
  - Cost transfers after the grant had closed

## Recent Settlements/Audits: Detailed Cases

### Subcontracts:

#### ◆ University of Massachusetts Medical School (UMMS) and Yale University

- NIH Award to UMMS
- UMMS issued subaward to Yale University
- Audit report alleges that Yale claimed \$193,779 in costs that did not comply with OMB Circular A-21 and the terms of the subgrant.
- Because Yale received its funds through a subgrant from UMMS rather than directly from NIH, audit recommended under separate cover that UMMS reimburse NIH for unallowable subgrant costs totaling \$193,779.
- This was an audit - there has not been a settlement to date.

### Specialized Service Facilities:

#### ◆ University of Connecticut

- \$2.5 million settlement partially related to specialized service facilities
- DOJ contended that University had submitted numerous false claims because it had not updated its billing rate structures for two specialized service facilities since 1996.

# Recent Settlements/Audits: Detailed Cases

## Clinical Trial Billing:

### ◆ Rush University Medical Center

- \$1 million settlement
- Improper Medicare/Medicaid billing for cancer treatments for patients who were part of clinical trials at the Medical Center.
- Billing for certain physician professional services and hospital inpatient and outpatient services that were not reimbursable under the Centers for Medicare & Medicaid Services' (CMS) national coverage decision (NCD) on clinical trials, which was issued in 2000.

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# Key Elements of Effective Compliance Programs

# Key Elements of Effective Compliance Programs

The NIH Office of the Inspector General (OIG)\* identified the following eight elements considered as necessary for a comprehensive compliance program.

## 8 Elements

- ◆ **Policies and Procedures:** Implementing written policies and procedures that foster an institutional commitment to stewardship and compliance
- ◆ **Roles and responsibilities:** Defining roles and responsibilities across the institution and assigning oversight responsibility
- ◆ **Compliance Leadership:** Designating a compliance officer and compliance oversight committees
- ◆ **Training:** Conducting effective training and education
- ◆ **Communication:** Developing effective lines of communication
- ◆ **Monitoring:** Conducting internal monitoring, quality review, auditing, and assurance
- ◆ **Enforcement:** Enforcing standards through well-publicized disciplinary guidelines
- ◆ **Corrective Response:** Responding promptly to detected problems, undertaking corrective action, and reporting to the appropriate agencies

## How Institutions Should Respond

- ◆ **Explicit written policies, institutional codes of ethics and conduct**
- ◆ **Adequate institutional and Board-level oversight of the compliance function**
- ◆ **Designation of a responsible institutional official with appropriate authority and expertise**
- ◆ **Adoption of adequate procedures, resources, and systems to permit compliance**
- ◆ **Maintenance of a process to allow anonymous reporting of alleged non-compliance**
- ◆ **Protection of employees who file reports**
- ◆ **Regular monitoring and quality review audits to test compliance**
- ◆ **Mechanisms to enforce rules and discipline rule violators, take corrective action and communicate results**

*\* Note: Responsibility for this program has recently been transferred to the Office of Science and Technology Policy (OSTP)*

# Key Elements: Policies and Procedures

## Common oversights:

- ◆ Lack of policies and procedures in key compliance areas
- ◆ Policies and procedures exist but they are not easy to find and are not catalogued
- ◆ Policies and procedures exist but they are not followed

## Best practices:

- ◆ Standardized policies and procedures for all compliance topics
- ◆ Policies and procedures available on intranets and internal networks
- ◆ Employee code of conduct

# Key Elements of Effective Compliance Programs

## Coupling employee codes of conduct with comprehensive communication:

- ◆ **The Report of the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines (dated October 7, 2003) recommended adding to the organizational sentencing guidelines a specific requirement that organizations seek to develop a culture in which compliance with the law is the expected behavior.**
  - **Employee code of conduct may be the first step to establishing this culture**
  - **Code must be followed by executives and employees and executives must communicate and demonstrate the importance of the code and culture of compliance**

# Key Elements: Roles and Responsibilities

## Common oversights:

- ◆ Lack of clearly defined roles and responsibilities
- ◆ Unrealistic roles and responsibilities given resources for different units
- ◆ Lack of training for roles and responsibilities

## Best practices:

- ◆ Clearly defined roles and responsibilities that are communicated to research community
- ◆ Roles and responsibilities matrix
- ◆ Roles and responsibilities section in policies and procedures
- ◆ Training and education sessions on roles and responsibilities

# Key Elements: Roles and Responsibilities

## Best Practice Example: Roles and Responsibilities Matrix

		ROLES							
		Department / Division			Central Administration				Other
		PI	Dept / Div Admin	Dept / Div Chairman / Chief	RASP			Finance Office: (Research Accounting, Indirect Cost, Accounting Services, Payroll)	Offices or Committees
RESPONSIBILITIES					Research Compliance Office	Grants & Contracts Office	Research Integrity Office		
<b>Proposal Budget</b>									
78	Prepare proposal budget and budget justification commensurate with sponsor and College policies	P	S	I		O			
79	Provide help as needed to PIs and others on preparation of budgets and other forms		P	I		S			Institute for Clinical Research - S
80	Request matching funds or identify in-kind contributions according to College policy	P		S		I			
81	Identify and evaluate issues related to program income	P			O	O		O	
82	Verify that budget items are in accordance with A-21 (which also includes cost accounting standards)	P	S			O		I	

**KEY**  
**P = PRIMARY RESPONSIBILITY**  
**S = SECONDARY RESPONSIBILITY**  
**O = INSTITUTIONAL OVERSIGHT**  
**O - L = LOCAL OVERSIGHT**  
**I = PROVIDE INPUT**

# Key Elements: Compliance Leadership

## Common oversights:

- ◆ No compliance officer or one that lacks a position of authority
- ◆ Compliance roles and responsibilities are separated among several individuals who do not coordinate their activities
- ◆ Compliance officer is not supported by adequate number and diversification of staff

## Best practices:

- ◆ Compliance Officer who has broad responsibility for compliance
- ◆ Compliance Committee consisting of senior administration staff that support the Compliance Officer
- ◆ Separation of responsibilities for different types of compliance – e.g. research compliance versus health care compliance
- ◆ A Compliance Officer position that is not an operational position

# Key Elements: Training, Education and Communication

## Common oversights:

- ◆ No training and education program to communicate compliance standards
- ◆ Training exists but it is not mandatory for people who need it most
- ◆ No effective training programs for PIs
- ◆ No periodic follow up or proactive staff reminders

## Best practices:

- ◆ Policies and procedures are communicated throughout the organization and employees know where to go for policy interpretation
- ◆ Comprehensive training and education program covering a wide spectrum of compliance topics
- ◆ Web-based or other non-lecture training options for PIs
- ◆ Certification programs
- ◆ Different levels of training for different people
- ◆ Executive summary level communication – consistent “sound-bites”

# Key Elements: Training, Education and Communication

## Best Practice Example: Sponsored Programs “Exam”

- ◆ **University created a sponsored programs “exam” (300 multiple choice questions) to measure the knowledge of University personnel related to the critical financial and non-financial aspects of sponsored program management.**
  - **Basic Cost Principles**
  - **Cost Sharing and Matching**
  - **Cost Transfers**
  - **Direct and Indirect Costs**
  - **Effort Certification**
  - **Program Income**
  - **Travel**
- ◆ **University used the results of the “exam” to determine areas for further training, education and communication and also to assign roles and responsibilities to administrators.**

# Key Elements: Training, Education and Communication

## Best Practice Example: Sponsored Programs "Exam"

### Question

- ◆ **According to University policy, which of the following costs should normally be treated as a direct cost?**
  - a) **Salaries and wages of clerical personnel**
  - b) **Office equipment**
  - c) **Local telephone charges**
  - d) **Salaries and wages of technicians**

### Answer

- d) Salaries and wages of technicians**

# Key Elements: Training, Education and Communication

## Best Practice Example: Sponsored Programs “Exam”

### Question

- ◆ According to OMB Circular A-110, all of the following can normally be included as cost sharing or matching EXCEPT:
  - a) Volunteer services furnished by professional and technical personnel
  - b) Donated supplies
  - c) Donated equipment
  - d) Contributions included under another federally-sponsored program

### Answer

- d) Contributions included under another federally-sponsored program

## Key Elements: Monitoring

### Common oversights:

- ◆ No reviews or audits of departments that receive sponsored research funding
- ◆ No defined method for employees to report non-compliance
- ◆ Perception that organization is compliant because no serious A-133 findings are identified

### Best practices:

- ◆ Periodic audits by internal audit to assess the capability of internal controls to deter non-compliance
- ◆ Publicized method for employees to report suspect activity to the institution without fear of retribution – employee “hotlines”
- ◆ Review of departments by central research offices or outside party

# Key Elements: Monitoring

## Best Practice Example: Sample Interview

### Compliance Review at a Large Academic Medical Center – Sample Interview of a Department Grants Administrator

**Q: What is your understanding of the Cost Accounting Standards?**

**A: What are the Cost Accounting Standards?**

**Q: For example, Cost Accounting Standard 502 deals with the consistency in allocating costs incurred for the same purpose in like circumstances.**

**A: Oh yeah that. We do a good job of monitoring how we treat costs. For example, we never charge clerical salaries to grants.**

**Q: Good. Can you explain how you would charge general supplies such as note pads, printer paper, etc.**

**A: I usually talk to my investigator to determine which grant the supplies belong to or I charge it to our largest NIH grant because it is well funded.**

# Key Elements: Enforcement

## Common oversights:

- ◆ Not enforcing policies and procedures
- ◆ Inconsistent enforcement of policies and procedures (e.g. we made an exception for Dr. X because she brings in lots of money to the Medical School)

## Best practices:

- ◆ Development and implementation of disciplinary mechanisms
- ◆ Including a description of the consequences for non-compliance in policy and procedure documents and in investigator education sessions
- ◆ Establishing policies and procedures to review allegations of misconduct reported to or discovered by the institution

# Key Elements: Corrective Response

## Common oversights:

- ◆ Treating incidents as unique events that don't require review or follow up
- ◆ Incomplete or ineffective follow up
- ◆ Allowing for special circumstances for top investigators

## Best practices:

- ◆ Conduct a review of administration, procedures and tools related to identified incidents
- ◆ Periodically test revised procedures and controls to gain confidence in compliance
- ◆ Monitor the types of problems as well as number of problems

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# Compliance Risk Assessments

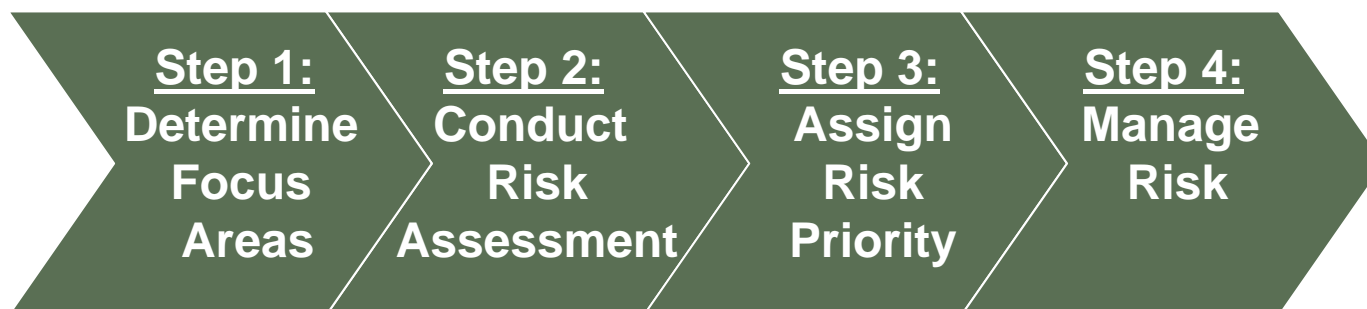
# Compliance Risk Assessments

## Additional Element for Effective Compliance Programs

- ◆ **Report of the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines (dated October 7, 2003) recommended an additional element for effective compliance programs.**
  - **“The organization shall conduct ongoing risk assessment.”**
- ◆ **Utilize risk assessment to determine relationship to broader features of effective programs**
- ◆ **Results of assessment should influence the design and implementation of compliance program**

# Compliance Risk Assessment – One Approach

The following outlines an approach to conducting a compliance risk assessment:



# Compliance Risk Assessment – One Approach

## Step 1: Determine Focus Areas



- ◆ **Determine the universe of compliance risks**
- ◆ **Discuss compliance risks with university management**
- ◆ **Prioritize compliance risks to be addressed**
- ◆ **Possible areas to include in review include:**
  - Direct charging practices
  - Cost transfers
  - Effort reporting
  - Cost sharing
  - Period of performance
  - Prior approvals
  - Unallowable costs
  - F&A cost rate issues
  - Recharge centers
  - Human subjects (IRB)
  - Animals (IACUC)
  - Conflict of interest
  - Scientific misconduct
  - Clinical trials
  - Fraud
  - NIH Salary cap
  - Fringe benefit costing

# Compliance Risk Assessment – One Approach

## Step 2: Conduct Risk Assessment



- ◆ Interview key executives with responsibility for research
- ◆ Perform a high-level review of policies and procedures
- ◆ Conduct limited transaction reviews
- ◆ Interview faculty and staff involved in research
- ◆ Interview key research administrators

# Compliance Risk Assessment – One Approach

## Step 3: Assign Risk Priority



- ◆ **Conduct a preliminary assessment of the risk associated within each of the focus areas**
- ◆ **Assess risk based on likelihood and significance of adverse events**

# Compliance Risk Assessment – One Approach

## Step 4: Manage Risk



- ◆ **Recommend changes to current practices**
- ◆ **Implement changes to current practices**
- ◆ **Modify compliance program as a result of risk assessment**

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# Summary

The following characterize the changing compliance landscape:

- ◆ Research volume and complexity are increasing
- ◆ The number of research constituents is increasing
- ◆ Numerous areas exist for potential non-compliance
- ◆ The risks of non-compliance are high
- ◆ Federal guidelines are getting more rigorous

## Result

- ◆ A risk profile that is increasing and should be proactively understood and managed.

## Solution

- ◆ A compliance program that contains the key criteria discussed today and/or an assessment that can help you identify and better understand risks as well as prioritize risk management.

# Benefits of an Effective Compliance Program

- ◆ A proactive approach to creating a compliance program will allow an institution to manage its compliance risk without imposing unnecessary constraints on the institution's operations
- ◆ Strong compliance programs benefit research institutions by reducing the risk of significant non-compliance
- ◆ Compliance programs reduce the negative impact of having non-compliance discovered by regulators or funding agencies
- ◆ The accountability, clarity, and information requirements of a strong compliance program are often beneficial in terms of institutional management

# Contact Information

◆ **For additional information please contact:**

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