



Establishing a “Balanced Culture of Support” for Research

The University of Georgia’s Special Topics Workshop

October 31, 2007

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Today's Agenda

- ◆ **UGA's Current Research Opportunities & Achievements**
- ◆ **Engagement Overview**
- ◆ **Overview of Compliance Environment**
- ◆ **The Government's Current Focus**
 - **DHHS OIG Work plan**
 - **NSF Management Challenges**
 - **DHHS OIG Compliance Program Guidance**
- ◆ **Recent Settlements/Audits**
 - **Summary**
 - **Detailed Cases**
- ◆ **Elements of Effective Risk Management Programs**
- ◆ **Risk Assessments**
- ◆ **What All This Means for UGA**

UGA's Current Research Opportunities & Achievements

UGA's Current Research Opportunities & Achievements

UGA is recognized for a number of institutional achievements in Research:

- ◆ **UGA research efforts span numerous concentrations from genetics, molecular biology and physics, to agriculture and food safety, to social and public policy, humanities and fine arts.**
- ◆ **UGA ranks 29th among public universities and 43rd among private and public universities in total research expenditures based on NSF rankings.**
- ◆ **UGA ranks 89th among public and private universities in Federal R&D expenditures.**
- ◆ **Research, instruction and outreach programs span 16 colleges and schools and in FY 07 attracted \$219 million a year in external grants and contracts.**
- ◆ **Rapid growth of sponsored research funding continues – even in the face of flat or falling funding levels.**
- ◆ **Licensing and royalties generated more than \$15 million in 2006.**

UGA's Current Research Opportunities & Achievements

UGA Research enjoys widely circulated headlines and attention – a busy month...

- 10/12/2007** Children sought for study on effects of zinc on bone health
- 10/11/2007** New class of drug offers hope to treatment-resistant AIDS patients; Major license to Georgia biopharmaceutical company benefits UGA
- 10/02/2007** National Science Foundation awards University of Georgia \$865,000 grant to study organic sulfur cycling in oceans; related to greenhouse gases
- 9/25/2007** Research on teaching led by UGA education professor Peter Smagorinsky receives second national award
- 9/20/2007** New use for stem cells found in war on terrorism
- 9/19/2007** UGA Odum School of Ecology assistant professor receives grant to study West Nile Virus dynamics in New York City
- 9/17/2007** \$2.5 million National Science Foundation grant to UGA will fund research on invasive species in China and U.S., graduate training, undergrad study abroad
- 9/14/2007** Bluebird enthusiasts, scientists to gather at UGA
- 9/10/2007** Dartmouth scholar offers insights on bio-defense and research for UGA Sciences and Security Lecture Series
- 9/07/2007** UGA researchers discover how human body fights off African parasite; could lead to new methods of controlling similar parasites that cause endemic diseases
- 9/06/2007** Professor of biochemistry and molecular biology at University of Georgia named Georgia Power Professor in Biotechnology

Engagement Overview

Engagement Overview

Mission and Charge to Huron:

- ◆ **UGA recently proclaimed their desire for a “true and **balanced** culture of support” in order to promote the efficiency, effectiveness and compliance of its research administration operations. Three primary goals encapsulate this initiative:**
 - 1. Assess existing research and grant administrative and compliance processes and make recommendations to improve administrative efficiency and effectively manage compliance risk, with particular consideration to the challenges presented by interdisciplinary and other emerging research trends.**
 - 2. Assess existing roles and responsibilities for all participants involved in sponsored research and make recommendations for changes and new definitions.**
 - 3. Assess current educational mechanisms for PIs and research administration personnel, and make recommendations for measures to ensure that they receive proper instruction and have the tools necessary to meet their responsibilities.**

Engagement Overview

Huron's Tailored Approach for UGA:

- ◆ **Task 1 - Confirm the Project Objectives, Scope and Approach**
- ◆ **Task 2 - Conduct Organization Kick-Off Meeting with Committee**
- ◆ **Task 3 - Document Objectives, Scope and Timeline**
- ◆ **Task 4 - Facilitate, Support and Oversee Committee Activities**
- ◆ **Task 5 - Assist in Compilation of Final Report and Recommendations**
- ◆ **Task 6 - Present to UGA's Special Topics Workshop**

**Overview of Res.
Compliance**

Government's
Focus

Recent
Settlements

Key Elements of
Compliance

Compliance Risk
Assessments

Summary

Overview of Compliance Environment

Overview of Compliance Environment

Trends related to research compliance at universities include:

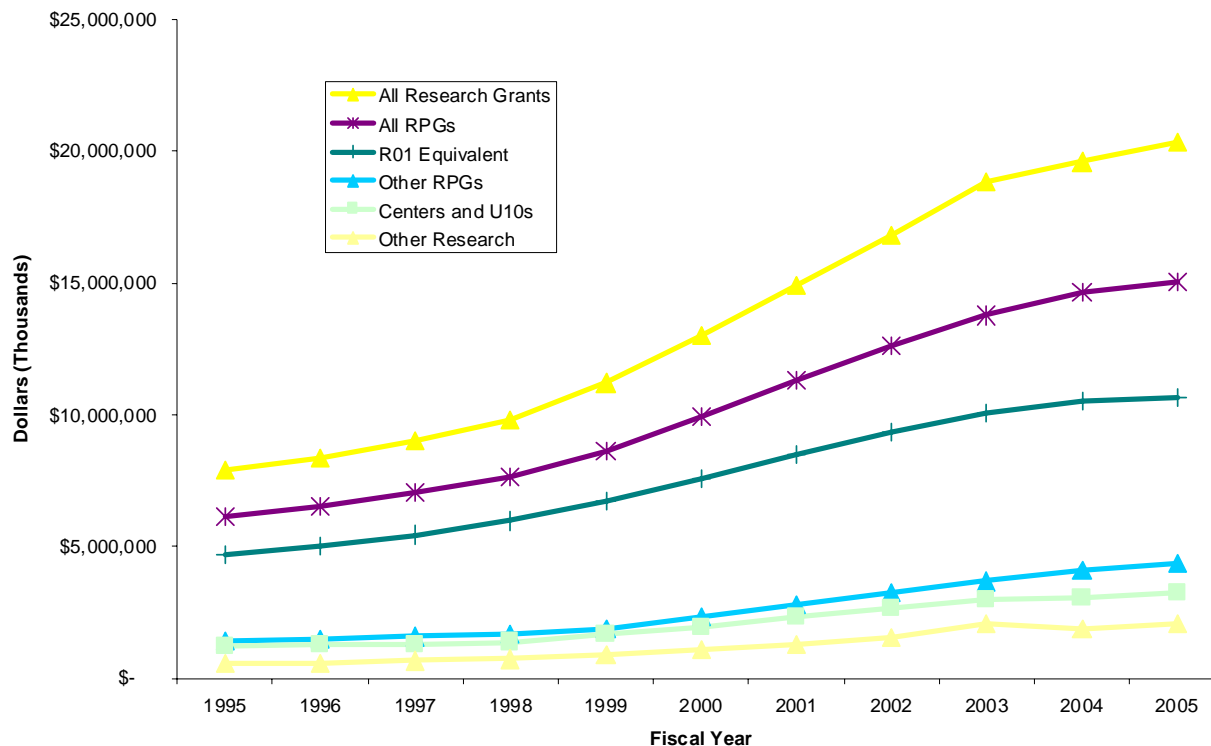
- ◆ **Rapid growth of sponsored research funding**
 - **Congress has fulfilled a commitment to significantly increase federally funded research.**
 - **The doubling of NIH funding.**
 - **With increased funding comes increased scrutiny by regulators.**
 - **Institutions experiencing rapid growth often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

Overview of 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 Compliance Environment

Trends related to research compliance at universities include:

- ◆ **Scrutiny by regulators is increasing. A recent OIG semi-annual report 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.**

Overview of 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 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 Compliance Environment

Trends related to risk management 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 2006/7 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 sub awards 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 2006/7 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 2006/7

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 2006/7

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

Historical Context for establishing compliance programs elements:

- ◆ **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.
- ◆ **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**

Key Elements of
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Recent Settlements / Audits

Recent Settlements/Audits: Summary

Institution	Headline	Source	Date
Yale University	<i>Yale's Use of Research Grants Attracts Government Scrutiny</i>	<i>Wall Street Journal</i>	July 5, 2006
Howard University	<i>Howard Mismanaged NSF Funding</i>	<i>Report on Research Compliance</i>	April 13, 2006
University of Connecticut	<i>U. of Connecticut Agrees to Settle Federal Allegations of Over billing on Research Grants</i>	<i>The Chronicle of Higher Education</i>	January 11, 2006
Rush University Medical Center	<i>Rush U. Settles Over billing Case</i>	<i>The Chronicle of Higher Education</i>	January 6, 2006
University of Texas Medical Branch, Galveston	<i>Texas Medical College Agrees to Pay \$1.7-Million for Medicare and Medicaid Over billing</i>	<i>The Chronicle of Higher Education</i>	July 12, 2005

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

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
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

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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Elements of Effective Risk Management Programs

Key Elements of Effective Risk Management Programs

The NIH Office of the Inspector General (OIG)* identified the following eight elements considered necessary when designing comprehensive risk management programs.

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 “Line of Action”
- ◆ **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 like UGA 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: 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	Dept / Div	RASP			Finance Office: (Research Accounting, Indirect Cost, Accounting Services, Payroll)	Offices or Committees
Admin	Chairman / Chief		Research Compliance Office	Grants & Contracts Office	Research Integrity Office				
RESPONSIBILITIES									
Proposal Budget									
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: 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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Conducting Risk Assessments

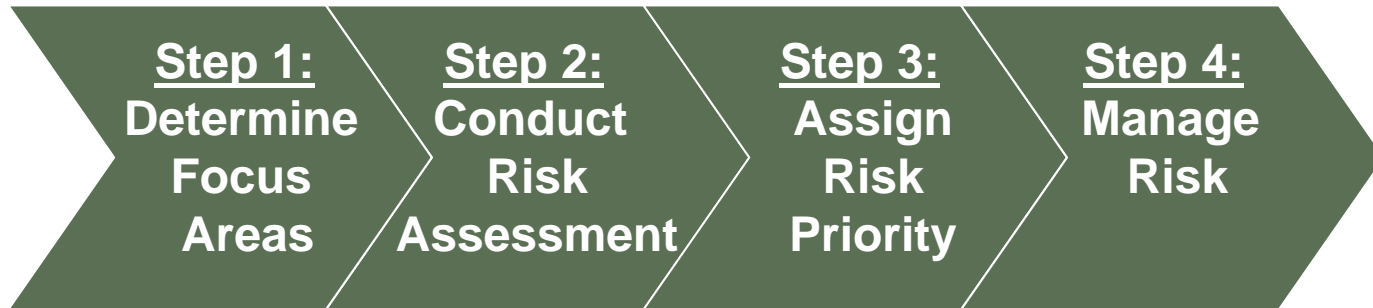
Conducting Risk Assessments

Additional Element for Effective Risk Management 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**

Risk Assessments – One Approach

The following outlines an approach to conducting a risk assessment:



Risk Assessments – 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

Risk Assessments – 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

Risk Assessments – 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**

Risk Assessments – 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**

Risk Assessment Coverage - Top Risks in Research Administration

1. Effort Reporting
2. Direct vs. Indirect Cost Charging Practices
3. Charging Costs at End of Grant Period
4. Appropriate Charging of Costs to Benefiting Grants
5. Recharge Center / Service Center Rates
6. Fixed Price Agreements
7. Financial Status Reports
8. Mandatory Cost Sharing
9. Protection of Human Subjects
10. Protection and Charging of Animal Subjects
11. Cost Transfers
12. Export Controls
13. Clinical Trial Billing
14. Subrecipient Monitoring
15. Other Support
16. Conflict of Interest

Overview of Res.
Compliance

Government's
Focus

Recent
Settlements

Key Elements

Compliance Risk
Assessments

Summary

What This All Means for UGA

What this all means for UGA

The landscape for the conduct of Research at UGA:

- ◆ Research volumes and complexity are increasing at UGA
- ◆ The number of research constituents is increasing
- ◆ As at most peers of UGA, numerous areas exist for potential non-compliance
- ◆ Potential non-compliance poses risk to faculty, staff and the reputation of UGA
- ◆ Federal and sponsor guidelines are getting more rigorous for UGA faculty
- ◆ Increasingly, UGA faculty desire flexibility, latitude, and expanded authorities – even in the face of riskier environments

Result

- ◆ A risk profile for UGA that is increasing and should be proactively understood, managed, and appropriately balanced against the important needs and endeavors of faculty.

Solution

- ◆ A risk management program that contains the key criteria discussed today, along with an assessment approach that can help you identify and better understand risks and effectively balance the needs of faculty.

What this all means for UGA

- ◆ **A proactive approach to balancing faculty needs and creating a risk management program allows UGA to manage its risk without imposing unnecessary constraints on the institution's operations or faculty**
- ◆ **A strong risk management program benefits UGA by reducing the risk of significant non-compliance; addressing only the highest risk areas and affording UGA faculty and staff maximal latitude and flexibility**
- ◆ **An effective risk management program at UGA reduces the negative impact of having non-compliance discovered by regulators or sponsor agencies**
- ◆ **The accountability, clarity, and information requirements of a strong risk management program at UGA benefit both faculty and institutional leadership**

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