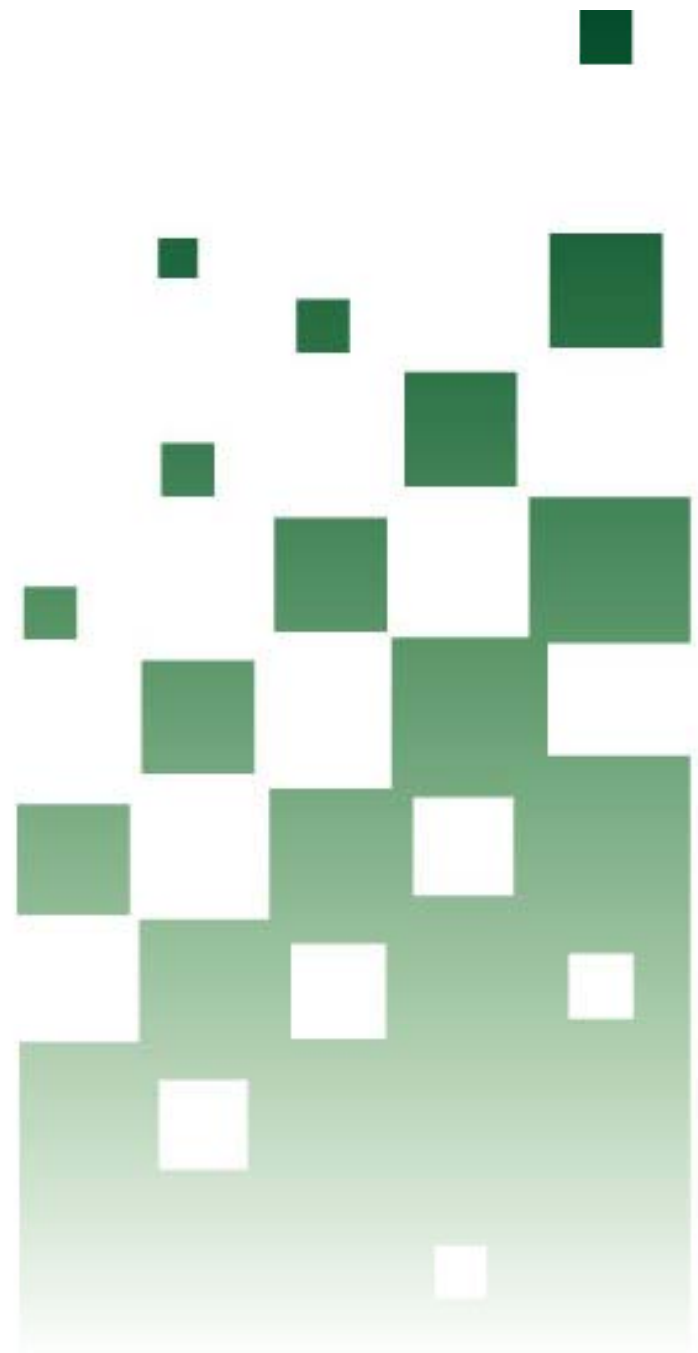


Federal Investigations of University Research: How to Avoid Trouble

Robert J. Kenney, Jr.
Federal Research Group
Hogan & Hartson LLP



What's the Problem?

- ◆ The last five years have seen an alarming increase in the number of federal fraud cases in the university research area
- ◆ Many universities are not well prepared for the scrutiny that a federal fraud investigation entails
- ◆ Old compliance strategies aren't working

Recent University Cases

- ◆ Jun 2006 – Yale -- three parallel Inspector General subpoenas -- pending
- ◆ Apr 2006 – Clark Atlanta -- \$5M
- ◆ Jan 2006 – U Conn -- \$2.5M
- ◆ Jun 2005 – Cornell -- \$4.4M
- ◆ May 2005 – Mayo Clinic -- \$6.5M
- ◆ Apr 2005 – U Ala. Birmingham -- \$3.4M
- ◆ Feb 2005 – Florida Int'l -- \$11.5M
- ◆ Oct 2004 – George Washington U. -- \$1.8M
- ◆ Jul 2004 – Harvard -- \$3.3M
- ◆ Feb 2004 – Johns Hopkins -- \$2.6M
- ◆ Feb 2003 – Northwestern -- \$5.5M

The False Claims Act – A Prosecutor’s Dream

- ◆ No need to prove intent to defraud
- ◆ No need to prove actual knowledge of falsity
- ◆ Deliberate ignorance or reckless disregard can be enough
- ◆ No need to prove Govt was misled
- ◆ No need to prove Govt was damaged
- ◆ Treble damages or up to \$11,000 per claim
- ◆ Whistleblower (*qui tam*) cases
 - 15% to 30% share of recovery

Federal Enforcement Trends

- ◆ Most cases start with a whistleblower
- ◆ Some voluntary disclosures
- ◆ No indication of concerted federal program targeting universities
- ◆ But prosecutors are much more willing to pursue research cases
- ◆ So far dollars have been relatively small compared to Medicare billing settlements – that could change
- ◆ The costs of responding to an investigation can be very high

How Should Universities Respond?

- ◆ Everybody talks about the increase in university fraud cases, but what can we actually learn from them?
 - The Govt's "hot button" issues
 - Why compliance problems happen
 - How to minimize future problems

The “Hot Button” Issues

- ◆ Effort reporting and commitments
- ◆ Cost transfers
- ◆ Salary supplementation
- ◆ Direct charging of administrative costs
- ◆ Recharge centers
- ◆ Overlap with Medicare billings
- ◆ ...among others

Making Compliance Happen

- ◆ The old-fashioned concept of compliance
- ◆ A smarter concept : compliance is a management problem, not a legal problem or a “specialist” problem

The Old Fashioned Concept of Compliance

Employees do bad things because...

- ◆ They are “bad apples”
- ◆ They think they won’t get caught
- ◆ They don’t understand the rules
- ◆ They don’t understand the consequences of breaking the rules
- ◆ They’re out for themselves, not the institution

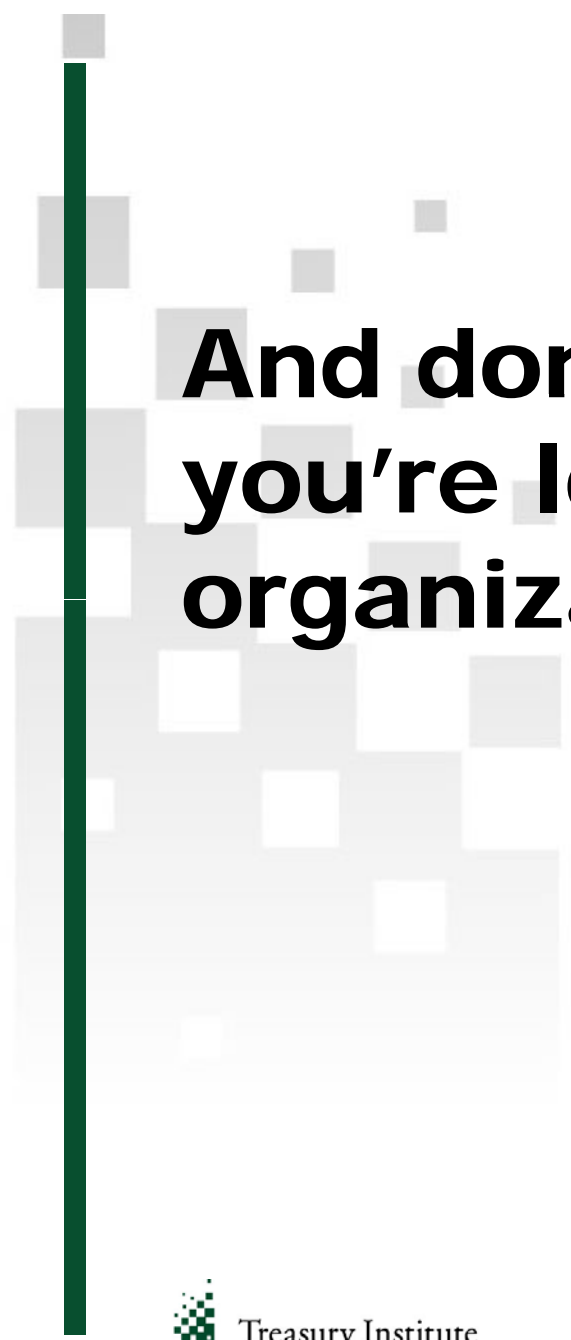
A Management Approach to Compliance

- ◆ “Compliance” = removing organizational obstacles to good behavior
- ◆ The ability to remove such obstacles does not necessarily reside with the subject matter experts or the lawyers
- ◆ The keys to success are the same as with any other complex management undertaking
 - Commitment of top management -- \$\$ and otherwise
 - Knowledge of how the organization works, and how to fix things when they’re broken
 - Strong project management
 - Measurement of results
 - Follow-up

Think Smart About Why Things Go Wrong

“Organizational obstacles” can take many forms, including

- Skewed compensation incentives
- Lack of funds to support non-sponsored activity
- Institutional dysfunctions
- Poor communication
- Poor financial reports
- Ineffective reporting relationships
- Cultural factors
- Remote leadership



And don't forget to ask, when
you're looking for
organizational obstacles....

...whether you are part of the solution or part of the problem.



Establishing Effective Research Compliance Practices

Andrew B. Rudczynski, Ph.D.
Associate Vice President for
Research Administration
Yale University



Agenda

- ◆ University Commitment
- ◆ Policy Inventory
- ◆ Policy Review
- ◆ Effective Practices
- ◆ Financial Control Tools
 - Quality Assurance
 - System audits vs. transaction audits

University Commitment

- ◆ Support from the top
 - Not just an administrative exercise but an overt commitment
- ◆ Communicate to faculty and staff institutional commitment and expectations

Policy Inventory

- ◆ Which policies exist and which ones are missing
 - Utilize materials from NCUBO, NCURA, and COGR
 - Learn from colleagues and audits
- ◆ OIG work plans
 - Cross-walk institutional policies against OMB Circulars A-110, A-21

Policy Review

- ◆ Systematic and documented periodic review
 - Knowledgeable compliance personnel
 - Prevent “silos” of information
 - Financial Policies
 - Involve Sponsored Projects Office staff (pre & post, costing analysts, etc)
 - Sponsored Projects Policies, Procedure and Guides
 - Involve Financial Staff (Controller, AP, Purchasing, etc)
 - Departmental Business Offices
 - Uncovers divergent practices
 - Academic Leadership
 - Affect faculty and postdoctoral appointments and expectations
 - Inform faculty and get input
 - Maintain Historical Policy Compendium for audit purposes
 - Faculty and Sponsored Projects Handbooks

Policy Review

- ◆ Be wary of what's in policies versus procedures
 - E.g. specific timelines where no specific standard exists
 - Strive to keep general statements of policy separate from procedural documents
- ◆ If have a formalized policy review/approval process, think about how complex it is
 - Do all reviewers/approvers have an equal voice?
 - Not all policies may have “choices”
- ◆ Be aware of financial linkages with “non-financial” compliance areas such as purchase of animals, analysis of human subjects data
 - Awards not properly linked to congruent protocols

Effective Practices

- ◆ Define Roles and Responsibilities
 - Important area of concern for NIH
 - Faculty, business offices
- ◆ Training & Education
 - Required vs. voluntary
 - Web based vs. Instructor-led
 - Use quizzes for assessment
 - “Brown Bag” sessions
 - Newsletter directed at Policies and Practices
 - Part of an effective communication plan
 - Separate out from operational news
- ◆ Establish an authoritative “court of appeals”
 - Prevent “shopping” for answers
 - Include Internal Audit, Pre-award, Post-Award, Research Compliance Officer
 - Publish cases

Financial Control Tools

- ◆ Central review of cost transfers greater than threshold
 - Establish review thresholds for types of expenditures or risky timing (e.g. <90 days from budget end, >90 days from posting to G/L, dollar value, etc.)
- ◆ Departmental/Central report card
 - Timely award set-up
 - Timely effort reporting
 - Timely FSR submission

Important Foundations

- ◆ Customer Service
 - Require pre- and post award staff to be experts in their domains
 - Responsiveness
- ◆ Systems and Processes
 - Assess and provide quality of information available to PI and business manager
 - Assess and refine “convoluted” or “non-value added” processes
- ◆ Education and Training
 - Have community (practitioners) teach community