



Enhanced Institutional Research Compliance: Partnering of Legal Counsel and the Research Office

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Learning Objectives

- Recognizing legal components of research compliance responsibilities
- Strengthen research compliance programs by partnering with Legal Counsel
- Distinguishing legal vs. operational aspects of research compliance mandates



Framework for Research Compliance—The “Why”

- United States Sentencing Guidelines
- DHHS OIG Model Compliance Program Guidance
 - Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards (2005)
- OIG Work plans & Audit Reports
- False Claims Act (State & Federal)




U.S. Sentencing Guidelines

§8B2.1 Effective Compliance and Ethics Program**


- Implementing written policies & procedures
- Compliance officer & compliance committee
- Effective training and education
- Effective lines of communication (hotline suggested)
- Enforcing standards
- Responding promptly to detected problems
- Defining roles & responsibilities and assigning oversight
- Conducting risk assessment

** January 2010 proposed amendments adopted April 7, 2010; effective November 1, 2010



Draft OIG Compliance Guidance for Recipients of PHS Research Awards

- Published in Federal Register Nov 28, 2005
- Risk areas identified:
 - Time & effort reporting
 - Properly allocating charges to award projects
 - Reporting of financial support from other projects



2010 DHHS OIG Work Plan

- University compliance with A-21 Cost Principles
- University indirect costs claimed as direct costs
- Classifications of federal pass-through funding
- Institutional financial interests of NIH grantees
- Violations of select agent requirements
- Medicare/Medicaid health information privacy
 - Security of portable devices

Federal False Claims Act

- Establishes liability for filing false claims with the government
- Amended in May 2009 to expand liability
 - Parties indirectly receiving govt funds
 - Knowingly retaining an overpayment
 - No intent to defraud is required
- Patient Protection & Affordable Care Act
 - Amends FCA & may expand number of qui tam complaints & number that survive motion to dismiss under the Public Disclosure Bar

University Research False Claims Act Settlements

- Yale \$7.6M Dec 2008
 - Improper cost transfers
 - Time & effort reporting
- Mayo Foundation \$6.5M Jun 2005
 - Improper cost transfers
- Florida International \$11.5M Feb 2005
 - Mischarged costs
 - Overbilled DOE grants & contracts

NSF Grantee Responsibilities

NSF Grantee Responsibilities Section 1:

"c. By acceptance of this award, the grantee agrees to comply with the applicable Federal requirements for grants and cooperative agreements and to the prudent management of all expenditures and actions affecting the award. Documentation for each expenditure or action affecting this award must reflect appropriate organizational reviews or approvals that should be made in advance of the action."

PHS Grantee Certification

PHS Form 398:
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE:

"I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties."

Recognizing Legal Components of Research Compliance Responsibilities

○ How do you look at the following issues from a legal standpoint?

- Sponsored Contracts
- Export Control
- Conflict of Interest
- Research Misconduct
- A21 Compliance
- Privacy and Information Security
- Responsible Conduct in Research Education

Contracting Issues

- Contracts for research/services in foreign countries
- Liability for foreign travel
- Indemnification when institution is self-insured
- Potential false claims
- Logistical delays and other drawbacks to seeking legal guidance
- Willingness of institution to assume risk when they understand the implications vs. when it is clear they do not understand potential consequences
- Protecting information
- Products liability insurance
- Tax-exempt bond issues

Strengthening Research Compliance Programs by Partnering with Legal Counsel

- How do university sponsored programs and compliance offices work with legal counsel?

Distinguishing Legal vs. Operational Aspects of Research Compliance Mandates

- Who is the decision maker?
- Who is seen as impeding research?
- When does the university approach legal counsel under attorney client privilege?
- How does one engage legal counsel before its too late?
- How do you work with senior leadership when you recognize the level of risk is much greater than their perception? . . . is much lower . . . ?
- How much risk is your university willing to accept?

References and Resources

False Claims Act Investigations Involving Federal Research:
Learning from the Misfortunes of Others, Robert J Kenney Jr, Esq.

http://www.hhlaw.com/files/Publication/ed7d740c-cd26-4000-892e-46d5e38d52d6/Presentation/PublicationAttachment/25c498dd-8973-48b2-a22f-5451a6c2c750/FedResearchUpdate_5_21_09.pdf

FY 2010 Office of the Inspector General Work/Audit Plans

http://oig.hhs.gov/publications/_workplan/2010/Work_Plan_FY_2010.pdf
<http://www.nsf.gov/oig/FY2010AuditPlan.pdf>

NSF General Grant Conditions

<http://www.nsf.gov/pubs/gc1/jan09.pdf>

Draft OIG Compliance Program Guidance for Recipients of PHS
Research Awards

<http://oig.hhs.gov/iraud/docs/complianceguidance/PHS%20Research%20Awards%20Draft%20CPG.pdf>
