

Auditing & Monitoring Your Research Program

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Auditing and Monitoring

Objectives:

- Discuss the need and importance of auditing and monitoring in the research arena.
- Identify those areas that should be audited and monitored.
- Provide practical and usable strategies and tools for auditing and monitoring IRBs, research operations and clinical trial billing.

Auditing and Monitoring

WHY:

Regulatory

- OIG
 - Hospital Guidance (1998)
 - Supplemental Guidance (2005)
 - PHS Research Guidance (2005)
- U.S. Sentencing Guidelines
- FDA
- OHRP
- ORI
- CMS
- HIPAA
- DOJ
- Organizational/Board Support



Compliance Environment

Overview of Research Compliance Environment

Trends related to research compliance include:

- In addition to flat funding and increasing demand for research, scrutiny by regulators is increasing. OIG's semi-annual report (4/01/07 through 9/30/07) 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 tripled, to 447 in FY2004. Additionally, there were 262 civil actions.
- Increased number of false claims/whistleblower (*qui tam*) suits
 - 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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Overview of Research Compliance Environment

Institution	Headline	Source	Date
UCSF, U of Connecticut Health Center, U of Arizona, NYU and others	<i>OHRP Issues Six Determination Letters (Human Subjects Protections)</i>	<i>Report on Research Compliance</i>	Jan. 10, 2008
Brandeis University	<i>OIG Finds \$31,000 in Misclassified Costs at Brandeis</i>	<i>Report on Research Compliance</i>	Oct. 18, 2007
University of Massachusetts Medical School	<i>OIG Recommends University of Massachusetts Repay NIH for Subawardee Overcharges</i>	<i>Report on Research Compliance</i>	Nov. 2, 2006
University of Pennsylvania	<i>NSF Audit of Penn Finds Systemic Weaknesses in Effort Reporting</i>	<i>Report on Research Compliance</i>	Jul. 27, 2006
Yale University	<i>Yale's Use of Research Grants Attracts Government Scrutiny</i>	Wall Street Journal	Jul. 5, 2006
University of Connecticut	<i>U. of Connecticut to Settle Federal Allegations of Overbilling on Research Grants</i>	The Chronicle of Higher Education	Jan. 11, 2006
Rush University Medical Center	<i>Rush Pays \$1 Million After Admitting Overbilling Medicare for Patients in Research</i>	The Chronicle of Higher Education	Jan. 6, 2006
The Mayo Clinic	<i>Mayo Pays \$6.5M to Settle Fraud Dispute</i>	Minneapolis Star Tribune	May 27, 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>	The Chronicle of Higher Education	Apr. 15, 2005

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FDA GCP Compliance: Case 1

Research non-compliance can turn to outright fraud:

- Two doctors defrauded the institution of approximately \$10 million:
 - Ineligible subjects were enrolled
 - Medical decisions (e.g., drug dose adjustments) were made by staff without proper medical training
 - PI oversight was questionable
 - Falsified documentation
- Employees of the physicians raised concerns
- Found guilty of conspiracy to commit an offense against the United States and making false statements in matter within jurisdiction of the FDA (18 USC 1001)
- Doctors received:
 - 15 year prison terms plus probation
 - Paid restitution of \$5 million (combined)
- Institution established an office to oversee compliance with clinical research

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Overview of Research Compliance Environment

In addition to civil and criminal penalties, consequences: can include:

- Negative publicity for institution and individuals involved
- Significant difficulty negotiating F&A rates
- Increased administration costs
- Exceptional Status
 - Risk of decrease in award funding
 - Greatly reduced flexibility in the management of federally provided resources due to loss of Expanded Authority provisions. This allows NIH more oversight of its funds than would be feasible under the administrative procedures normally associated with its grant programs. Expanded Authority provisions that are lost may include:
 - Extension of project period without prior approval
 - Carryover of unobligated balances
 - Waiver of certain cost-related prior approvals
 - Pre-award costs
 - Special terms and conditions for awards
 - Requirement for a Corrective Action Plan

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Auditing and Monitoring

Visuals:



Auditing and Monitoring

Developing the auditing and monitoring plan:

Definitions –

- Risk Assessment
The identification, measurement and prioritization of likely relevant events or risks that may have a material consequence on an organization's ability to achieve its objectives.
- Auditing
Formalized, independent and objective review of a process, program or system.
- Monitoring
Day-to-day review of the process, program or review.

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Auditing and Monitoring

Developing the auditing and monitoring plan:

- Conduct a risk assessment.
- Prioritize the risk.
- Identify the needed resources.
- Determine the costs.
- Get buy in from Compliance Committee, Administration and The Board.

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Auditing and Monitoring

Conducting the Audit:

- Define, Review Scope & Assumptions
- Develop Review criteria
- Conduct review
- Document Findings and Observations
- Obtain management Response
- Remediate
- Finalize Report & Corrective Action Plan

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Monitoring:

- Review conducted by the business unit.
 - Self reviews
 - Peer reviews
 - Formal vs. informal
 - Use audit results

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Auditing and Monitoring

Risk Areas:

- Clinical Trial Billing
- Effort Reporting
- Cost Transfers
- Protection of Human Subjects
- IRB Operations
- Medicare Double Billing
- Data Security
- Scientific Misconduct
- Conflict of Interest
- Animal Research
- Informed Consent process



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Review Auditing Tools:



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Auditing Research Administration & Compliance

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