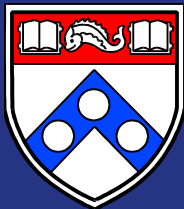


Managing Research Compliance Risks

James Moran, J.D., CPA
Executive Director of Compliance,
University of Pennsylvania
School of Medicine



Rick Rohrbach, MBA, CPA
Senior Manager,
Healthcare Consulting Practice
PricewaterhouseCoopers



Meeting Objectives

- Understand the risks and compliance implementation challenges involved with five high-profile research compliance areas.
- Learn how to prioritize your own research risk areas for compliance plan development and implementation.
- Share practical strategies for overcoming the challenges.

Agenda

- Research compliance areas
 - Overview of issue
 - Implementation challenges
- Risk assessment and prioritization techniques
 - Frameworks
- Questions

Five High-Profile Risk Areas in Research Compliance

- Clinical trials billing compliance
- Human subject protections
- Conflicts of interest
- FDA Good Clinical Practices (GCPs)
- Health Insurance Portability and Accountability Act (HIPAA)

Clinical Trials Billing Compliance

Overview

- CMS (formerly HCFA) National Coverage Decision; September 2000
- Requirements:
 - Tests to determine if individual trials qualify for coverage
 - Registration of "covered" trials in a National Medicare clinical trials database
 - An implicit requirement to clearly document the segregation of charges

- Double dip
 - Billing of insurers for costs that belong on clinical trials, or billing both for the same tests

Related Financial Compliance Issues

- Use of residual funding
 - Could be viewed as kickback
- Finders' fees or other incentives
 - OHRP is particularly concerned that excessive research compensation may motivate a PI to "cram" subjects into research studies

Clinical Trials Billing Compliance

Risk Management Considerations

- Clinical trials billing is a complex issue
 - Three fundamental “truths” that make implementation of the CMS policy difficult:
 1. Segregating charges between “trial-induced” and “standard therapy” is not always an easy process
 2. Process touches many different people in many different departments
 3. Billing systems are not designed to handle the complexities of research

Clinical Trials Billing Compliance

Risk Management Considerations

- “It’s not a problem”
 - Investigators and departments with the greatest volumes of trials believe they have control over billing compliance; however, nearly all admit that patients have called to complain about being billed for trial-related charges
- Resistance to Change
 - Many involved in the process are comfortable with their departments’ approach and are resistant to changes to their current practices
- Lack of ownership, authority, accountability
 - As clinical trials have become increasingly complex, institutions have not kept pace and have not clearly defined the roles and responsibilities of individuals involved with clinical research billing
- The billing process tends to be viewed in isolation and not as part of a larger continuum or business cycle

Human Subject Protections Regulations

Overview

- Different regulations and regulatory authorities for research
 - Research supported by 17 federal agencies “Common Rule”
 - Drugs, devices, and biological products regulated by FDA
 - HIPAA Privacy Regulations
- Several shutdowns of prominent research programs due to systematic compliance concerns
- Several recent research-related deaths of healthy volunteers
- Increased media attention and Congressional inquiry
- Several research-related lawsuits
- Recent attempts at voluntary accreditation of human research participant programs
- Professionalization of IRB personnel

Human Subject Protections Regulations

Risk Management Considerations

- Ensuring regulatory compliance
 - Policies and procedures
 - Actual review procedures
- Monitoring
 - IRB effectiveness
 - Continuing review
 - Investigator compliance
 - Good Clinical Practices
- Education
 - IRB
 - Investigators
 - Study coordinators
 - Institutional officials with oversight responsibility
- Accreditation
- Human subject protection operations
 - Information technology
 - Resources
 - Staff
 - IRB workload burden
 - Adequate institutional placement of IRB
 - Achieving proper institutional culture for the protection of human subjects

Human Subject Protections Regulations

Risk Management Considerations

- Adverse event reporting
 - Different regulatory requirements for drugs and devices
 - No trend analyses unless Data Safety Monitoring Board exists
- Research in emergency situations
 - Legally authorized representatives (determined by State law)
 - Planned emergency research
- Conflicts of interest among IRB members who are also researchers
- Focus on compliance versus ethical implications of research
- Potential Public Relations Risk

Conflicts of Interest

Overview

- Different regulations, with different requirements and reporting thresholds:
 - Food & Drug Administration
 - Public Health Service
- Currently no one government agency with oversight authority for ensuring compliance with conflict of interest regulations
- Individual versus Institutional conflicts of interest
- Several recent controversies that negatively effected public trust in the research enterprise
- Several recent reports and guidance documents from government agencies and professional associations
 - AAU Report
 - AAMC Report on Individual COI
 - AAMC Report on Institutional COI

Conflicts of Interest

Risk Management Considerations

- Should the policy cover other individuals involved in research decisions, oversight, and the institution's financial holdings?
 - Answer depends on types of research the institution conducts or sponsors
- What threshold for reporting should be used?
 - Many institutions choose to adopt a single disclosure threshold (PHS is lower than FDA)?
- Conflict of interest official or an entire committee? Factors to consider:
 - Institution size / resources
 - Review / investigation workload
 - Diversity of input
 - Involvement from major constituencies at the institution
- Should policy scope be expanded to cover all research, regardless of funding source?

Conflicts of Interest

Risk Management Considerations

- When does an interest create a conflict and how should conflicts be managed?
 - Perceived or actual conflict (reputational risk=on the front page of the newspaper)
- What standard should be used to make this judgment?
 - “Rebuttable presumption / “compelling circumstances”
 - “Zero tolerance” policy (all interests are reported, only those that conflict are managed)
- What types of management plans will be utilized?
- Who should be notified regarding conflicts of interest? Some controversial options:
 - Journal editors
 - Public presentations
 - Research subjects
 - The public

Conflicts of Interest

Risk Management Considerations

- Infrastructure / Operational challenges:
 - Information technology to automate review / updating
 - Policies on-line?
 - Educational programs
 - Staff, space, and resources
 - Compliance oversight: How to monitor?
 - Establish “firewall” between offices responsible for financial and research decisions?

Good Clinical Practices

Overview

- Consequences of investigator or IRB noncompliance:
 - Subjects possibly harmed or injured
 - FDA audits (the dreaded “483”) and responses to same
 - Harm to one’s own or one’s institution’s reputation
 - Rejection of data, suspension of studies, disqualification of investigator, disqualification of the IRB (loss of future research dollars)
 - Introduction of bias or conflicts of interest into the research

Good Clinical Practices

Risk Management Considerations

- Ensuring investigator compliance with:
 - GCP responsibilities
 - IRB requirements
 - Protocol requirements
 - Informed consent requirements
 - Documentation requirements
 - Safety reporting requirements
 - Disclosure of financial interests
- Ensuring IRB compliance
- Monitoring:
 - Investigators and their research to ensure compliance
 - IRB to ensure compliance
 - Interacting with study monitors and FDA inspectors from the Bioresearch Monitoring (BiMo) Program
- Many of the same challenges in human subject protections are shared with GCP requirements

HIPAA

Overview

- Non-compliance penalties:
 - \$100 per violation (max \$25K per requirement per year)
 - Penalties could reach millions of dollars per year
- Other costs and impacts:
 - Customer satisfaction and confidence
 - Reputation
 - Tort claims and costs
- Wrongful disclosure of health information penalties:
 - Simple disclosure=fines up to \$50K and/or 1 year in prison
 - Disclosure under false pretense=fines up to \$100K and/or 5 years in prison
 - Disclosure with intent to sell or use=fines up to \$250K and/or 10 years in prison
- Institutional changes in research practices will be required

HIPAA

Risk Management Considerations

- Regulations are complex, burdensome, and costly
 - Increase paperwork and IRB responsibilities (est. costs \$30M in 2003, up to \$29M by 2013).
 - Regulations apply to all research, whereas current human subject regulations only apply to federally supported or FDA regulated research
- Regulations are ambiguous at best
 - Many in research industry fear liability from enforcement (potential suspension of research programs)
- Subject recruitment in research might be hampered because authorization or waiver is required for disclosure to third parties

HIPAA

Risk Management Considerations

- Individuals are given new rights to access, inspect, and copy all protected health information about them in a designated record set under certain conditions
- Deadlines for compliance:
 - Privacy: April 2003
- Uses and Disclosures of Protected Health Information in Research
 - Generally, a “covered entity may not use or disclose PHI, except as permitted or required by” the regulation.
 - There are **FOUR** ways to use PHI in Research:
 - (1) Use De-Identified Data
 - (2) Use Limited Data Set
 - (3) IRB Waiver of Authorization
 - (4) Authorization

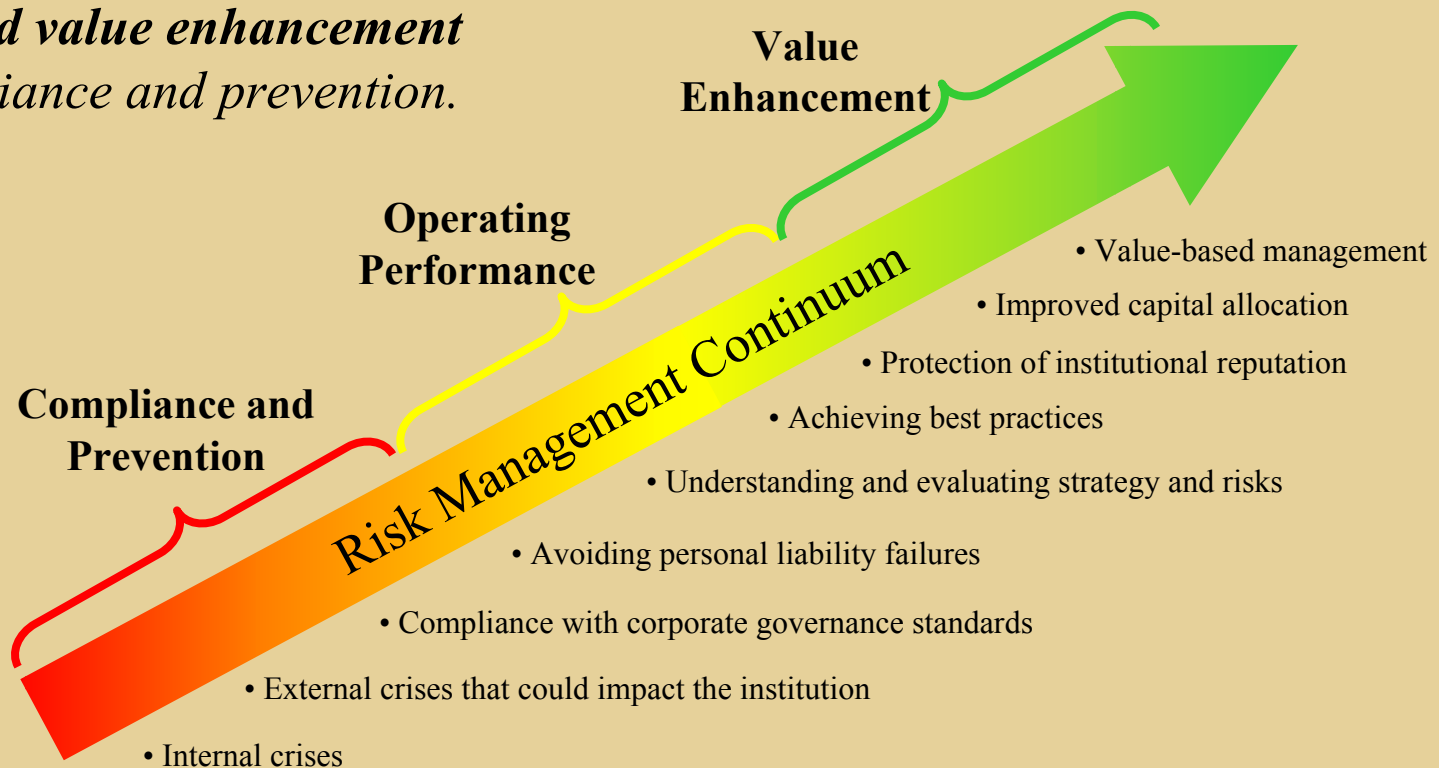
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Strategic Risk Assessment

What is the goal?

*Institutional risk management needs are increasingly related to **operating performance and value enhancement** as well as compliance and prevention.*



Strategic Risk Assessment

Where to look

The strategic risk assessment is a process which results in identifying areas that need immediate attention to reduce risk to the institution.

- Known soft spots not being addressed
- The government's current enforcement agenda
- Whistleblower suits
- Transactions with Potential for False Claims
- Large dollar volume processes
- Adverse public relations
- What has changed?

Strategic Risk Assessment

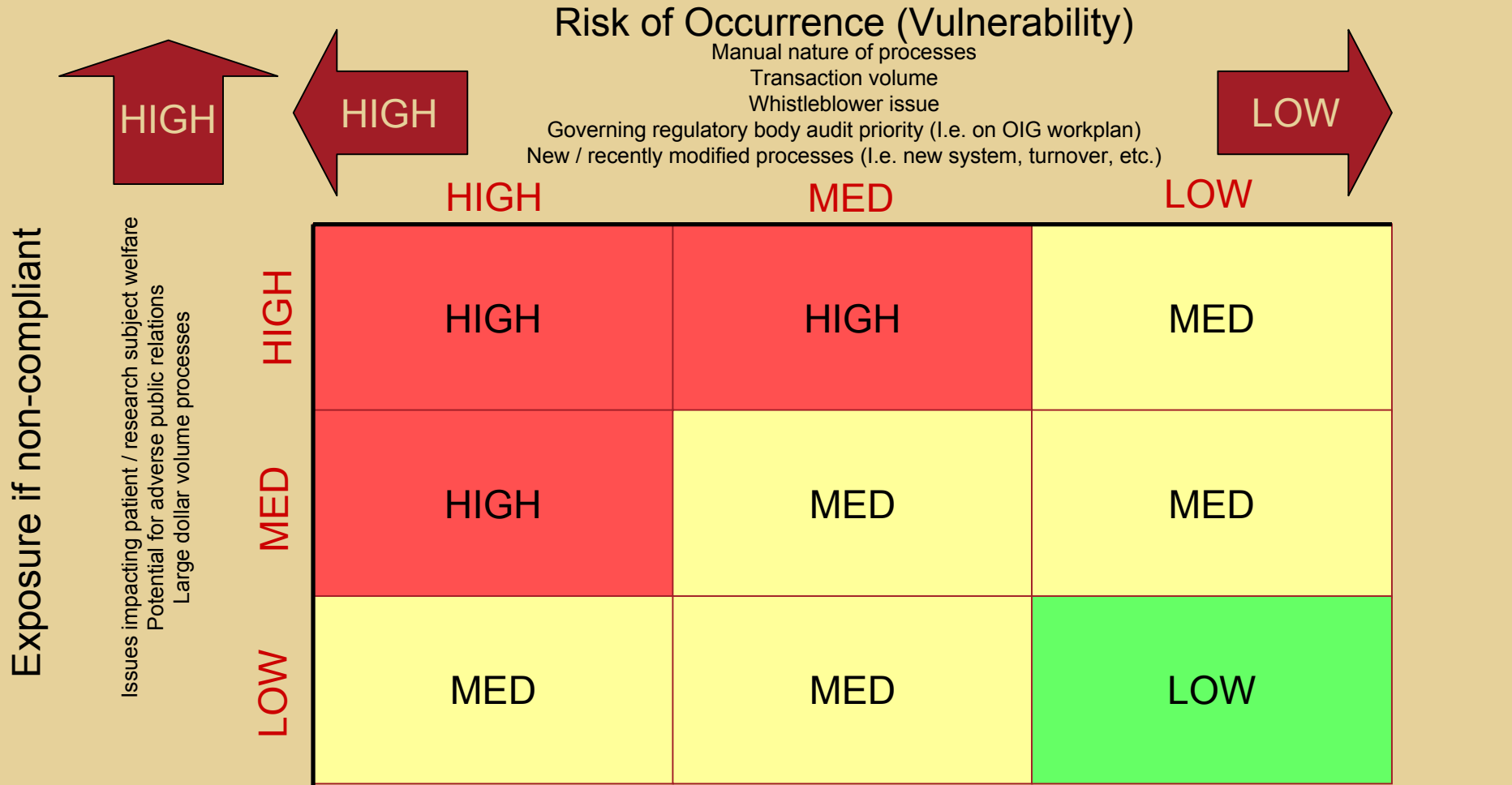
What to do

Five-step Process

- Compilation of a list of likely areas of difficulty
- Survey of documented institutional issues
- Discussion with key officials
- Development of draft priority list
- Review and Approval of priority

Strategic Risk Assessment

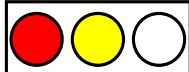
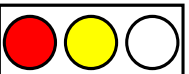
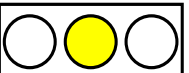
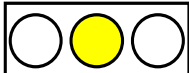
Assigning Priority to the Risk Areas



Strategic Risk Assessment

Putting it all together...

Reporting Frameworks

Clinical Trials Business Cycle Stage	Risk Summary														
Budget Development and Approval 	<ul style="list-style-type: none"> Budget process is highly distributed and variable – many do not consider all costs. Most departments interviewed are not segregating research charges from standard of care charges during the budgeting process. 	Summary of Clinical Trials Business Cycle Practices According to Priority / Rank													
Registration of Research Subjects 		<ul style="list-style-type: none"> Research subjects are not always properly identified. Information needed to segregate research charges is not always communicated during registration. 	<table border="1"> <thead> <tr> <th data-bbox="794 708 1470 793">Administrative Activity</th> <th data-bbox="1470 708 1711 793">Priority</th> <th data-bbox="1711 708 1761 793">Overall Ranking</th> </tr> </thead> <tbody> <tr> <td data-bbox="794 793 1470 851">Registration of Research Subjects</td> <td data-bbox="1470 793 1711 851">High</td> <td data-bbox="1711 793 1761 851">1</td> </tr> <tr> <td data-bbox="794 851 1470 908">Budget Development and Approval</td> <td data-bbox="1470 851 1711 908">High</td> <td data-bbox="1711 851 1761 908">2</td> </tr> </tbody> </table>	Administrative Activity	Priority	Overall Ranking	Registration of Research Subjects	High	1	Budget Development and Approval	High	2			
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Registration of Research Subjects		High	1												
Budget Development and Approval	High	2													
Charge Capture / Billing for Research-related Services 	<ul style="list-style-type: none"> The process for ordering research services is not always clear. No system-generated report to patient/subject. The hospital billing system does not always act as a research charge modifier. 	<table border="1"> <tbody> <tr> <td data-bbox="794 908 1470 965">Contracting Development and Negotiation</td> <td data-bbox="1470 908 1711 965">High</td> <td data-bbox="1711 908 1761 965">3</td> </tr> <tr> <td data-bbox="794 965 1470 1022">Charge Capture / Billing for Research Services</td> <td data-bbox="1470 965 1711 1022">High</td> <td data-bbox="1711 965 1761 1022">4</td> </tr> <tr> <td data-bbox="794 1022 1470 1079">Process for Resolving Billing Inquiries / Complaints</td> <td data-bbox="1470 1022 1711 1079">Medium</td> <td data-bbox="1711 1022 1761 1079">5</td> </tr> <tr> <td data-bbox="794 1079 1470 1136">Research Account Close-Out / Treatment and Distribution of Residual Funds</td> <td data-bbox="1470 1079 1711 1136">Medium</td> <td data-bbox="1711 1079 1761 1136">6</td> </tr> </tbody> </table>	Contracting Development and Negotiation	High	3	Charge Capture / Billing for Research Services	High	4	Process for Resolving Billing Inquiries / Complaints	Medium	5	Research Account Close-Out / Treatment and Distribution of Residual Funds	Medium	6	
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Process for Resolving Billing Inquiries 	<ul style="list-style-type: none"> Institution does not have a policy for resolving billing inquiries. 	<table border="1"> <tbody> <tr> <td data-bbox="794 1143 1470 1200">Management of Receivables from Clinical Trial Sponsors</td> <td data-bbox="1470 1143 1711 1200">Medium</td> <td data-bbox="1711 1143 1761 1200">7</td> </tr> <tr> <td data-bbox="794 1200 1470 1258">Trial Evaluation and Authorization</td> <td data-bbox="1470 1200 1711 1258">Medium</td> <td data-bbox="1711 1200 1761 1258">8</td> </tr> <tr> <td data-bbox="794 1258 1470 1315">Research Account Establishment</td> <td data-bbox="1470 1258 1711 1315">Low</td> <td data-bbox="1711 1258 1761 1315">9</td> </tr> </tbody> </table>	Management of Receivables from Clinical Trial Sponsors	Medium	7	Trial Evaluation and Authorization	Medium	8	Research Account Establishment	Low	9				
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Questions?

James Moran, JD, CPA

Executive Director

Research Integrity & Compliance

University of Pennsylvania

36th & Hamilton Walk

403 Anat/Chem Bldg.

Philadelphia, PA 19104

(215) 573-8800

(215) 573-0280 (Fax)

jmoran@mail.med.upenn.edu

Rick Rohrbach, CPA, MBA

Senior Manager

Healthcare Consulting

Life Sciences Practice

PricewaterhouseCoopers LLP

2001 Market Street, Suite 1700

Two Commerce Square

Philadelphia, PA 19103

(267) 330-2470

(267) 330-4128 (Fax)

rick.rohrbach@us.pwcglobal.com