Implementing a Research Auditing Program

HCCA Compliance Institute
National Harbor, MD

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Pre-Conference Morning Breakout Session

Presentation Objectives

- Review the necessity of an effective Research Audit Program given the risks implicit within health care organizations that nurture research.
- Describe the importance of an effective Risk Assessment process.
- Summarize approaches for operationalizing an appropriate Research Monitoring Plan.
- Detail the fundamentals of how to develop a customized, issue-oriented Research Audit Approach.
- Introduce alternatives for how to address certain Error Rates and Error Thresholds.
- Provide sample audit plans for common risk areas
Complicated Settings, Complicated Risks

Overview of the Pressures and Risks
Institutions That Support Research Bear a Considerable Burden

| Number of IT Systems that Process PHI | ↑  |
| Complexity of Caregiver Relationships / Contracts | ↑  |
| Complexity of Research Participant Billing Responsibilities (i.e., pro-fee, hospital, etc.) | ↑  |
| Competition for Research Funds | ↑  |
| Scrutiny from Federal Regulators | ↑  |
| Demand for Accountability | ↑  |
| Large Investments in Facilities & IT | ↑  |
| Pressure to maintain / reduce admin costs | ↑  |
| Staff Dedicated to Assurance-based Functions | ↓  |

During a time where many of these growth factors are occurring simultaneously, many organizations are failing to make associated and proportionate investments in the research compliance infrastructure necessary to keep risks in check.
### Multiple Factors Influence Organizational Risks
#### Understanding the Research-related Challenges is Imperative

- Faculty start-ups
- Conflicts of Interest
- Equity interests of institution
- International collaboration
- Sub-recipient monitoring
- Human subjects protections
- Researcher misconduct
- HIPAA / Privacy
- Researcher misconduct
- Effort, salary allocation, unique employment terms / appointments, consulting arrangements and other complexities associated with salary and compensation
- OMB Circular A-21
- Cost Accounting standards
- Technology transfer / patent protections
- Clinical trials billing
- Stem cells and/or other scientific controversy
- Compliance with grants.gov and clinicaltrials.gov
- Sunshine Rule

### Multiple Factors Influence Organizational Risks
#### Understanding the Research-related Challenges is Imperative

- Often, there are competing or misaligned interests which may exacerbate an institution’s risk profile and the compelling need for a robust Research Auditing Program.
  - Principal investigators (“PIs”)
  - Research support (research assistants, coordinators, research nurses, lab technicians, etc.)
  - Students
  - Board members
  - Tax payers
  - Federal agencies
  - Commercial sponsors
  - Suppliers and procurement specialists
  - Foundations
  - Donors and investors
  - Human subjects
  - Advocacy groups
  - Institutional, Departmental, and Divisional administrators
  - Physician practices
  - Agents
Importance of the Audit Role to a Research Compliance Officer

Evolution of Research ~ Evolution of Auditing

Shifting Compliance Environment Necessitates Change

• Increasing coordination among federal and state law enforcement officials
• More sharing of health fraud information with insurers.
• Greater degree of Congressional oversight.
• More litigation.
  – Qui Tam actions
  – Class Action
  – More resources, tools, investigative techniques, etc.
• Heightened financial pressure.
• OIG priorities
• Regulatory requirements...HIPAA, Sunshine Rule.

Among the Seven Elements, the presence of an effective monitoring and auditing program remains vital. An institution nurturing a research program must take reasonable steps to safeguard compliance. Proactive auditing and monitoring efforts can help.
Evolution of Research ~ Evolution of Auditing  
Shifting Compliance Environment Necessitates Change

- Once merely a line item in a broader Compliance Auditing/Monitoring Work Plan, research is an activity that can no longer be dealt with reactively or with only periodic auditing focus.

- A good plan includes these essential characteristics:
  - Internal controls in place as defined in regulatory requirements
  - Annual audit plan reflects outcome orientation
  - Audit methodology appropriate for type of area being reviewed
  - Audit outcomes reported to appropriate level of management
  - Audit frequency appropriate for level of risk to organization
  - Proactive vs. reactive audits
  - Audit strategy – protection of work papers and findings
  - Corrective Action verified
  - Re-audit to assure no re-occurrence of non-compliance
  - Audit of new processes, i.e.: new requirements, computer conversions, etc.

Evolution of Research ~ Evolution of Auditing  
New Role and New Expectations

- Research Audit plans must balance the needs of diverse stakeholders with the responsibility of measuring structural and systemic risk within the Research Program.
  - Prior mindset
    - Auditors issue reports and monitor progress against corrective actions
    - Limited role in implementing recommendations, design improvement plans or contributing to more prospective matters.
    - Standardization in approach, rigid methodologies, template-driven reports.
    - “Close the gap” rather than “value-added” corrective actions.
    - “Check the box” and “tick and tie” mindset.
    - Preserve independence.
  - New mindset
    - Partner with management to identify, define, measure, and create value for the Research Program.
    - Consultative and collaborative.
    - Collaborate with Research Program leaders.
    - Demonstrate an ability to offer valued input to strategic research initiatives as they are being developed rather than as after-the-fact auditors.
Evolution of Research ~ Evolution of Auditing
New Role and New Expectations

- Effective development and execution of a Research Audit Plan hinges on proactive engagement with Senior Management.

- Participation in the discussion of risk, risk tolerance, development of strategic and operational objectives, and showing a more dynamic and active side of their department can add tremendous value.

- Research growth plans can be facilitated by faster data and information flow, thoughtful analysis, and flexible strategies in order to effectively perform and compete.
  - Audit and compliance teams that are involved only “after the fact” or that are positioned to respond to heightened, potential, or actual research risks are passé.
  - Ambitious organizations need research compliance auditors who function in a consultative, professional services-oriented fashion.
  - Real time auditing is imperative.
  - Working with research leaders and providing proactive, analytical input as opportunities are evaluated or regulatory concerns surface is ideal.

Value Creation
Reactions to an Audit

- Enthusiasm
- Cynicism
- Obligation
- Doubt
- Exhaustion
Value Creation
Improving Research Risk Assessment

**Priorities**
- Enhance risk identification processes.
- Develop adaptive audit schedules that properly align with the significant risk factors.
- Maintain clear understanding of your institution's strategic and operating priorities.
- Working with management, develop familiarity of which research business processes are most important for creating value (i.e., effective budgeting, coverage analysis, contract negotiation, study identification, vetting, etc).
- Focus on protecting against value erosion.
- Participation and engagement with research administrative/clinical/medical/ and other leaders is crucial. PEOPLE SUPPORT WHAT THEY HELP CREATE.

Value Creation
Shifting Roles Aid Risk Assessment Process

**Audit**
- Evolve such that its output is not punitive in nature.
- Approach must lead to enhanced processes and prescriptive, achievable corrective actions.
- Flexible, adaptive, and prompts change quickly.
- Meet the demands of the day.
- Shift away from conducting routine audits based upon research risk profiles from previous years.
- Engagement and collaboration with management.
- Called upon to assist with opportunity analysis rather than respond, look back, and assess failures "after the fact."

**Compliance**
- Proactive, thoughtful, and focused on education.
- Creating a culture where doing the right thing is easier than doing the wrong thing.
- Anticipate risk, regulatory pressures, and compliance challenges.
- Able to provide analytical feedback on metrics, performance, and data.
Risk Assessment

Definition

- The process of evaluating a potential hazard, likelihood of suffering, or any adverse effects
Risk Assessment

Key Considerations to Start the Process

- Ensure that there is an evaluation of how individual risks interrelate.
  - Are sufficient resources already dedicated to mitigating identified risks?
  - Are insufficient resources managing high risk areas? In other words, are there one or two people with specialized knowledge? Is there a “hit by the bus” problem / risk?

Answers to these questions may influence risk prioritization.

- Categorization
  - Reputational
  - Financial
  - Operational

- Compliance / Regulatory – Market
- Strategic – Credit
- Legal – Administrative

- Factors that influence risk aversion / acceptance
  - Economy
  - Brand equity
  - Competition

- Recent investigations, CIAs, CCAs, etc.
- Enforcement environment
- Strategic position
- Personality of Board and Senior Leaders

Risk Assessment

Reputational Risks

- Evaluate the implications of a specific risk area being left unchecked only to manifest itself in a way that impacts brand, affects image, suggests ineptitude, or lack of institutional controls.
  - No organization wants to become the “poster child” for wrongdoing.
    - Northwestern ($5.5MM), Hopkins ($2.6MM) & Harvard ($2.4MM) – effort
    - Penn – informed consent & COI
    - Mayo Clinic ($6.5 MM) & Yale ($7.6MM) – cost transfers, effort, cost sharing
    - Rush ($1MM) – clinical trial billing
    - Vermont – research misconduct
    - U. of Oklahoma – informed consent
  - These cases, and many others, have brought considerable unwanted attention to research institutions.
Risk Assessment
Key Considerations to Start the Process

Regulatory Consequences

• Confirm familiarity with the regulatory landscape.

• Ensure that those building your research audit plan are reading, participating on listservs, attending professional conferences and ensuring awareness of what is coming.

• To the extent that there are recent changes, put them on your audit plan to determine organizational readiness.

• Without, there are implications including the following:
  – Corporate Integrity Agreements and Certification of Compliance Agreements
  – Loss of letter of credit funding authorization
  – Suspension, debarment, and exclusion of individuals (or even entire programs or institutions) engaged in research
  – Additional monitoring

Risk Assessment
Key Considerations to Start the Process

Operational Changes

• Document and track new/recent systems implementations (i.e., EMR, etc.), recent policy changes, new procedural requirements, or other directives of key operational leaders.

• In the absence of effective controls, the impact on operations is often significant. It can result in many of the following outcomes:
  – Additional training
  – New policies and SOPs
  – New work flow
  – Re-organization of personnel
  – Additional approvals and review periods from superiors
  – Heightened credentialing expectations
Financial Repercussions

- Consider risk areas to determine whether the implications of non-action or skipping an audit in a certain area could lead to considerable, undesirable costs, or unplanned expenses.

- Ineffective planning or overlooking certain areas that carry with them a certain financial risk can lead to the following:
  - Fines and penalties
  - Cost to enhance operations
  - Litigation and legal defense costs – considerable liability risk
  - Funding loss
  - Financial impact of reputational consequences cited on prior slide

Risk Assessment
Key Considerations to Start the Process

- Risk reduction and avoidance of these undesirable outcomes is a priority for Compliance Officers and those who build Audit Plans...regardless of the area.

- There are no shortage of reasons why a Compliance Officer may view their responsibilities as particularly challenged when they work in an organization with research programs.
  - Multiple stakeholders
  - Major funding
  - Opportunity for abuse
  - Physician and/or Principal Investigators’ objectives not always aligned with institutional objectives

- These challenges are often exacerbated by the prevailing mindset of a PI and the pressures they are under to bring in funding.

Given the issues, Compliance Officers have unique points of view on how to fulfill their responsibilities and ensure that risks are reduced for the “research enterprises” that they support.
Risk Assessment
Driving the Prioritization and Focus of Audit Resources

• The starting place for any research audit plan is in identifying and scoring organizational risks.

• Proactive consideration of the external environment is crucial.
  – OIG work plan, recent litigation, what has happened to peers, enforcement agenda, actions of 3rd party payors; and
  – Health care legislation from state and federal entities (e.g., HIPAA, Sunshine, etc.)

• Compiling a comprehensive list of internal operational challenges, issues, risks, and strategic plans is vital to developing a complete risk profile.
  – New opportunities and investments may imply unexpected or unanticipated risks.
  – Some risk areas are issues every year. This justifies continuous monitoring.

It is imperative that organizations that wants to nurture compliant growth in their research programs, at a minimum, should engage operational areas in the following ways:
1. Continuous, direct, in-person meetings with management to talk through risk areas.
2. Proactive, consultative engagement.
3. Consideration of a framework that enables prioritization of compiled risks.
4. Ability to differential risks from opportunities.

Risk Assessment
Alternative Methodologies

• Audit Universe:
  – Gather feedback of senior leaders.
  – Score risks and set priorities based experience, judgment, and other input.

• Risk-based auditing:
  – Develop a risk-profile for entire business.
  – Identify and prioritize all related risks.
  – Deconstruct business processes and determine root cause and potential sources of risk that, if left unchecked, could trigger higher levels of risk.

• Qualitative Risk Assessment:
  – Task or threat analysis….study each task in an operation and identify potential hazards, accidents, etc. that could occur by human error, equipment failure, natural phenomenon.
  – Considers consequences on a continuum of severity.

• Quantitative Risk Assessment:
  – Measures and anticipates risk numerically based on a data set.
  – More objective measure of risk.
  – Magnitude and probability must be considered.
Risk Assessment
Additional Thoughts

• No research compliance officer can be expert in all of the complex and complicated business functions that pervade the research enterprise.

• Those who “live” the day to day are best suited to identify and score the risks that impact their areas.

• Regardless of which methodology that is selected, it is critical that the process is characterized by:
  – Consistent, in-person and ongoing collaboration with operational stakeholders throughout the research program (i.e., PIs, IRB members, research accountants, etc.).
  – Participation in consultative discussions as new strategic plans are hashed out or as business processes are redesigned.
  – Carefully thought out discussions that will help operational leaders sift through all levels, categories, and types of risks inherent to their area or purview.

The evolution of your Compliance Function to manage a Research Audit Plan will rely necessarily on more integration and engagement with those who carry out essential operations.

Establishing a Research Auditing & Monitoring Plan
A Compliance’s department budget, like many, may be limited or even under resourced in terms of staff, technology and training...particularly in a specialty area like research.

- Efficiency and timeliness is more important than ever.
- Value is created when you are able to conduct more audits and investigations across a spectrum of issues without increasing costs.
- This implies knowing your issues, having a plan, and carrying out smaller and more targeted audit investigations.
- Unless an specific function or business unit requires a thorough analysis of data in order to evaluate risk, audits should be kept small.
- Don’t over burden staff with planned audits and compromise ability to engage in investigations and other for-cause audits.

Step 1: Assemble Identified Research Risks, Score, and Prioritize

- Knowledge of what risks an institution faces is a pivotal first step and effective Risk Assessment will help achieve this.
- Scoring these risks and initiating the process of prioritization depends, necessarily, on an appreciation for the macro and micro environmental factors that a research program faces:
  - Macro: regulatory, political, economic
  - Micro: Strategic priorities, risk appetite, competition, growth plans, leadership changes

A properly designed plan should mirror the issues facing the Research Program. This further underscores the need for representatives from the Compliance function (including Research Compliance specialists) to be deeply engaged with research program and other research operational leadership to understand priorities and plans.
Plan Development
Essential Steps to Track, Monitor, and Audit Identified Risk Areas

**Step 1: Assemble Identified Research Risks, Score, and Prioritize**

- **Event Identification:**
  - *Identify the meaning of each risk event*, how it can be tested, and what the impact may be on the institution.
    - Internal and external events affecting achievement of an entity’s objectives must be distinguished between risks and opportunities.
  - *Categorize each risk event* by using a methodology applied to all events.
    - Risk and exposure.
    - Impact to institution.
    - Likelihood of detection.
    - Frequency of occurrence.
    - Or other key metrics.
  - Using the approved categories, *prioritize each risk event* before the events are placed into a risk assessment audit plan.
  - *Create a risk event matrix.*

- **Research Events / Risks**
  - Effort reporting
  - Research accounting
  - Physician disclosure
  - Conflict of Interest
  - Hospital billing and coding
  - Research medical records
  - Laboratory practices
  - Physician contracting
  - Stark anti-kickback compliance
  - GCP
  - Gaps in policies and procedures
  - Budget development
  - Managed care contracts
  - Institutional Review Board
  - Residual funds
  - Medicare cost report
  - Financial reporting
  - Pharmacy
  - Investigator Initiated trials
  - Research administration
  - Patient care/quality
  - Registration & patient accounts
  - Healthcare quality and outcomes
  - HIPAA
  - Patient safety
  - Clinical trials billing
  - Fair market values
  - Consenting process

* For the sake of consistency, the term “risk events” also means opportunities for enhancement going forward.
Plan Development
Essential Steps to Track, Monitor, and Audit Identified Risk Areas

**Step 1: Assemble Identified Research Risks, Score, and Prioritize**

- **Risk Assessment:**
  - Use the prioritized risk events to *populate a risk event profile*. Lists each risk event, and categorize them to create the basis for an assessment/audit schedule.
  - Determine priority for assessing/auditing risk events and identify what risk events must be reviewed and which may not require reviewing at the current time.
  - Determine frequency of assessment/audits for each risk event.
  - Determine assessment/audit responsibilities for each risk event and who will conduct testing evaluations.
    - Integrate the assessment/audit function within the institution’s internal audit department, compliance department, or utilize external/independent consultants to conduct the work.
    - Generate assessment/audit modules in concert with stakeholders, internal audit, and other key leadership so that performance and risk can be evaluated.
    - Communicate the initiative to the institution and the expectations of collaboration.

*This is an example of a risk matrix and does not categorize risk/exposure of these events based on fact or opinion.*
Plan Development
Essential Steps to Track, Monitor, and Audit Identified Risk Areas

Step 1: Assemble Identified Research Risks, Score, and Prioritize

- Risk Event Profile is used to prioritize, categorize, and track the progress of evaluating the portfolio of risk events for non-compliance and exposure.

### Institutional Risk Event Profile

<table>
<thead>
<tr>
<th>Risk Event</th>
<th>Risk Group</th>
<th>Risk Priority</th>
<th>Test Frequency</th>
<th>Last Test Date</th>
<th>Testing Responsibility</th>
<th>Test Results Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effort Reporting</td>
<td>Operations</td>
<td>1 Semi Annually</td>
<td>12/8/2012</td>
<td>Internal Audit</td>
<td>Pass</td>
<td>Remediate</td>
</tr>
<tr>
<td>Electronic Letter of Credit Draw</td>
<td>Operations</td>
<td>3 Every Other Year</td>
<td>11/23/2012</td>
<td>Internal Audit</td>
<td>Pass</td>
<td>Manage</td>
</tr>
<tr>
<td>Research Accounting</td>
<td>Operations</td>
<td>1 Semi Annually</td>
<td>12/10/2012</td>
<td>Internal Audit</td>
<td>Pass</td>
<td>Manage</td>
</tr>
<tr>
<td>Research Medical Records</td>
<td>Compliance</td>
<td>3 Every Other Year</td>
<td>10/23/2011</td>
<td>Compliance Dpt</td>
<td>Pass</td>
<td>Remediate</td>
</tr>
<tr>
<td>Indirect Cost</td>
<td>Operations</td>
<td>2 Annual</td>
<td>12/8/2012</td>
<td>Internal Audit</td>
<td>Pass</td>
<td>Manage</td>
</tr>
<tr>
<td>Cost Transfers</td>
<td>Operations</td>
<td>1 Semi Annually</td>
<td>12/12/2012</td>
<td>Internal Audit</td>
<td>Pass</td>
<td>Remediate</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Compliance</td>
<td>2 Annual</td>
<td>5/14/2012</td>
<td>Compliance Dpt</td>
<td>Pass</td>
<td>Remediate</td>
</tr>
<tr>
<td>Patient Safety</td>
<td>Compliance</td>
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<td>10/20/2012</td>
<td>Compliance Dpt</td>
<td>Pass</td>
<td>Remediate</td>
</tr>
<tr>
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<td>Compliance</td>
<td>2 Annual</td>
<td>5/15/2012</td>
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<td>Pass</td>
<td>Remediate</td>
</tr>
<tr>
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<td>Pass</td>
<td>Manage</td>
</tr>
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<td>Billing Clinical Trials</td>
<td>Operations</td>
<td>1 Semi Annually</td>
<td>9/7/2012</td>
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<td>Remediate</td>
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<tr>
<td>Subrecipient Monitoring</td>
<td>Operations</td>
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<td>7/18/2012</td>
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<td>Pass</td>
<td>Remediate</td>
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<tr>
<td>Gaps in Policies or Procedures</td>
<td>Compliance</td>
<td>3 Every Other Year</td>
<td>3/20/2011</td>
<td>Compliance Dpt</td>
<td>Pass</td>
<td>Remediate</td>
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<tr>
<td>Budget Development</td>
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<tr>
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<td>4/10/2012</td>
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<td>Manage</td>
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<tr>
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<td>Compliance</td>
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<td>5/11/2012</td>
<td>Compliance Dpt</td>
<td>Pass</td>
<td>Remediate</td>
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<td>Compliance</td>
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<td>7/3/2012</td>
<td>Compliance Dpt</td>
<td>Pass</td>
<td>Remediate</td>
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<td>Animal Care and Use</td>
<td>Compliance</td>
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<td>3/1/2011</td>
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<td>Remediate</td>
</tr>
<tr>
<td>Good Clinical Practices</td>
<td>Compliance</td>
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<td>6/3/2011</td>
<td>Compliance Dpt</td>
<td>Pass</td>
<td>Remediate</td>
</tr>
<tr>
<td>Research Marketing Materials</td>
<td>Strategy</td>
<td>3 Every Other Year</td>
<td>7/21/2011</td>
<td>Compliance Dpt</td>
<td>Pass</td>
<td>Remediate</td>
</tr>
</tbody>
</table>

Plan Development
Essential Steps to Track, Monitor, and Audit Identified Risk Areas

Step 2: Determine What Should & Can Be Monitored Rather Than Audited

- Certain research risk areas by their data intensive and quantitative nature should be studied by reviewing a consistently produced set of reports (i.e., effort reports, informed consent, AEs, SAEs, timeliness of CRF submissions, enrollment/accrual figures, financial status reports, etc.).

- Tracking performance measures and crafting reports that can survey trends that could be indicative of new risks or higher risks are crucial.
  - Establishing thresholds levels for underperformance and/or minimum necessary performance metrics can help calibrate situations that may justify investigations, audits, or further operational reviews.
  - Identify values within those metrics that could be classified as “normal” and ranges of values that may be indicia for additional reviews, investigations, or full blown audits.
  - Places emphasis on the quality, content, and analysis of reports.
  - Establishing the expected ranges (and values) that gathered data should fall into is useless to organizations that take an analytical approach to monitoring key performance metrics.
Plan Development
Essential Steps to Track, Monitor, and Audit Identified Risk Areas

**Step 3: Consider Audit Resources and Who is On Point**

- Recognize that universal knowledge and skills in all research risk areas rarely exist within the typical Compliance function.
- Leveraging the appropriate institutional resources to lead audits is necessary.
  - Practice plan personnel
  - Patient Financial Services
  - Safety & Security
  - Risk Management
  - Quality
  - External Consultants
  - Lawyers & legal professionals

**Step 4: Determine What Kind of an Audit is Necessary and Appropriate**

- Depending upon the issue, objective, the risk, and the anticipated outcome, there are various Auditing methodologies that should be considered.
- An organization’s audit philosophy should be carefully considered for certain categories of risk and for certain kinds of data analysis.
- When various components of an organization that has multiple business functions engaged in things like billing and claims audits, a common philosophy about how to audit is crucial.
- The mindset can be variable depending upon which compliance function is engaged.
  - Hospital / Medical Center compliance
  - System-level compliance and/or integrity professionals
  - Practice plan compliance professionals
  - Internal audit
  - HIM
Plan Development
Essential Steps to Track, Monitor, and Audit Identified Risk Areas

**Step 5: Build the Plan**

- Based on decisions made about risk prioritization, monitoring vs. auditing, resource allocation, and audit methodology… **DRAFT THE PLAN.**

- The responsible professionals associated with research compliance should present the draft to the Compliance Committee for review.

- Upon review, edit and approval, present the draft plan to the Board-level Compliance Committee.

- Also, the Audit Committee should be engaged and looking at risks as they are identified, vetted, and considered throughout the process.
  - For each issue/risk presented, they should ask, “So what?”
  - If responses to this simple query are insufficient or there is no discernable impact that an identified risk has on core business issues and priorities, do not audit that area.

Crafting and finalizing the plan should be iterative, collaborative, and inclusive of impacted operational stakeholders, Board members, and Senior Management.

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Audit Execution
The Audit Process

“The process of audit should be relevant, objective, quantified, repeatable, and able to effect appropriate change.”

Auditing Approach

Introduction

- The implications for using one approach or another may trigger legal risks and other regulatory risk.
  - Baseline audits
    - Establish the error rate and performance levels in the “as is” state (i.e., without the benefit of any education).
    - Leverage probe sampling:
      - Target a specific issue.
      - Vary in size depending upon the size of the population.
      - Limit adherence to a standard norm or range (i.e., 30-50) for what defines a probe sample amount.
  - Prospective or concurrent auditing
    - As it happens. Real time
    - E.g., Prior to finalizing a business process such as billing.
  - Retrospective auditing
    - Looking back at a set of data from a defined time period that occurs in the past.
    - Could be a probe sample or statistically valid sample.
    - Be careful
Auditing Approach
Use Your Audit to Identify and Mitigate Risk NOT Create More Risk

Auditing and monitoring in real time or in a concurrent fashion – rather than evaluating significantly aged data – is preferred. This allows for corrective actions to occur prior to small issues becoming major legal risks.

1. Start with a Baseline Audit.
   - Prospective set of data gathered in real time before sent outside (i.e., to a federal payor) where it could be deemed as fraudulent.
   - Sample size small, non-statistically valid and random.

2. Review Results and Consider Remediation Steps.
   - Train auditees. Offer education in various forums. Ensure that education is timely, relevant, and specific. Consider use of other practitioners to conduct some of the training (i.e., train the trainer or physician to physicians training).

3. Re-Audit.
   - Consider focus on only those areas or those practitioners with higher error rates.
   - Larger sample, still non-statistically valid, and random.

4. Review Results.
   - Evaluate root cause, target specific practitioners or business/clinical functions that are still out of compliance
   - Train. Use combination of classroom training, shadowing, and other one-on-one educational options.

5. Re-Audit and/or Turn to Concurrent Monitoring for Consistent Underperformance in Certain Areas.
   - Larger sample, retrospective and prospective.
   - Still probe sample and non-statistically valid.
   - Avoid use of sample sizes that could be extrapolated.

   NOTE: As an alternative to conducting this third, more prescriptive and targeted audit, may choose at this point to perform concurrent monitoring at the practitioners expense.

As this Audit Approach implies, providing education as a precursor to successive audits is crucial. However, when issues persist in spite of training efforts, more serious findings and consequences may be appropriate.
Auditing Approach
Use Your Audit to Identify and Mitigate Risk NOT Create More Risk

Report Writing

- Ensure that language used is not inflammatory or trite. Remove phrases and other linguistic tactics that are colloquialisms. Stick with fact-based statements.

- Reports should remain open to edits by auditees and other responsible executives (or managers) prior to finalizing reports.

- Ensure that careful consideration is given to audits and other situations that may contribute to findings that could create more (or legal) risks.
  - Engagement of the Counsel may be appropriate. Use of Attorney-Client Privilege is often a good idea in these circumstances.

- Where unable to draw fact-based conclusions, consider use of words and phrases such as “may,” “could,” “might,” or “often.”
  - Decisive language is helpful but avoid absolutes such as “every,” “all,” and “always.”

- Avoid conclusionary, particularly legal conclusionary, words in reports.
  - It can be damaging to use terms such as “fraud,” “illegal,” “criminal,” or other terms that an audit officer is not trained/educated/informed enough to state as a truth.
Auditing Approach
Error Rates

- A common characteristic within top performing Compliance functions is to have an established policy, procedure and action plan for how error rates identified through an audit will be dealt with.

- Acceptable error rates must be defined pre-audit.

- Depending upon a certain error rate, there are numerous potential outcomes.
  - Re-audits....When? How frequent? What audit approach is reasonable for future and re-audit efforts based on certain thresholds of errors?
  - Training….Classroom? Shadowing? Sent to a conference or off-site training?
  - Discipline.
  - Some combination.

- Error rates and the threshold levels that may give rise to these consequences must be developed by the Compliance function.
  - This should be done in collaboration with a Compliance/Audit Committee, legal, and operational business units that are the subjects of audits.

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Auditing Approach
Error Rates

- The implications for higher than acceptable error rates can be severe.

- This underscores the importance of working with legal (as necessary) to establish the auditing approach/methodology.

- Organizations that deal in millions of dollars of clinical claims – some of which may be being sent to federal payors – must audit and monitor claims data.
  - It is critical that the audits of this data are measured in at least three ways
    - Acceptable
    - Problematic
    - Unacceptable error rates.
  - Establishing thresholds and the consequences and actions steps associated with each will help streamline audit and response procedures.
Auditing Approach
Error Rates

• The OIG’s Voluntary Disclosure Protocol states that they will not accept a probe sample under 30 claims.
  – The OIG’s CIA Guidance for Compliance Programs suggests a probe sample of 30-50 claims depending on the size of the universe of claims during the sample period.
  – A probe sample size should be determined by a statistician to ensure relevant extrapolation criteria.

• The OIG’s typical Corporate Integrity Agreement threshold for error rate is 5% and in no event greater than 10%.
  – In most cases (but not in all cases) where the error rate exceeds 10%, the OIG often requires that organizations should be prepared to expand the audit to conduct a statistically valid, retrospective, follow up audit at some date in the future.

• Each of these audits and the error rates analyzed should be considered on a case by case basis.

Guidance on appropriate threshold levels are laden in federal regulations and accessible through CMS, DHHS-OIG and associated compliance guidance, work plans, and policy statements

– OIG Voluntary Disclosure Protocol
– Sample OIG Corporate Integrity Agreements
– Sample OIG Corporate Compliance Agreements
Sample Audit: Clinical Research Billing

- This is an area that overlaps multiple segments of the business and is complex to monitor. But, because of this, it is a popular process to audit.
  - Clinical research billing is an ideal example of how an institution could benefit from an ERM type of approach. The COSO ERM framework is a comprehensive model to monitor research compliance as cross functional, flexible and not static.

Clinical Research Billing (if left unchecked) can adversely impact nearly every function and operation in a hospital. Effective Clinical Research Billing requires understanding of the unique regulatory requirements it demands as well as an understanding of how it impacts the normal operation of the business it is built upon.
Reporting Frameworks of the Clinical Trials Billing Cycle

<table>
<thead>
<tr>
<th>Process</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budget Development and Approval</td>
<td>Process is highly distributed and variable</td>
</tr>
<tr>
<td>Registration of Research Subjects</td>
<td>No segregation and no tracking mechanism</td>
</tr>
<tr>
<td>Charge capture/billing for research related services</td>
<td>No system for tracking or reporting</td>
</tr>
<tr>
<td>Process for Resolving Billing Inquiries</td>
<td>Complaints and whistleblowers</td>
</tr>
</tbody>
</table>

Sample Audit
Clinical Research Participant Billing - Questions

- In assessing one’s own process for managing clinical trials billing, there are numerous questions to be asked PRIOR to testing/auditing.
  - Operations
  - Financial Management
  - Compliance Management
  - Personnel

Operations:
- Segregation of charges
  - Are billable charges being separated from charges that should be debited against a study/grant account?
  - Who is determining what is billable to 3rd party payors? PIs? Coordinators?
  - Is this determination objective or subjective?
  - Is there a documented plan that is accessible by those performing charge capture so that they have reference material at this pivotal point in the billing continuum?
## Sample Audit
Clinical Research Participant Billing - Questions

### Operations:
- **Registration**
  - Are study subjects identifiable in registration (or scheduling) systems?
  - Is there an easy way for check-in personnel to validate a patient’s status as a research participant?
  - Are all points of entry for your facility equipped to deal with research patient scenarios?
- **Charge Capture**
  - Do clinicians not associated with the study (i.e., other than the PI, a research nurse, or coordinator) have a simple to understand approach to noting a patient as a research participant?
  - Do lab techs and other non-research personnel have training in how to route research charges or how to identify and route routine test/procedure charges?
- **Billing**
  - Is there a way to “scrub” charges before bills are dropped or prevent over- or inaccurate billing?
  - Is there a “bill hold” or some other manual, back-end bill review process?
  - What is the time line expectation for reviewing bills on hold and passing them along for final billing by a patient financial services staff member?

### Financial Management:
- **Budgeting**
  - Is sponsor funding sufficient to cover costs of research? Of start up? Of performing a coverage analysis? Other fees?
  - Who drafts the budget? Where do they get access to charge master rates?
  - Is there a research rate schedule?
  - Is a coverage analysis being performed in consideration of Medicare standards, the NCD, or LCDs?
  - What other medical literature is used to independently determine conventional care?
  - Do sponsor contracts/agreements clearly state which patient care costs are covered?
- **Accounts Receivable**
  - Are sponsors being billed and payments being collected (and credited to study accounts) in a timely manner?
  - When sponsors make payments, where do the checks go? Who is accountable?
- **Professional Fees**
  - Are these being included in study budgets?
  - Being billed at all? Debited against the study budget?
Sample Audit
Clinical Research Participant Billing - Questions

Compliance Management:
– Investigations and Monitoring
  • Does compliance look at residual balances?
     Could be viewed as kickback or may indicate that non-billable patient care events are not being debited against study accounts
     PIs sometimes use surplus in a study to fund something else disconnected to the study
     PIs may use surpluses to fund coordinators on a different study
     What becomes of funds above a certain threshold?
     Is a policy in place that defines how surpluses (and deficits) are reconciled?
     If a deficit, is the PIs department accountable in any way for making up the difference?
  • Does compliance take a sample of studies and a sample of research participants on these studies and trace some bills through the process continuum to identify where (if any) control weaknesses may exist?
– Finders fees and other incentives
  • Are there conflicts of interest that are incentivizing shady billing practices or leading to cases of non-disclosure of other fees?
– Training
  • Is there a research compliance curriculum for PIs? Coordinators? Billing personnel? Those who develop coverage analyses?

Sample Audit
Clinical Research Participant Billing - Questions

Personnel:
– Roles and Responsibilities
  • Who is accountable for what?
  • Does your organization have appropriate controls in place to manage everyone from PIs to check-in personnel?
  • Are the often multiple competing interests and agendas understood?
     PIs
     Clinical trials office staff
     Contracting / Tech transfer
     Research finance & Billing
     Department administrators
     IT staff
     Registration staff
     Medical records & Coding
     Pharmacy, lab, other ancillary services
     Compliance
     Counsel
     Internal Audit
– Communication
  • Does your organization have a research portal or website with policies, information, downloadable forms, training, and FAQs?
  • Do PIs have a simple way to get information about their studies? Status of study initiation procedures? Financial status of study account?
Sample Audit
Clinical Research Participant Billing - Study-level Analysis & Testing

What Documents Do You Need?:

- May choose to do a sample from an array of various departments
- May choose to deal with only outpatient-focused studies initially
- May choose to select studies from high-volume departments that do a lot of research
- May choose to select studies that have the highest enrollment of research participants

- For each study selected:
  - Study protocol (may want to look at list of all current, active trials prior to selection)
  - IRB-approved Informed Consent Form
  - Contract or NOGA
  - FDA Status of Investigational Item (IND or IDE)
  - Proposed / Sponsor Budget

Sample Audit
Clinical Research Participant Billing - Study-level Analysis & Testing

QCT Analysis:

- Purpose of trial must be the evaluation of an item or service that falls within a Medicare benefit category and is not statutorily excluded.

- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. **NOTE: Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.**

- Trials must be deemed to have desirable characteristics.
  - Funded directly (or indirectly as in a cooperative group) by NIH, CDC, ARHQ, CMS, DOD or VA
  - IND has been reviewed by FDA or has been given exemption
Routine Costs Analysis:

- Items and Services that are:
  - Ordinarily provided to beneficiaries and covered by Medicare.
  - Typically provided absent a clinical trial (*conventional care*).
  - Required solely to administer the investigational drug.
  - Provided for the clinically appropriate monitoring of the effects of prevention of complications from the investigational item.
  - Needed to deal with the diagnosis or treatment of complications.

- Does not include items and services that are:
  - Provided solely to satisfy data collection.
  - Provided free of charge.
  - Statutorily excluded or for which there is non-coverage decision.

Don't forget to review the ICF. If it states that a patient shall have no monetary responsibility, then no items involved in the protocol may be billed to the patient.

But, How Do You Know What *Conventional Care* Is?:

- Review credible sources
  - National Guideline Clearinghouse – AHRQ / NIH
  - National Comprehensive Cancer Network
  - American College of Cardiology (and others)
  - JAMA, NEJM, etc.
  - Attestation of PI

Document the analysis:

- Medicare Coverage Analysis
  - Use Protocol as foundation
  - Record the services analysis on a billing grid
  - Document the QCT analysis
  - Cite sources
  - CPTs?
Make Sure That You Understand Accountability for Research Related Injury:

- **CMS**
  - “The clinical trial sponsor’s agreement with participants that it will pay for medically necessary services related to injuries participants may receive as a result of participation in the trial constitutes a plan or policy of insurance under which payment can reasonably be expected to be made in the event such an injury occurs.”
  - “[CMS] believes that Medicare would not be the primary payor in such a situation.”
    - Correspondence from CMS, Financial Services Group (April 13, 2004)

- **Industry / Sponsor**
  - Sponsor pays primary to Medicare if the sponsor is (1) a “primary plan,” i.e., a liability insurance policy or plan (including self-insurance plans) with (2) a “demonstrated” responsibility to pay under the MSP laws.
  - Both a “liability plan” and “demonstrated responsibility” turn on whether there is liability at issue. **A promise to pay for research-related injuries, in and of itself, does not suffice to create “liability” as that term has been defined by courts.**
  - Indeed, a promise to pay may be made to further ethical principles of research and not to discharge a liability.

Medicare as Secondary Payor: CMS interpretation vs. Sponsor interpretation:

- **All or Nothing!!**  Well, all or half…
  - Sponsor agrees to pay for all RRI – Site bills sponsor, not payor
  - Site agrees to absorb costs for all RRI – Site does not bill sponsor or payor
  - Sponsor agrees to pay for RRI of any federal health care program enrollee
    - Include affirmative provision that Site will not bill FHCP at all
    - Check managed care/commercial agreements for MFN
Sample Audit
Clinical Research Participant Billing - Patient-level Analysis & Testing

**What Documents Do You Need?:**

- Select a sample of 2 to 3 research participants for each of the clinical trials selected for testing.

- For each patient, you need:
  - UB-04 (i.e., CMS 1450)
  - CMS 1500
  - EOB
  - On-study & Off-study date
  - Billing activity
  - Medical record
  - Verification whether the participant is a screen failure
  - Signed informed consent

**Where Do You Start?:**

- Verify that the patient received the services per the clinical trial protocol.
- With the MCA as your guide…..
  - Verify that the charges for each item or service associated with conventional care were posted to the patient account.
  - Verify that the charges for each item or service considered “research related” were posted (or written off) to the research account.

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Sample Audit
Clinical Research Participant Billing - Patient-level Analysis & Testing

**Check Bills for Appropriate Modifiers:**

- The Centers for Medicare & Medicaid Services (CMS) has discontinued the QA (FDA Investigational Device Exemption), QR (Item or Service Provided in a Medicare Specified Study), and QV (Item or Service Provided as Routine Care in a Medicare Qualifying Clinical Trial) HCPCS modifiers as of December 31, 2007.

- Effective for dates of service on and after January 1, 2008, CMS has created the following two new modifiers that will be used solely to differentiate between routine and investigational clinical services:
  - Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
  - Q1 – Routine clinical service provided in a clinical research study that is in an approved clinical research study.
How Do You Know When *Modifiers* Are Required?:

- Depends on the type of claim
- **Inpatient: No**
  - Use V70.7 (i.e., Examination of a participant in a clinical trial) and,
  - Condition Code 30 only. This indicates that you are working with a "qualified clinical trial." When this condition code is reported on a claim, it generally means the service is part of a CMS related clinical trial, demonstration or study.
- **Outpatient: Yes-Q1**
  - *Routine* clinical service provided in a clinical research study that is in an approved clinical research study.
  - Use it to identify routine services provided in the trial/study
- **Outpatient: Yes-Q0**
  - *Investigational* clinical service provided in a clinical research study that is in an approved clinical research study.
  - Use it to designate the item under investigation in the trial/study

What Else Should Be Looked At?:

- For conventional care procedures that are payable by Medicare but performed outside the normal allowable time limit, refer to the ICF to determine if they should be written off or billed to a research participant's payor.
- Verify items charged to a payor on UB-04 agree with allowable items per the MCA.
- Verify that bills match the revenue that was paid.
  - Look for denials.
  - Look for partial payments on remittances.
- Calculate excess charges and calculate excess reimbursement received.
- **Cost Report**
  - Research-related costs should not be included in relevant areas of Cost Report.
  - Calculate impact of research-related procedure costs to the Cost Report.
Sample Audit
Clinical Research Participant Billing - Patient-level Analysis & Testing

Final Step:

- **Look at study accounts vis-à-vis budget**
  - High surpluses or residuals may imply that accountable persons are not consistently debiting study accounts for non-conventional care (i.e., non-billable, research-related activity).
  - High deficits may imply absence of effective planning, low accruals, or other issues.
    - Sponsor invoicing is not consistent.
    - Cash flow and collections from sponsor is slow.
    - Poor planning on budget assumptions.
    - Checks from sponsors not being deposited to correct account.
    - Too many patient care charges hitting study account and not enough being billed to 3rd party payors.
  - May choose to look into these sorts of irregularities and conduct a root cause analysis.

- **Confirm signed ICF is in medical record.**

- **Confirm summary of protocol is in medical record.**

Sample Audit: Financial Management of Federal Awards
Managing a research portfolio that includes federally sponsored awards implies additional oversight. Effort reporting, sub-recipient monitoring, cost transfers, cost sharing, and dealing direct & indirect cost accounting concerns create considerable challenges which must be addressed by a compliance program.

**Effort Reporting:**

- Is committed effort on awards greater than 100 percent?
- Who is certifying effort? Suitable means of verification?
- Are faculty members with “other” duties charging 100 percent to sponsored projects?
- Is committed cost sharing being reported? Confirm signed ICF is in medical record.
- Confirm summary of protocol is in medical record.

**Cost Transfers:**

- Does your organization have an irregularly high number of cost transfers? Are too many of them greater than 90-120 days after original charge?
- Is documentation on cost transfers adequate?

**Sub Awards:**

- Are internal controls in place to perform monitoring on sub-awards?
- Are there unallowable costs or lack of cost sharing documentation on sub-awards?
Sample Audit
Financial Management of Federal Awards - Questions

Charging and Accounting Practices:
• Are there charges for routine admin support inappropriately charged as direct costs?
• Are departmental/institutional business managers allocated to multiple awards?
• Have audits been performed to review expenditure allowability?
• Are close outs revealing irregular accounting or billing practices?
• Are policies routinely followed for closing out accounts or do a number of accounts for dormant research remain open?

Sample Audit
Financial Management of Federal Awards - Obtain Data

General Data (select a sample of awards):
• Grant proposal including budget submission
• Notice of Grant Award (NGA)
• Grant budgeting correspondence
• Any approval notices or other pertinent correspondence from granting agency
• Current grant budget to actual analysis (activity in general ledger account)
• Detailed list of grant transactions (including budget transactions)
• Due dates for progress report submissions
Salary Data associated with selected grants/awards:

- Summary of salary expenditures/transactions on the grant, including:
  - Employee name
  - Title
  - Role on the grant
  - Percent of effort
  - Amount of salary charged to the grant by pay period

- All time and effort reports pertaining to the period under review.

Transaction Testing Supporting Documentation:

- All supporting documentation of non-salary transactions, including:
  - Journal entries (transfers, corrections and budget adjustments)
  - Purchase requisitions and invoices
  - Approvals
  - Any other relevant documentation necessary to validate grant expenditures

Sample Audit
Financial Management of Federal Awards - Grant Review Plan

General:

- Review the NGA to identify any special terms and conditions that could impact the costs charged to the grant or research site’s responsibilities under the award (e.g., cost sharing and program income). Note the Activity Code for any restrictions or specific policy guidance.

- Review the grant proposal and application to identify any planned cost-sharing use of program income or other special provisions.

- Review budget correspondence to identify any special terms, agreements, or clarification between research site and the funding agency.

- Review budget transactions to identify significant rebudgeting.

- Review significant variations of actual grant charges from budget.
## Sample Audit
Financial Management of Federal Awards - Personnel Charges

### General:
- Consistency between salary expenditures/transactions and general ledger salary amount in the grant account. *Note: If amounts do not agree, request grant financial staff to reconcile and explain the difference.*
- Compare personnel data per summary to the grant proposal budget and inquire as to any significant variances.
- Compare percentage/amount of budgeted effort and salary to actual. *Note: NIH prior approval may be required for changes in key personnel or levels of effort of key personnel.*

### Effort:
- Note any missing reports. Confirm that reports were appropriately signed and done so in a timely manner.
- Recalculate employee benefits. If grant indicates a different fringe rate than the institution’s rate, may want to request that grants management personnel reconcile/explain the variance.

## Sample Audit
Financial Management of Federal Awards - Other Direct Costs

### Allowability:
- Review supporting documentation to determine if the goods or services are allowable (ref. NIH Grants Policy Manual, A-21, institutional policies, etc.).
- Note any unallowable costs charged against the grant for reporting purposes.
- Evaluate each test based on the following:
  - Reasonableness
  - Allocable
  - Consistently treated
  - Conformance to any limitations or exclusions set forth in relevant OMB Circular or the sponsored agreement.
Sample Audit  
Financial Management of Federal Awards - Specific Direct Costs

**Travel:**
- Consider whether expenses are justifiable based on institutional policy.
- Determine if travel is support by the sponsored project.
- Evaluate a travel expense in the context of the NIH Grants Policy Manual (i.e., must provide direct benefit to the project, lowest reasonable commercial airfares, etc.)
- Ensure that the salary of the employee to whom the travel charges related was being charged to the project during the time of travel.

Sample Audit  
Financial Management of Federal Awards - Specific Direct Costs

**Equipment:**
- Consider whether expenses are justifiable based on institutional policy (i.e., contractor selection process, basis for cost or price, etc.)
- Determine if equipment is support by the sponsored project (i.e., included in the proposal budget).
- Evaluate the results of any recent equipment inventory initiatives.
- Confirm where ownership of the equipment will reside when grant is over.
### Sample Audit
Financial Management of Federal Awards - Cost Transfers

**Documentation:**
- Determine whether the cost transfer is related to the specific activities supported by the sponsored project.
- Review documentation of cost transfers to determine if they appear valid. Transfers of cost from one project to another or budget prior to the next solely to cover cost overruns are not allowable.
- Transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the grantee.

**Timing:**
- Transfers should be made within 90 days of when the error is discovered.
- Transfers that are not made promptly, must include an adequate explanation of why there was a delay in correcting the error.
- Check institutional policies.

### Sample Audit
Financial Management of Federal Awards - Other Areas of Focus

**Sub-Contracts:**
- Determine that invoices were properly prepared to effect timely payment, the costs were reviewed and approved by the PI as allowable expenditures and were properly prepared to effect timely payment.

**Reporting / Close Outs:**
- Review award document and identify due dates for technical progress reports and other financial reporting requirements. Confirm that these submission requirements were made in a timely manner and after discussion with the PI and review of documents as necessary.
- Ensure that financial report reconciles to accounting records.
- Verify that the reports are reviewed and signed by appropriate institutional personnel.
- Confirm that awards are closed in a timely manner.
Sample Audit
Financial Management of Federal Awards - Other Areas of Focus

**Cost Sharing:**
- Review grant proposals and awards to determine whether the sponsored agreement includes mandatory or voluntary cost sharing.
- Review expenses included in the cost sharing to ensure that they are allowable, necessary / reasonable, incurred during effective dates of award, meet terms/conditions of award, etc.

**Program Income:**
- Review grant proposals and awards to determine whether the sponsored activity is expected to generate program income.
- Determine the treatment method applied (i.e., additive, deductive, combination, matching, etc.).
- Review accounting records to ensure that program income is being properly recorded according to the specified treatment method.
- Allowable, reasonable, necessary, reported on FSRs, etc.

Sample Audit:
Conflicts of Interest
Sample Audit
Conflicts of Interest - Context

The focus on Conflicts of Interest in Research has been sharpened since 2009 when the OIG prioritized the exploration of financial COI in NIH funded research in its annual Work Plan. Among the results was the 5/8/2009 ANPRM which introduced new enforcement initiatives. Ultimately, the PPACA paved the way for to the passage of the so-called Physician Payments Sunshine Act in January 2013.

Understanding the Sunshine Act's impact:

• Requires applicable manufacturers of drugs, devices, biologicals, or medical supplies to report annually to the Secretary of HHS certain payments or other transfers of value to physicians and teaching hospitals.

• Requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

Provider organizations need suitable policies, mechanisms, tools, oversight, templates, and committee structures to confirm that Investigators and other research personnel are conforming to the evolving regulatory landscape for COI.

Sample Audit
Conflicts of Interest - Clinical Investigator Responsibilities

21 CFR Part 54:

• Affects Investigators linked to clinical data submitted to the FDA in marketing applications for drugs, biologics, and devices.

• Applicants must disclose or certify information concerning financial interests of all clinical Investigators who conducted covered clinical studies.
  – Financial arrangements between a sponsor and the Investigator.
  – Significant payments (i.e., >$25,000).
  – Proprietary interest (i.e., patents, trademarks)
  – Significant equity interest (i.e., stock or other ownership interest valued at >$50,000).
Sample Audit
Conflicts of Interest - Questions

**DHHS Guidance:**

- Does your institution have COI policies? Are they understood? Communicated? Expectations clear? Etc.?
- Is it clear what constitutes “institutional” COI?
- Is there a COI Committee? Is its role, purpose, purview, authority, charter, policies and procedures understood and effectively communicated?
  - Are there counsel or compliance professionals who serve on or attend these meetings?
- How often are clinicians required to disclose any potential conflicts? Different rules for clinicians acting as research investigators?
- What type of training is available institution-wide on COI, the disclosure process, etc?

Sample Audit
Conflicts of Interest - Key Areas of Review

**Self-Diagnosis:**

- First assess whether the potential or risk of COI are low, medium, or high.
- Determine what times of COI predominate:
  - Individual or institutional? Do you understand the difference, implications, etc.
  - Do they involve procurement?
  - Are they primarily research related?
- Confirm that policies, procedures and process flows are developed.
- Evaluate how effectively such documentation has been disseminated.
  - Prioritize looking at federally regulated areas
  - Ensure that “significant financial interests” and significant equity interests” are understood, being reported, and being tracked.
  - How recently have polices, procedures, training, etc. been updated?
Oversight Mechanisms:

- Review the frequency of disclosures, the transparency of the process, and the information requested through disclosure forms.

- Confirm that the process is appropriate and the controls are sufficient depending upon the type or category of employee.

- Evaluate the reporting, evaluation and management process:
  - Conflicts of Interest Committee (COIC) or, if a smaller entity with comparatively smaller resources, an external reviewer.
  - COIC should have an administrative arm (similar to an IRB)
    - Document minutes of meetings
    - Collect and store disclosures
    - Maintain records (e.g., issues management plans)
    - Coordination of meetings with Investigators

External or Automated Resources:

- Many providers are turning to software and 3rd-party vendors to supplement their disclosure process.

- In effect, it is designed to confirm that information being documented on disclosure forms is accurate.

- Online tracking systems like HCCS COI Smart provide for the development of multi-level branching questionnaires, automated assignment of reviewers, the development of COI management plans, and data mining tools for auditing, tracking and reporting on potential conflicts of interest.

- Other systems from vendors like ClickCommerce, Meditract, Osprey can serve as an efficient ways to support internal processes.
Sample Audit: GCP Review

Know your study inside and out
- What does your approved protocol state?
- What does your SOP/MOO state?
- What does your IND/IDE application state?

Know your study staff
- Who is responsible for each step of study process?
- Ensure staff understands their on-going responsibilities
- Ensure all pertinent staff is available as needed

Know your study documents
- Do you have all required documents?
- Are documents organized, complete and current?
- Are all documents easily available?
• Verify study drug/device accountability

• Verify regulatory compliance, including but not limited to the following:
  – Updated FDA Form 1572/1571
  – On-going IRB review and approvals
  – IND Safety reports
  – Updated Investigator’s Brochure and Protocol
  – Financial Disclosures
  – Communication with Sponsor and FDA

• Verify Investigator and staff training and credentials, including but not limited to:
  – Medical License
  – In-service training(s)
  – CVs/Resume (current within 2 years)
  – Other training records (e.g. CITI)

Sample Audit
FDA Audit - Preparation

• Acknowledge and explain all protocol deviations/exceptions and any follow-up corrective actions (as applicable)

• Verify identification and reporting of adverse and unanticipated events, and demonstrate adequate follow-up per approved protocol

• Verify subject existence

• Confirm subject eligibility at enrollment
  – Source documents, such as:
    • Medical Records
    • Visit/Clinic Notes
    • Shadow Charts
    • Lab/Test Results
    • Prescriptions
    • Signed Informed Consent
Sample Audit
FDA Audit - Preparation

- Verify informed consent was properly obtained and signed prior to study participation and screening
- Verify data collected and submitted through comparison of complete and accurate case report forms (CRFs) with source documents (e.g. medical records, visit notes)

Sample Audit
FDA Audit – Data Integrity

- SOP and Regulatory Compliance
- Robust Processes
- Consistency and Transparency
Comparison of source data with information includes but not limited to:
- Medical/clinic/hospital records and test results
- Case Report Forms
- List of number of subjects on study, drop outs and lost to follow up
- Adverse events, device affects and deaths
- Documentation of deviations from protocol, reasons and corrective actions
- Data tables
- Demonstrate study compliance (complete and accurate CRFs with supporting source documentation)

Red Flags: indicators of problems

Perfect work: no mistakes or corrections, complete and “perfect” CRFs

Subjects with 100% compliance

All subjects screened, enrolled and completed trial

Questionable expertise and capability of staff, equipment and resources compared to quality and output of work

Unusually high volume of work compared to available resources

Repeated, uniform data patterns or inconsistent data

Inconsistent use of ink or type of pen

Consistent writing style on all CRFs

General suspicious behavior of research staff
Thank You

Questions?