Objectives

- Discuss the research compliance rules and regulations.
- Designing a research compliance program.
- Where does research compliance fit in the organization.

Compliance Program

Compliance
A Systematic Approach to Ensure the Organization and Its Employees Comply with Applicable Substantive Laws and Regulations.

(Not operations)
Why compliance

In five words: to protect participants, taxpayers, us

Laws, Regulations and Rules

<table>
<thead>
<tr>
<th>False Claims Act</th>
<th>Export Controls</th>
<th>Scientific Misconduct</th>
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<tr>
<td>FDA approval process</td>
<td>HIPAA, HITECH</td>
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False Claims Act
- Reducing Assurance
- “Common Rule”
- Scientific Misconduct

Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Centers for Medicare and Medicaid Services (CMS, “Medicare”)
- Office of Human Research Protection (OHRP)
- Office of Research Integrity (ORI)
- Agency for Healthcare Research and Quality (AHRQ)
- Office of Management and Budget (OMB)
- National Science Foundation
- United States Department of Agriculture
- And many others
Why Compliance

Building a strong research compliance program:
- Protects our patients and animal subjects
  - Safety, autonomy, fairness, privacy, protection against inadvertent misbilling
- Protects taxpayers
  - Federal use of funds
- Protects our institution, employees, colleagues
  - From negative publicity and fines
- Is the right thing to do
  - Federal requirement is the minimum
  - Compliance meets those reqs, but goes beyond to ethics

Designing
Best Compliance Program

There is not one, it's yours because you are driving it.

There is not an "out of the box" or "one-size-fits-all" way to manage compliance and integrity.

The Seven Elements of an Effective Compliance Program

1. Standards & Procedures
   Implement written policies and procedures and standards of conduct.

2. Oversight
   Designate a compliance officer and coordinate.

3. Training & Education
   Conduct regular and relevant training and education.

4. Reporting
   Develop lines of communication for reporting of compliance/ethical issues that protect anonymity, prevent retaliation.

5. Enforcement & Discipline
   Enforce standards through and utilized and utilized disciplinary procedures.

6. Auditing & Monitoring
   Conducting internal monitoring and auditing.

7. Investigation & Remediation
   Responding promptly to detected offenses and undertaking corrective action.

Implementation
Risk Assessment
The 8th Element

is 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. Process by which risks are identified, evaluated and prioritized.

Risks are all around Us

Why
Resources can be limited in comparison to the risks that exist within the Research Program.

We have to make choices as to where to allocate resources to achieve the highest levels of protection.
Research 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
- Financial reporting
- Pharmacy
- Investigator Initiated trials
- HIPAA
- Patient safety
- Gaps in policies and procedures
- Budget development
- Managed care contracts
- Institutional Review Board
- Residual funds
- Medicare cost report
- Research administration
- Patient care/quality
- Registration & patient accounts
- Healthcare quality and outcomes
- Clinical trials billing
- Fair market values
- Consenting process

Operations/Compliance Structure

Is research compliance in research? Or general compliance?

Reporting structures may need analysis and determination

- Investigators: responsible to know the rules of their engagement
- Research staff, administrators: assist investigators in meeting them
- Compliance officer charged with knowing current rules
- Well situated for process improvement
- Policy owner can match process

But:

- Delicate relationships
- Classic separation supports role definition
- Role mix may cause tension
- Goal of “objectivity” needs new understanding

Operations/Compliance Relationship

Benefits, challenges

- Compliance starts with operations
- Investigators: responsible to know the rules of their engagement
- Research staff, administrators: assist investigators in meeting them
- Compliance officer charged with knowing current rules
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But:

- Delicate relationships
- Classic separation supports role definition
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Operations/Compliance

If compliance develops new processes, assess for coverage and distancing needs
Who will audit, investigate, enforce?
Use of external auditors and/or internal support staff?
Find methods to ensure sufficient perspective and measure

Who will train and provide educational materials?
Who will conduct risk assessments?
If research compliance officer is
Role mix may cause tension
Goal of “objectivity” needs new understanding

Summary
➢ Understand why compliance.
➢ Compliance program basics.
➢ Challenges of implementation

Questions

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