Designing & Implementing an Effective Research Compliance Program
2017 Hawaii Regional

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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

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<thead>
<tr>
<th>False Claims Act</th>
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<td>IRS non-profit status</td>
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<td>Stark; Anti-kickback</td>
<td>Animal Welfare Act</td>
<td>Allowable Costs</td>
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<td>Document Consistency</td>
<td>Investigational Device Exemption billing</td>
<td>Coverage Analysis</td>
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<td>Conflict of Interest (COI)</td>
<td>Clinical Trials Agreement</td>
<td>Good Clinical Practices</td>
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<td>Social Security Act (Medicare)</td>
<td>FDA Amendment Act (clinicaltrials.gov)</td>
<td>Investigational Drug Services</td>
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<td>Open Payments (aka “Sunshine Act”)</td>
<td>Medicare claims processing rules</td>
<td>Coverage with Evidence Development</td>
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Why Compliance

Research operations is beholden to:

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

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<td>1. Standards &amp; Procedures</td>
<td>Implement written policies and procedures and standards of conduct</td>
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<td>2. Oversight</td>
<td>Designate a compliance officer and committee</td>
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<td>3. Training &amp; Education</td>
<td>Conduct regular and relevant training and education</td>
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<td>4. Reporting</td>
<td>Develop lines of communication for reporting of complaints/incidents that protect anonymity, prevent retaliation</td>
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<td>5. Enforcement &amp; Discipline</td>
<td>Enforcing standards through well-publicized and utilized disciplinary guidelines</td>
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<td>6. Auditing &amp; Monitoring</td>
<td>Conducting internal monitoring and auditing</td>
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<td>7. Investigation &amp; Remediation</td>
<td>Responding promptly to detected offenses and undertaking corrective action</td>
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# 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.

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**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
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

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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