

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.





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Compliance Program

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

(Not operations)

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Why compliance

In five words: to protect participants, taxpayers, us



Laws, Regulations and Rules

False Claims Act	Export Controls	Scientific Misconduct
IRS non-profit status	FDA approval process	HIPAA, HITECH
Effort Reporting	Federalwide Assurance	"Common Rule"
False Claims Act	Export Controls	Scientific Misconduct
IRS non-profit status	FDA approval process	HIPAA, HITECH
Effort Reporting	Federalwide Assurance	"Common Rule"
Stark; Anti-kickback	Animal Welfare Act	Allowable Costs
Document Consistency	Investigational Device Exemption billing	Coverage Analysis
Conflict of Interest (COI)	Clinical Trials Agreement	Good Clinical Practices
Social Security Act (Medicare)	FDA Amendment Act (clinicaltrials.gov)	Investigational Drug Services
Open Payments (aka "Sunshine Act")	Medicare claims processing rules	Coverage with Evidence Development

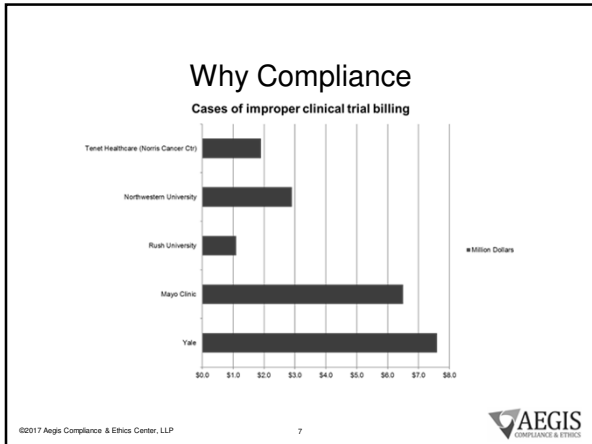


Why Compliance

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 now?

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

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Designing

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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

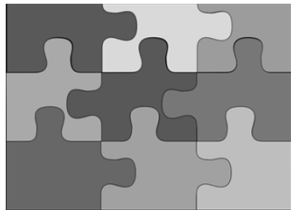


The Seven Elements of an Effective Compliance Program

1. Standards & Procedures	Implement written policies and procedures and standards of conduct
2. Oversight	Designate a compliance officer and committee
3. Training & Education	Conduct regular and relevant training and education
4. Reporting	Develop lines of communication for reporting of complaints/incidents that protect anonymity, prevent retaliation
5. Enforcement & Discipline	Enforcing standards through well-publicized and utilized disciplinary guidelines
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 | Gaps in policies and procedures |
| Research accounting | Budget development |
| Physician disclosure | Managed care contracts |
| Conflict of interest | Institutional Review Board |
| Hospital billing and coding | Residual funds |
| Research medical records | Medicare cost report |
| Laboratory practices | Research administration |
| Physician contracting | Patient care/quality |
| Stark anti-kickback compliance | Registration & patient accounts |
| GCP | Healthcare quality and outcomes |
| Financial reporting | Clinical trials billing |
| Pharmacy | Fair market values |
| Investigator Initiated trials | Consenting process |
| HIPAA | |
| Patient safety | |

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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



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Operations/Compliance Relationship

Benefits, challenges

- Compliance starts with operations
 - Investigators: responsible to know the rules of their engagement
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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




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Summary

- Understand why compliance.
- Compliance program basics.
- Challenges of implementation

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Questions



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