

Designing & Implementing an Effective Research Compliance Program

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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

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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
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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

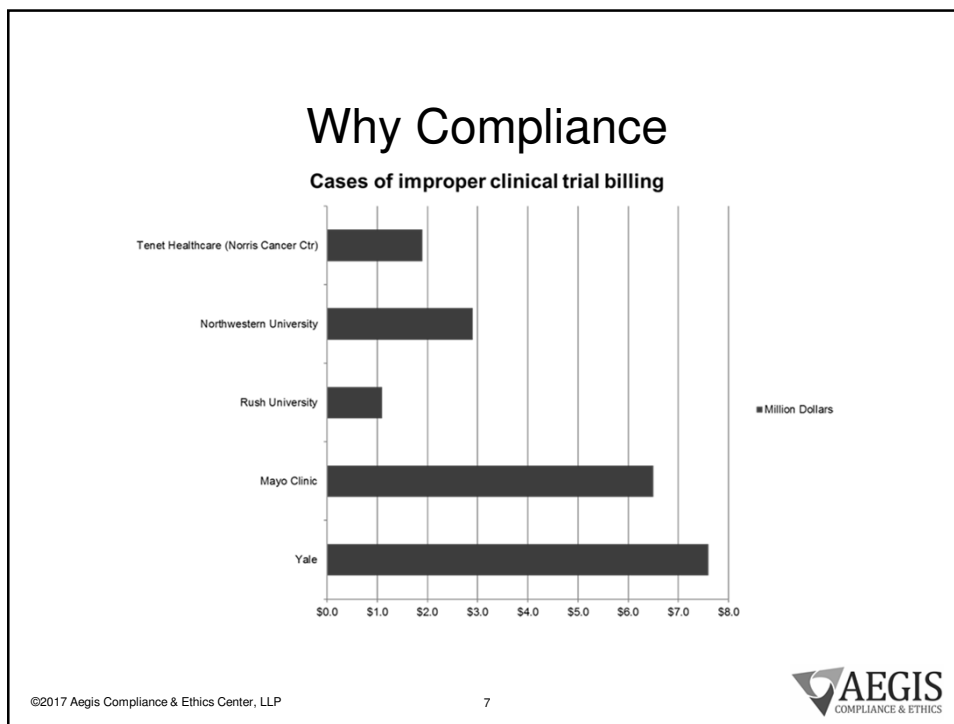


Why Compliance

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?

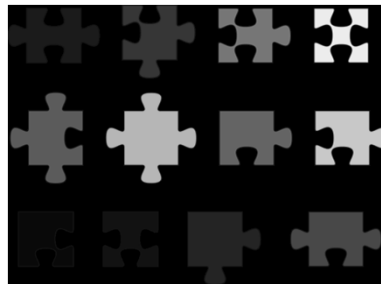
Building a strong research compliance program:

- 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



Best Compliance Program

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

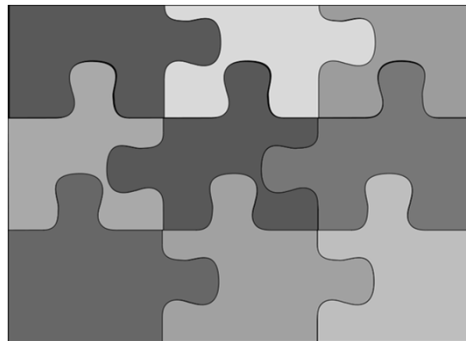
There is not an “out of the box” or “one-size-fits-all” way to manage compliance and integrity



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
 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

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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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