

Research Compliance 101

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- Federal Sentencing Guidelines
- Clinical Trials/Protecting Participants
 - Informed Consent
 - Billing
 - Auditing and Monitoring
- Informed Consent
- Conflict of Interest and Commitment
- Responsible Conduct of Research
 - Falsification, fabrication, and plagiarism
- HIPAA
- “Hot” Issues and Traps
 - Effort Reporting
 - Tissue Banks/Anatomical Gift Programs
 - Animals
- Protecting Information
- Investigations/Working with the Press
- Structuring a Compliance Office

Federal Sentencing Guidelines

- (a) To have an effective compliance and ethics program...an organization shall—
 - (1) exercise due diligence to prevent and detect criminal conduct; and

- (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law. Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.

- (3) The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization any individual who the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program,³

■ (4)

(A) The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subdivision (B) by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.

(B) The individuals referred to in subdivision (A) are the members of the governing authority, high-level personnel, substantial authority personnel, the organization's employees, and, as appropriate, the organization's agents.

■ (5) The organization shall take reasonable steps—

(A) to ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct;

(B) to evaluate periodically the effectiveness of the organization's compliance and ethics program; and

(C) to have and publicize a system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization's employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.

(6) The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through⁴

1) appropriate incentives to perform in accordance with the compliance and ethics program; and

2) appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.

(7) After criminal conduct has been detected, the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program.

Clinical Trials

- Informed Consent
- Billing
- Auditing and Monitoring

Protection of Participants or Human Subjects

The Common Rule

- Application: 17 U.S. Government Depts., Agencies or Subject to F.D.A. regulations
- Education required of all investigators submitting to N.I.H. (Oct. 1, 2000)

Informed Consent

- 45 C.F.R. 46
- 50 C.F.R. 20-27

Governing Statutes, requirements:

45 C.F.R. 46: Basic regulations for protection of Human Subjects (subparts B-D for “vulnerable” populations)

The Belmont Report

- Institutional Assurances
- I.R.B. Assurances
- Informed Consent

Informed Consent Requirements- 21 CFR 50.25

- Introduction (“This is research”)
- Purpose of study
- Description of study procedures (“experimental”)
- Duration of subject involvement
- Potential risks or discomforts of participation
- Potential benefits of participation
- Alternatives (treatments, other research, etc.)
- Confidentiality of records statement
- Compensation for injury statement (for greater-than-minimal-risk studies)

Informed Consent Process

- Contact persons
- Statement of voluntary participation
- Unforeseen risks
- Reasons for involuntary termination of participation
- Additional costs to participate
- Consequences for withdrawal
- New findings statement
- Number of subjects
- Payments (incentives, etc.)

Billing

■ O.I.G. Workplan

How does “Double Billing” occur?

Systems “Challenges”

Fraud/Fine implications

Critical Components of the Process:

- Budget Preparation
- Protocol Approval
- Consenting Subjects/Informed Consent
- Registration of Subjects
- Billing Requirements
- Treatment of Residuals
- All source material must be complementary and internally consistent (i.e. the Informed Consent and Sponsored Research Agreement must align)

National Coverage Decision

- NCD (9/19/00) Defines requirements and procedures for submitting “routine costs” associated with “qualifying” clinical trials
- Available at
<http://www.cms.gov/quality/8d2.htm>

Auditing and Monitoring

Who is Responsible?

Laboratories/C.L.I.A.

- To whom does Clinical Laboratory Improvement Act Apply?
- Is there a “Billing” Safe Haven?

Conflict of Interest and Commitment

- A conflict of interest arises when financial or other personal considerations have the potential to influence (bias) judgment or objectivity.
- May be actual or perceived, and perception may have greater impact
- May put human subjects at risk (disclosure requirement)
- May jeopardize “public trust.”
- Is accommodation of conflicts possible?
- Remember “Institutional” conflicts

42 C.F.R. Section 50.603:

- Investigator: ...the principal investigator and ***any other person*** [emphasis added] who is responsible for the design, conduct or reporting of research funded by PHS, ...”investigators” include the Investigator’s spouse and dependent children.”

42 CFR Section 50.604:

- “If the institution carries out the PHS-funded research through sub grantees, contractors, or collaborators, the Institution must take reasonable steps to ensure the Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution’s policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this subpart.”

42 CFR Section 50.604:

- “Prior to the Institution’s expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced, or eliminated in accordance with this subpart...”

Responsible Conduct of Research

- Collaboration
- Intellectual Property
- Data Acquisition and Management
- Falsifying Data on CRFs
- Suppression of Data
- Falsification, fabrication and plagiarism

“Introduction to the Responsible Conduct of Research” – Nicholas H. Stenick –
<http://ori.dhhs.gov/education/products/RCRintro/>

“On Being a Scientist” -
<http://www.nap.edu/readingroom/books/obas/>

HIPAA

- Authorizations
- 18 Identifiers
- Limited Data Sets/Data Use Agreements
- Exemptions
- Accounting of Disclosures

“Hot” Issues and Traps

- Effort Reporting
- Tissue Banks/Anatomical Gift Program
- Animals

Protecting Information

- More HIPAA
- Identity Theft

Investigations/Working with the Press/Privilege

- Unannounced Investigative “Visits” vs. Audits
- Rehearse
- Attorney/Client vs. Peer Review

Summary of Audit Findings

<u>Institution</u>	<u>Penalty</u>	<u>Effort</u>	<u>Documenta tion</u>	<u>Clinical Trial / Medicare Billing</u>
Florida International University	\$11.5M	X	X	
The Mayo Foundation	\$6.5 million		X	
Northwestern	\$5.2M	X	X	X
Weill Medical College/Cornell	\$4.3M			
Univ. Alabama, Birmingham	\$3.4M	X		X
Harvard, Beth Israel	\$3.25M	X		
Johns Hopkins University / Bayview	\$2.6M	X		
University of California at Irvine	\$2.3M			X
East Carolina	\$565k - \$1.8M	X	X	
Univ. Massachusetts Med School	\$282k	X	X	
Northeastern University	\$61k	X	X	
Texas State Technical College	Unknown	X		
University of Washington	\$35M			X
Rush University Medical Center	\$1M			X

Structuring a Compliance Office (approaches)

- Responsibilities
- Staffing (Monitoring and/or Auditing?)
- Reporting Structure

Questions?