Overview of Research Compliance

Historical Timeline

Pre - 1974

- Nazi experiments
- Nuremberg Code
- Tuskegee syphilis study
- Milgram, et al
- Declaration of Helsinki
- Human radiation experiments
- Willowbrook
- Jewish Chronic Disease Hospital
Overview of Research Compliance

Historical Timeline

Pre 1973 - Present

• Kennedy Hearings “Quality of Health Care – Human Experimentation” (1973)
• National Research Act (1974)
• Federal Regulations 45 CFR 46
• Creation of National Commission
• Required IRB review of research involving HEW
• Creation of OPRR (1976)
• Belmont Report (1979)
• OHRP (2000)

Financial Compliance: Federal Funds

Financial compliance in research is governed by a variety of regulations and rules depending on venue & funding source.

Federal funds:

Cost Principles
  • OMB Circular A-21
  • OMB Circular A-87
  • OMB Circular A-122

Administrative Requirements
  • OMB Circular A-102
  • OMB Circular A-110

Audit Requirements
  • OMB Circular A-133

The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for federal awards can be found at:

2 CFR Part 200
Financial Compliance: Federal Funds

Federal funding:

Contractual obligations
• Notice of Award (NoA)
• Funding Opportunity Announcement (FOA)

Standard F & A rates
• Rates must be consistent across all Federally funded projects at an institution.

Adherence to financial statements in ICFs
• E.g. “no cost to participants”

Financial Compliance: Non-Federal Funds

Industry & other non-federal funding:

Contractual obligations
• Contract
• Budget
• Medicare coverage analysis (MCA)

Adherence to financial statements in ICFs
• E.g. “no cost to participants”

Beware of per-pt rates!
• Per-pt rates often do not cover actual costs
Financial Compliance: COI

Financial Conflicts of Interest in Research:

2011 rules
• $5,000 reporting threshold
• Includes investigator meeting expenses
• Required COI training
• Publish conflicts on web-site

COI disclosure, review and management process: Critical to avoid enforcement actions.

Physician Sunshine Act
• Industry may report research funds to PIs/Institutions as part of the PSA requirements

Financial Compliance: AMCs

AAMC, CMS and Academic Medical Centers

AAMC (Association of American Medical Colleges)
• AAMC Medicare Direct Graduate Medical Education Payments
• AAMC Medicare Indirect Graduate Medical Education Payments

CMS (Center for Medicare and Medicaid Services)
• CMS for teaching physicians
• Physician Payments Sunshine Act Fact Sheet

AMCs: May qualify as safe harbors for some financial regulations
• FMV
• Stark
• Anti-kickback
Financial Compliance: Hot Topics.1

Accurate centralized contracting & budgeting
- Don’t let physicians, scientists do their own!
- Extra scrutiny of liability language in device research contracts
- Extra scrutiny of ‘per-patient’ research payments

CMS: use of V70.7 code and Q0 & Q1 modifiers for research billing to CMS

CMS: use of NCT# on CMS claims involving research
- Conduct research billing audits!

Financial Compliance: Hot Topics.2

Fair Market Value
- Discounts for young investigators?
- Discounts for research programs or senior researchers?

Stark: Prohibits certain types of physician referrals where financial relationships are involved

Anti-kickback: Prohibits certain activities involving offering, paying, soliciting or receiving anything of value to induce referrals
Current Hot Topics: Stark

Section 1877 of the Social Security Act (42 U.S.C. § 1395nn), also known as the physician self-referral law and commonly referred to as the “Stark Law” prohibits physicians from referring Medicare patients for certain designated health services (DHS) to an entity with which the physician or a member of the physician’s immediate family has a financial relationship (ownership, investment, or compensation), unless an exception applies. It also prohibits an entity from presenting or causing to be presented a bill or claim to anyone for DHS furnished as a result of a prohibited referral. This referral prohibition has been extended to the Medicaid program.

Stark is a civil statute and applies to individual physicians.

Institutions that qualify as true Academic Medical Centers (AMC) may also qualify for exceptions and safe-harbors to complying with the Stark Law. CHI Legal Services must be consulted to determine if an institution qualifies as an AMC, and thereby also qualifies for the AMC exception.

Current Hot Topics: Anti-kickback

The purpose of the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) is to protect patients and the federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions. The Statute prohibits offering, paying, soliciting or receiving anything of value to induce or regard referrals or generate Federal health care program business.

Anti-Kickback is a criminal statute and applies to organizations.

The United States Congress designated specific “safe harbors” for various payment and business practices that, while potentially are prohibited by the law, would not be prosecuted. For a comprehensive list of regulatory safe harbors and their respective requirements, please see 42 CFR § 1001.952
Research compliance has traditionally been practiced by compliance officials isolated from research operations in a post-hoc fashion.

Is there a better way than “gotcha!”?

**Research Compliance Oversight: Preëmptive or Post-hoc?**

*Compliance activities must occur as a function independent of operations.*

Independence does not commit one to post-hoc or “gotcha” compliance.

**Compliance-Operation partnership commits Research Compliance Officers to:**

- having superior knowledge of operations, regulation, GCP.
- both meta- and micro-compliance activity
- clearly articulating and communicating compliance goals and path for attainment to all levels of operations
Managing Distinct, but Connected Interests

Moral Imperative to Conduct Research

Reality of Conducting Research

Laws & Regulations Governing Research

Creating an Infrastructure for Clinical Research at CHI: Operations and Compliance

Facility Research Centers
Physicians (Community)
Physicians (Employed)
Other Clinicians (eg RN, Pharm)
Academia

Research Investigator Community

CIRI Alliance

Operations

Funding

Sponsors
Industry Partners

Government

Physician Leadership
Business Intelligence
CHI Foundation
Service Lines
Compliance
Finance
Legal

10/15/2014

8
If people don’t understand what you want them to do, the probability that they will do it is small.
Analogy: Building architects and landscape architects work independently with some similar and some dissimilar materials, tools, principles and methods toward independent, but conjoined ends. Communication and collaboration from the ground up is critical for a successful project.

If one builds compliance infrastructure that:

- Helps researchers to be compliant, it will be easy to do the right thing.
- Is carefully constructed to yield compliance data, monitoring and auditing can be automated.
- Is not operationally insane compliance is all-but-assured.
Research Compliance Oversight: From the Ground Up

Build compliance into everything operations does!

- Human Research Protections Program (HRPP)
- Research Billing
- IRB Operations
- Data Management
- Regulatory Reporting

Compliant Research Operations

Compliance-Operations team approach to creation of:

- Formal work-stream documents
- SOPs (for everything!)
- Policies
- Clear escalation processes for compliance issues
- Compliance presence in operations
Build compliance into everything operations does!

- Human Research Protections Program (HRPP)
- Research Billing
- IRB Operations
- Data Management
- Regulatory Reporting

Questions?