Contracting With Research Sites
And Investigators:
A Fraud And Abuse Primer

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Checklist for Compliance: Contracting Guidelines

- Evaluate purpose/scientific value of proposed research project
- Develop research budget
  - FMV Evaluation
  - Contemplate allocation/return of excess funding
  - No profits
  - Time records/documentation
  - Limit to appropriate number of investigators/sites
  - No payments directly to investigators/sites
  - No incentives to increase subject participation
Checklist for Compliance: Contracting Guidelines

Identify Potential Investigators/Sites

• Beware of cumulative relationships
• Develop qualification criteria (don’t limit to high prescribers)
• Limit to appropriate number of investigators/sites
• No incentives for participation
Checklist for Compliance: Contracting Guidelines

1. **Require Written Documentation**
   - Meet safe harbor requirement

2. **Require Financial Conflict of Interest Disclosures**
   - Meet industry guidelines

3. **Research Meetings must be Modest, Limited, have Scientific Purpose and not be Promotional**
Checklist for Compliance: Contracting Guidelines

- Require Appropriate Written Documentation of Research
- Establish Appropriate Monitoring Systems for Billing Federal Health Care Programs
- Establish Monitoring and Checks and Balances for Contract Compliance
Legal/Regulatory Framework
For Compliance Checklist

- Federal Anti-kickback Statute
- Federal False Claims Act
- Physician Self Referral Law
- Industry Guidelines on Conflict of Interest
- AMA Guidelines
Contracting Guidelines: Legal Basis

- Evaluate Purpose
- Develop Research Budget
- Identify Potential Investigators
Legal/Regulatory Guidelines: Federal Anti-kickback Statute

It is a felony to:

- knowingly and willfully:
- solicit or receive any remuneration (bribes, kickbacks, rebates)
- directly or indirectly
- overtly or covertly
- in cash or in kind
- in return for:
  - referring an individual to a person for the furnishing or
  - arranging for the furnishing of an item/service; or
  - purchasing, leasing, ordering or arranging for or recommending
    purchasing, leasing or ordering any good, facility, service or item
- for which Medicare or a state health care program may pay
Federal Anti-kickback Statute

- Violators may be subject to the following penalties:
  - $25,000 for each offense
  - Imprisonment for up to 5 years
  - Exclusion from the Medicare, Medicaid and/or other Federal and State health care programs
  - Civil monetary penalties
Federal Anti-kickback Statute

It is significant to note that civil monetary penalties are widely applied to:

- Any individual entity that furnishes items or services that are reimbursable under the programs is subject to exclusion from the programs, \textit{regardless} of whether that individual or entity directly presents a bill to the program.
- Pharmaceutical manufacturers are indirect providers.
Federal Anti-kickback Statute: Special Fraud Alert

- Aug. 1994 Special Fraud Alert on Prescription Drug Marketing Schemes
- Identifies provision of substantial payments for de minimis research as problematic
- Investigation warranted if research has questionable scientific value or lacks scientific pursuit
Contracting Guidelines: Legal Basis

Require Written Documentation
Federal Anti-Kickback Statute

• Congress has adopted exceptions to the Federal Anti-Kickback Statute.

• Congress also has given HHS authority to issue “Safe Harbor” regulations to describe financial arrangements that fall outside of the Anti-Kickback Statute.

• Compliance with a Safe Harbor should offer protection against liability under the Anti-Kickback Statute.

• Conduct outside the Safe Harbors must be analyzed based on the “facts and circumstances” to determine whether a violation exists.
Personal Services and Management Safe Harbor

Requirements:

• signed, written document
• specifies services
• part-time vs. full-time
• at least one-year term
• aggregate compensation set in advance, fair market value, not based on referrals
• a legal activity
• commercial reasonableness
Contracting Guidelines: Legal Basis

- Require Written Financial Conflict of Interest Disclosure
Industry Guidelines: Conflict of Interest

Consensus Statement on Conflict of Interest Policies for Academic Institutions

- Developed by NIH-funded medical schools in January 2001
- Purpose is to clarify, strengthen and add structure to institutional conflict of interest policies governing collaboration between faculty and industry
Industry Guidelines: Conflict of Interest

- Written policy on financial interests related to research
- Application to all involved
- “Financial Interest” includes fees, gifts, honoraria, consulting arrangements, equity interests, stock options, directorships, special relationships with potential for personal material gain
- Disclosure Required
Contracting Guidelines: Legal Basis

Require Meetings
Industry Guidelines: AMA Guidelines

- Provides guidance on research related travel
  - genuine research purpose
  - payment only of “reasonable expenses”
  - no exotic location
  - modest hospitality only
  - meeting must be appropriate size to accomplish research purpose, no larger
  - not for promotional purposes
Industry Guidelines: AMA Guidelines

Definition of “Genuine Research Purpose”

- valid study protocol
- recruitment of physicians with appropriate expertise/qualifications
- recruitment of appropriate number of physicians
Contracting Guidelines: Legal Basis

Billing Federal Health Care Programs
Federal False Claims Act (‘‘FCA’’)  

- FCA prohibits:  
  A person from ‘‘knowingly’’ submitting claims or making false record or statement in order to be paid from the federal government  

- FCA defines ‘‘knowingly’’ to mean that a person:  
  → Has actual knowledge of information  
  → Acts in deliberate ignorance of the truth/falsity of information  
  → Acts in reckless disregard of the truth/falsity of information  

- Violators of the FCA:  
  Civil penalty for each claim of $5,000-$10,000 plus three times the amount of damages to the federal government.