Auditing & Monitoring Conflict of Interest

• What is a Conflict of Interest?
• What is a Conflict of Commitment?
• Key Regulatory Requirements?
• Why do we Care?
• What are the Goals?
• Elements of Effective Mitigation
• Monitoring
• Auditing / Investigation
What is a Conflict of Interest?

- Conflicts may be individual or institutional in nature.
- **Individual**: Webster’s defines “conflict of interest” as “a conflict between the private interests and the official responsibilities of a person in a position of trust.”
- **Institutional**: There’s no formal definition but I define it as “a situation that contradicts the mission or best interests of an organization (and its investors/stakeholders).”

What is a Conflict of Interest?

The AAMC’s Task Force on Financial Conflicts of Interest in Clinical Research discussed institutional conflicts as follows:

- “An institution may have a conflict of interest in human subjects research whenever the financial interests of the institution, or of an institutional official acting within his or her authority on behalf of the institution, might affect – or reasonably appear to affect – institutional processes for the conduct, review, or oversight of human subjects research.”
What is a Conflict of Commitment?

- There is no formal definition, Webster’s defines:
  - conflict as “competitive or opposing actions of incompatibles,”
  - “conflict of interest” as “a conflict between the private interests and the official responsibilities of a person in a position of trust,” and
  - commitment as “an act of committing to a charge or trust” and “an agreement or pledge to do something in the future.”
- So, we can define it as “a conflict between the private commitments and the official responsibilities of a person in a position of trust.”

Key Regulatory Requirements

- IRS – Intermediate Sanctions
- NIH – Requires Grantees and Investigators to Comply with the Requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought."
- STARK – Physician Referrals
- State Law – E.g., California Corporations Code - Self-Dealing Transactions (and indirectly Corporate Practice Medicine Prohibitions)
- Your Organization’s Specific Requirements
Why do we care?
We all share in two common beliefs:
The Ethic of Reciprocity

No Man Can Serve Two Masters

Why do we care?
Because
"our personal activities could unduly influence a professional judgment, or bring our primary obligations into question" ¹

And
"the problem occurs when conflicts are not appropriately disclosed and when conflicts are allowed to bias organizational decisions, research, teaching, or practice." ²

Why do we care?

Because

We don’t want real or perceived compromises of our primary obligations (i.e., mission) to provide quality patient care, research, education and training, and community service.

We don’t want real or perceived compromises of our primary obligation (or charge) to protect the rights and welfare of people who agree to voluntarily participate in research conducted at our organizations.

We don’t want it decided by the courts.

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Ezekial J. Emanuel, M.D., Ph.D.
NIH Dept of Clinical Bioethics

“Conclusions of trials were significantly more likely to recommend the experimental drug as the treatment of choice if the trials were funded by for-profit organizations.”

— Nielsen et al. JAMA 2003

Money Affects:
Research, Judgments & Dissemination
Why do we care?
To Help You and Your Organization stay:
Out of the press, "Student Loan Conflicts Of Interest Eyed"
- Education News, April 6, 2007
Out of the red,
Out of jail!

Some Headlines to Avoid
- WSJ – “When Doctors Go To Class, Industry Often Foots the Bill”
- InfactCanada – “Research and conflict of interest: how ‘truthful’ is corporate funded research”
- NewsMax.Com – “Conflict of Interest Questions Raised in GAO Enron Lawsuit”
- WSJ – “Student Doctors Protest Largess of Drug Makers”
- WSJ – “Desperately Seeking Kids for Clinical Trials”
- Associated Press – “Doctor Charged With Criminal Conflict Of Interest”
Some Headlines to Avoid

JUSTICE SCALIA REFUSES TO RECUSE HIMSELF OVER TRIP WITH CHENEY...

HUNTING ACCIDENT.

CREDIBILITY

What Are The Goals?

Ezekial J. Emanuel, M.D., Ph.D.

• Conflicts Cannot be Totally Eliminated
  – The Goal is to Minimize Them

• Protections Aim To Reduce:
  – The Likelihood of Harm
  – The Magnitude of Harm

• Three Main Protections:
  – Disclosure
  – Management & Oversight
  – Prohibition
What Are The Goals?

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- Conflicts Cannot be Totally Eliminated
  - The Goal is to Minimize Them
- Protections Aim To Reduce:
  - The Likelihood of Harm
  - The Magnitude of Harm
- Four Main Protections:
  - Disclosure
  - Management & Oversight
  - Prohibition
  - Recusal\Avoidance

Elements of Effective Mitigation

1. Definition
2. Policies & Procedures
3. Participants
4. Collection
5. Review and Oversight
6. Education and Communication
7. Leverage
8. Documentation
Definition

• Verify that organizational policy identifies what constitutes a conflict of interest and the types of issues it addresses.
• Some questions to consider:
  • At what level and what time does a gift create a conflict?
    – We’d all agree that a new car could definitely influence a decision to steer a purchase to a certain vendor, promote or purchase a certain drug, or alter research results. However, would a $100 bottle of wine create such a conflict?

What about?
• 1 share of stock versus 30,000?
• Potential future earnings of intellectual property?
• A trip to Hawaii? Fiji? Tahiti?
• Box seats at the Superbowl?
• $500 per hour for expert witness testimony or analysis relative to a lawsuit?
• Presenting Pharma Sponsored Research?
• Scientific Advisory Board Membership?
• Conference gifts like pens and calculators?
• $5,000 annually to sit on a board?
• Organization Funded “Consultant” Lunches?
Definition

What about?

• A nurse practitioner owns a $25,000 investment in a medical supply provider?
• The Director of Purchasing owns a $25,000 investment in medical supply provider?
• A medical staff member who is a private attending physician owns $100,000 investment in a medical supply provider?
• The Chair of the Medical Staff owns $100,000 investment in a medical device manufacturer?
• A part-time faculty member has a private practice?
• A full-time faculty member has a private practice?

Definition

What about you personally; would you?

• Rely on the local Ford dealer to tell you the best vehicle make and model for your needs?
• Trust your auto mechanic to use only original manufacturer replacement parts if they own a replacement parts factory?
• Put your money in a bank that invests all its holdings in derivatives?
• Consult a financial planner with no credentials or who has a significant vested interest in one specific brokerage firm?
• Hire a nanny or baby-sitter who is on the Megan’s Law list?
• Trust your doctor to prescribe the best cholesterol medicine for you if they have a significant interest in or are receiving research financing from Pfizer?
• Participate in research conducted by a researcher who is incentivized only on the number of research participants?
Definition
What are some of the types of conflicts that should cause concern?
• Related Party Investment Activities
• Gifts
• Entertainment / Travel
• Honoraria
• Consulting Activities
• Outside Businesses
• Relationships w\Government Entities
• Use of Corporate Assets/Information

Definition
What are some of the types of conflicts that should cause concern?
• Nepotism / Family Ties
• Institutional Relationships
• Intellectual Property
• Speakers Bureaus
• Pharmaceutical Companies
• Med\Surg Supply Vendors
• Equipment Vendors
• Relationships with Grant Sponsors
Policies & Procedures
COI policy should address:
• The conflict definitions
• Who must disclose
• How and how often they must disclose
• What they must disclose
• Process for review of disclosures made
• What will happen if they don’t comply
• What documentation must be maintained
• Disclosure during recruitment or upon hire
• When recusal is necessary
Policies

IRS Sample Policy:


NIH Guidance Related to Research:


Participants

- Recognize that everyone must avoid conflicts but that only certain individuals need to report in a positive periodic manner:
  - Usually those in decision making roles
- Understand the regulations
- Understand your corporate make up
- Understand what can be reasonably accomplished:
  - Review Takes Time
  - Disclosures Often Require Follow-up
  - Documentation Must be Maintained
Collection

• Establish a process that ensures 100% completion by all “participants” in a timely manner
• Track issuance and completion
• Establish a follow-up mechanism for “stragglers”
• Establish a review mechanism that ensures submissions are complete

Review and Oversight

• Involve knowledgeable individuals
• Review Disclosures and Non-Disclosures
• Decision Criteria:
  – How are conflict decisions rendered
• Establish Actions to be Taken
• Follow-up on Actions Taken
• Documentation
Communication and Education

• Communicate Disclosures Made to those who need to know
• Communicate Decisions Regarding Disclosures to those who need to know
• Educate and Communicate the Policy and Requirements Regularly (e.g., orientations, etc.)
• Provide Focused Training as necessary

Leverage

Complying with a conflict of interest policy is not on the top of everyone’s list

So, Be Creative….

• Make It Easy
• Provide Incentives
• Enforce Discipline
• Communicate Success
Documentation

Disclosures, Review and Decisions are Confidential. Be sure to document:

• Disclosures (made and not made)
• Review of Disclosures
• Decisions Rendered
• Follow-up
• Conflict Management Actions
• Reporting

Monitoring Techniques

• Are you as the Corporate Compliance Officer Part of the Conflict of Interest Review Structure?
• Are routine updates made to the corporate compliance committee?
• How are changes in activities that would require disclosure and conflict assessment identified and evaluated?
• How are disclosure reviews and related actions documented?
• Are proactive measures in place: e.g., recusal requirements, questioning of key applicants before/upon hire?
Monitoring Techniques

- Corporate Compliance should be involved in the process.
- Periodic mtgs w/ clinical department heads.
- Education on policy.
- Internet monitoring.
- Random participant selection and analysis of internet and other resources for comparison to disclosures.
- Random selection of individuals required to be participants to COI files.

Auditing Techniques

- Understand the laws, rules and regulations that impact your organization.
- Compare organizational policies to applicable laws, rules and regulations for policy gaps.
- Ensure your policies address the effective elements of conflict mitigation.
- Identify the governing body(ies) responsibility for COI review in your organization.
- Understand and document the conflict reporting and review process in your organization. Match actual process to regulations and policies.
Auditing Techniques

• Obtain the latest reports. Verify reported information to source documents. For example, number of reported participants, nature of disclosures, actions taken, etc.

• From the policies, identify the nature and source for participant identification. Based on this criteria, select samples from applicable source systems (e.g., HR system, research system, medical staff rosters, etc.) and verify that disclosures were pursued and reviewed for those individuals.

Auditing Techniques

• Where participant gaps were identified between regulations and policy, identify the nature and number of individuals not included.

• Select a sample of submitted disclosure forms:
  – Verify that where disclosures were made, a review of such was documented and any resulting actions were taken.
    • Ensure that documented conclusions appeared reasonable. Challenge accordingly.
  – Where similar disclosures are identified across participants, verify that actions taken and conclusions reached were consistent.
Investigation Techniques

Disclaimer: I am not affiliated with the Association of Certified Fraud Examiners, neither as an officer or a member.

RECOMMENDATION:

Association of Certified Fraud Examiners (ACFE)

Course Titled
“Investigating Conflicts of Interest”