Managing Conflicts of Interests in Healthcare, Education and Research

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Agenda

- Introduction & Recent Headlines
- Definitions
- Regulatory Framework
- Approaches
- Overlap With Other Compliance Areas
- Future Trends
Part I:

Background and Recent Headlines
COI – Ethics & Compliance

- Rules & Regulations
- Guidelines
- Processes
- Few Bright Lines
- “NY Times Test”
- Good Sense
- Ethics

From: The Ethicist, NY Times
COI issues are ubiquitous

- Not only Research Education & Healthcare
- Politics
- Law
- Purchase & Acquisition
- Employment
- Family
- Everyday Life
Target of inquiry by Senator Charles Grassley

- Senator Charles Grassley
- Patron saint of whistleblowers
- Would-be regulator of hedge funds
- Critic of the SEC
- Muckraker
- Investigating drug companies’ payments to psychiatric investigators at prominent universities
UCLA Surgeon Didn't Report Payments
By David Armstrong & Thomas M Burton – The Wall Street Journal
May 28, 2009

- Dr. Jeffrey Wang, Chief of Spine Surgery
- Paid $459,500 by Medical Device Companies from 2004 - 2007 (while testing their devices in some cases)
- Repeatedly failed to disclose to UCLA ("consistently checked no")
- On the board of the North American Spine Society
- No comments
Grassley Ups Total of Undisclosed Fees Paid to Prof by Glaxo

By Allecia Mundy – The Wall Street Journal

May 4, 2009

• Dr. Karen Wagner, Chairman of Psychiatry, UT Health, Galveston

• Paid $230,000 by Glaxo SmithKlein (+ a trip to Paris) while testing their drugs in children

• “…discrepancies in Dr. Wagner’s [disclosure] reports.”

• Recipient of a NIH grant Paxil use in teenagers

• Eight months after receiving Sen. Grassley’s letter, UT said they have been investigating the issue for two weeks.
“Diagnosis: Greed”
Judith Warner - New York Times
October 9, 2008

- Prompted by story of Dr. Charles Nemeroff
  - “…ever-unfolding saga of greed…”
  - “…Nemeroff’s story is hardly unique…”

- The latest in a string of stories
  - Drs. Joseph Biederman & Timothy Wilens – Harvard
  - Alan Schatzman – Stanford (President-elect of the American Psychiatric Association)
  - Melissa DelBello – University of Cincinatti

- “…tip of the iceberg.”

- **No one can be trusted.**
Part II:

Conflict of Interest Definitions
A Potential for COI Exists if an Individual...

- Receives research support from, or evaluates therapies of a business in which he or she or a family member has an ownership interest (stock/options/deferred compensation)
- Receives payments (consulting fees/honoraria/other) from an outside entity
- Uses institution’s resources for an outside entity, provides current or future rights to an entity for institution’s IP
A Potential for COI Exists if an Individual…

- Accepts compensation for serving on an advisory or governing board
- Can influence institution’s business decisions with an entity he or she has an ownership interest in
- Agrees to limits on publication, peer-review of research
- Agrees to favorable research results
- Conducts research with an invention (any IP) involving possible future royalties or other cash flows
- Supervises a member of his or her immediate family
Institutional Conflicts of Interest

- Any situation (often financial)
- Apparent or actual effect on institutional processes involving the conduct, review, or oversight of research
- Typical Scenario: Institution has a financial interest in a technology/company/invention and the research is conducted at that institution
- Can involve study finances, oversight, outcomes, reporting
Non-Financial Conflicts of Interest may also interfere with researchers’ decision-making

- Career Advancement
- Personal Advancement
- Favoritism – Family and Other
- Scientific Bias
- Glory – PR

Not easily identifiable or manageable
Conflicts of Interest Defined

- A situation in which financial or other considerations have the potential to compromise or bias professional judgment and objectivity.

- Involves the use of authority for financial or other gain.

- May involve both individuals and institutions.

- Planning, conduct, reporting of research.

- *Not* a statement of wrongdoing.
• “Conflicts of interest are ubiquitous and inevitable in academic life, indeed, in all professional life. The challenge for academic medicine is not to eradicate them, which is fanciful and would be inimical to public policy goals, but to recognize and manage them sensibly and effectively.”

• David Korn JAMA 284, 2234-2236, 2000
Many situational factors characterize any potential conflict of interest

- Primary vs. secondary interests
- Institutional or individual conflicts
- Real vs. perceived conflicts
A conflict of interests exists when a secondary interest conflicts with a primary interest.

Primary Interest
“Do what is right”

Secondary Interest
“Personal Financial Gain”

NOTE: A conflict of interests is NOT a statement of wrongdoing.
Secondary interests conflict with primary interests in a number of circumstances

- Primary interest: Stay late to take care of the patient
- Secondary interest: Go home early to be with one’s family

- Primary interest: Fully explain the study to a subject
- Secondary interest: Get the subject enrolled

- Primary interest: Report an adverse event
- Secondary interest: Get royalties on the patent
How to resolve tensions that exist between primary and secondary interests?

- Conflicts where we expect moral people to defer to the primary interest.
- Conflicts where we expect moral people might defer to the secondary interest.

The difference between these two is:
- Fluid and subject to debate
- Based in part on societal and peer expectations
- Based in part on the risk of yielding to the secondary interest
- A serious decision that all organizations must make
Either *individual* or *institutional* interests may create potential conflicts

- **Individual**
  - Investigators (PI, Co-I, Postdocs, Students)
  - Study Coordinators
  - Research technicians, data analysts
  - IRB members
  - Anyone involved in technology transfer
  - Anyone involved in procurement, education, healthcare

- **Institutional**
  - Financial & IP holdings of the institution
  - Allocation of resources for research
When addressing real vs. perceived conflicts of interest...

...Perception is Reality
Conflicts of Interest introduce a number of added risks to any research endeavor

- Human Subject Protection
- Research Integrity
- Individual Integrity
- Public Trust in Institution
- Research Participation
- Public Trust in Research
- Progress in Biomedical Research
- Funding and Reimbursement
Part III:
Regulations and Guidance
Multiple areas of federal regulations address Significant Financial Interest

- PHS
- HHS
- FDA
- NSF
PHS regulations addressing significant financial interests are found within 42 CFR 50, Subpart F

- Disclosure of any *significant financial interest* in entities that might be financially affected by the research

- Designate an *institutional official* – solicit and review the financial disclosure statements made by investigators

- Applies if institution has an FWA
PHS*- Significant Financial Interest

- Income (salary, royalties and other payments) which when aggregated for the investigator (spouse or dependent children) exceeds $10,000 over twelve months or

- An equity interest (including spouse and dependent children) in excess of $10,000 or 5% ownership in a single entity

*FDA regs are different – governing SPONSORS, not Institutions
NIH Grants Policy Statement

Approaches to Handling COI

• Applies to any entity funded by NIH
• *Public disclosure* of significant financial interests
• *Monitoring* of research by independent reviewers
• *Modification* of the research plan
• *Disqualification* from participation in all or part of the research
• *Divestiture* of significant financial interests
• *Severance* of relationships that create actual or potential conflicts
PHS – Limited COI Regulations

- Only the reporting of *financial* interests
- No requirement for recusal by the researchers with a COI
- No requirement for notification to research subjects
COI and Human Research Protections
COI and Human Research Protections

- 45 CFR 46.107(e) & 21 CFR 56.107(e)

- If there is a COI – no participation in initial or continuing review – except to provide information researchers with a COI

- Recusal is obligatory
Part IV: Approaches to Managing COI
How to Deal With COI?

• David Armstrong, The Wall Street Journal:

  – HHS requirement… to manage, reduce or eliminate conflicts

  – “How they do so is left largely to them.”
How to Deal With COI?

Bright Line
COI Continuum

- Risk
- Permissive
- Restrictive
How to Deal With COI?

• Policy or Policies
  – Research
  – Education
  – Procurement
  – Healthcare
Goals of COI Policy

• Protect research participants
• Protect the integrity of the research
• Protect the institution & faculty
  – Funding Status
  – Litigation
  – Reputation/Public Image
• Reconsideration & Noncompliance
• “Good Policy Practices”
Elements of COI Policy

- Purpose & Position & Principles
- Definitions, Limits
- Who Must Disclose
- Examples
- Process
- Responsibilities
- Consequences
How to Deal With COI?

- Standard Operating Procedures
  - Annual Disclosure
  - Ongoing/Incidental Disclosure
  - Analysis: Standards, Thresholds
  - Administrative Processes
  - COI Committee
  - Management Plans
  - Tracking and Monitoring Plans
Overview of Conflict-of-Interest Vetting and Management Process
Institutions must ensure that several identification and disclosure mechanisms are in place

- Formal – Annual & Incidental
- Must be Required
- Define Exemptions
- Project-Specific Disclosures
- Informal Disclosures (Document)
- Push and Pull
- Disclosure by Hotline
Policies & procedures must define to whom the financial disclosure requirements apply

- Principal Investigators
- Other Investigators
- Independent Contributions
  - Postdocs
  - PhD Students
  - Data Analysts
- Coordinators
- (Purchasing, Board, etc)
Financial Disclosure

Conflict-of-Interest Disclosure Form

I promise this is true and accurate

John Q Researcher

Financial Disclosure Form

I promise this is true and accurate

John Q Researcher
Policies & procedures must describe how financial disclosures are analyzed

- Is there a conflict?
- Real or perceived?
- Potential for future conflict?
- Federal thresholds
- Consistent with policy
- Simple or complex?
Simple conflicts of interest can be addressed in a straightforward manner within policies & procedures

- Exceed $$ Thresholds
  - but not by much

- Garden Variety
  - honoraria for speaking
  - consulting arrangements

- Standard Management Plans
  - disclosure

- Automated (Predetermined)
More complex conflicts of interest often require additional disclosure and/or a customized approach

- $$$$$ (Payments or Equity)
- Intellectual Property
- Private Equity
- Supervisory Relationships
- Institutional COI
COI committee membership should also be addressed within institutional policies & procedures

- Administration
- Legal
- Faculty
- IRB Member
- Community
- No Committee
Documented COI committee process should clarify committee operations

- Quorum Requirements
- Discloser Participation
- Plan Development
- Voting
- Minutes
COI management plans may include a range of actions depending on the nature of the conflict

- Manage or Reduce
- Eliminate (Recusal or Divestiture)
- Written
- Acknowledged
- Appeal or Reconsideration
- Shared Inside & Out (NIH)
- Monitored
- Audited
Elements of COI Management Plans…

- Disclosure to Participant
- Firewall
- Limits to Activities
- Limits to Role (PI)
- Independent Monitoring
- Reduced or End of Payments
- Partial or Complete Divestiture
- Individual Recusal
- Complete Recusal
How to manage the COI Management Plans?

• Database
• Track By Conflict
• Include Actual Sample Public Disclosures
• Flags & Ticklers
• Milestones
• Harmonize With IRB
COI Management – Broken?

- Press – yes
- Sen. Grassley – yes
- Perhaps – at some institutions
- Restore public’s trust
- Fix
- Improve
- Bolster
COI Management – Weakest Link

- Deception (dead end?)
- Consequences
- Public Records
- Industry Touch-points
- Contracts
- Purchasing
- Clinical Trials
- Donations
- Institutional Standards
Part V: Future Trends
Pending Legislation

- State-by-state patchwork
  May 20, 2009

Green Mountain for Docs? Vermont Wants Data on Industry Pay

- Federal legislation may help
  Physician Payments Sunshine Act
The Physician Payments Sunshine Act (S.301)

• Requires drug, biologic, and medical device manufacturers to report certain gifts and payments ("transfers of value") made to physicians.

• The information will be registered in a national and publicly accessible online database.

• Companies failing to report incur financial penalties.
The Physician Payments Sunshine Act (S.301)

- Companies will report
  - Name
  - Business Name
  - Address
  - Value of the payment or transfer of value
  - Dates of the payments or transfers
  - Description of the form of payment or transfer of value
Items to be reported

- Consulting Fees
- Compensation for services other than consulting
- **Honoraria**
- Gifts
- Entertainment
- Food
- Travel
- Education
- Research

- Charitable Contributions
- Royalties or licenses
- Current or prospective ownership or investment interests
- Compensation for serving as a faculty member or as a speaker for a continuing medical education program
- Grants
Disclosure Data
What Can We Expect?

- Greater focus by government
- Continuing focus by the press
- NIH audits
- OIG involvement
- Plaintiffs
How can you ensure that COI review at your institution accommodates these trends?

- Assess compliance with regulations
  - Identify individual COI (board members, executives, faculty, staff)
  - Identify institutional COI
  - Evaluate management procedures

- Recommend changes to P&Ps

- Identify & implement best practices

- Provide training
- Stay informed of new rules
Thank you!

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Part VI:
Hypothetical Scenarios
Hypothetical Scenario #1

- Dr. Bones – orthopedic surgeon (private)
- High-volume, high-margin knee repairs
- Implants the KneeJerk™ device nearly exclusively
- KneeJerk™ device is the most expensive
- Participates in the KneeJerk™ Registry
- Registry pays Dr. Bones up to $1,250/complete record
Hypothetical Scenario #1 (continued)

- Is Dr. Bones being paid to order the KneeJerk™ device?
- What if the payment was in the form of an Unrestricted Educational Grant?
- What if Dr. Bones had invented the device?
Hypothetical Scenario #2

- Dr. Valentin Ventriculo – cardiologist
- Thought leader
- Paid consultant to Implantronics – a medical device manufacturer
- Preclinical experiments & clinical trial design
- Invited to be one of 10 PIs
Hypothetical Scenario #2 (continued)

- Patients enrolled
- Belated disclosure
- Not in ICF
Hypothetical Scenario #2 (continued)

- Is the doctor conflicted?
- Does it matter if he is employed by hospital?
- Is the conflict limited to research?
- Are remedial steps necessary?
- Is administrative action necessary?
Hypothetical Scenario #3

- Dr. Pons – Brain Surgeon
- Brain biopsies and resections
- Wants to establish a brain tissue repository
- Future research
- Future therapies & diagnostics
- “It’s a goldmine!”
Hypothetical Scenario #3 (continued)

- Protocol, consent, IRB
- Remnant Specimens
- Is there a conflict?
- Who can obtain consent?
- Who determines remnant status?
- Should Dr. Pons know who consented?
- What should be disclosed?
Hypothetical Scenario #4

- Dr. Tammy Floo – ID Specialist
- University Professor
- Thought Leader
- Research with BigPharma
- Consultant to BigPharma
- Unique & Valuable Advice
- Well Compensated by BigPharma
Hypothetical Scenario #4 (continued)

- University Salary = $5,800/week
- Big Pharma – 1 week/year
- $35,000 Consulting Fees
- Paid Directly to Dr. Floo
- Donated to University
Hypothetical Scenario #4 (continued)

- Is there a conflict?
- Is it managed by the donation?
- Donation in Management Plan?
- Institutional Conflict?
- What if payments to University?
Hypothetical Scenario #5

• Ms. Ivana Moore-Cash – Med School CFO
• Evaluating Tech Transfer ($$)
• License Valuation
• Risks & Rewards
• First-in-Man Phase I Studies
• “It’s a goldmine!”
Hypothetical Scenario #5 (continued)

- Wants to build Phase I unit
- Raise valuation before selling licenses
- Do the work at the University
- Go for the glory
- Go for the gold
Hypothetical Scenario #5 (continued)

• Is there a conflict if there is no license sold yet?

• What would be the reaction of the press if disaster occurs with a healthy volunteer?

• What if the university is in an area with many disadvantaged people and recruits heavily among them?