Conflicts of Interest in Research, Education and Healthcare

Leah Guidry & Stuart Horowitz
Conflicts Of Interest

• Introduction & Recent Headlines
• Definitions
• Approaches
• Overlap With Other Compliance Areas
• Hypothetical Scenarios
COI – Ethics & Compliance

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

From: The Ethicist, NY Times
Ubiquity of COI Issues

• Not only Research Education & Healthcare
• Politics
• Law
• Purchase & Acquisition
• Employment
• Family
• Everyday Life
COI in The NY Times

Clinton Not Ready to Release Tax Returns
By THE ASSOCIATED PRESS  Published: February 12, 2008

Judge Removes Lawyer for Kerik From His Case
By ALAN FEUER  Published: January 25, 2008

Inquiry of Study Abroad Programs Grows
By JONATHAN D. GLATER  Published: January 21, 2008

Researchers Go Unchecked, Report Says
By GARDINER HARRIS  Published: January 19, 2008
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.
Types of Conflicts Of Interest

- **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
Conflicts Of Interest

Real

Perceived

Perception is Reality
COI – Risks

• Human Subject Protection
• Research Integrity
• Individual Integrity
• Public Trust in Institution
• Research Participation
• Public Trust in Research
• Progress in Biomedical Research
• Funding and Reimbursement
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 providing 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

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

Not easily identifiable or manageable
COI – Compliance

- 42 CFR Part 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
Significant Financial Interest
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
How to Deal With COI?

HHS requirement… to manage, reduce or eliminate conflicts

“How they do so is left largely to them.”

David Armstrong, The WSJ
How to Deal With COI?

Bright Line
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
Financial Disclosure

- Formal – Annual & Incidental
- Must be Required
- Define Exemptions
- Project-Specific Disclosures
- Informal Disclosures (Document)
- Push and Pull
- Disclosure by Hotline
Financial Disclosure – Who?

• 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
Analysis of Disclosure

• Is there a conflict?
• Real or perceived?
• Potential for future conflict?
• Federal thresholds
• Consistent with policy
• Simple or complex?
Simple Conflict of Interest

- Exceed $$ Thresholds
  - but not by much
- Garden Variety
  - honoraria for speaking
  - consulting arrangements
- Standard Management Plans
  - disclosure
- Automated (Predetermined)
Complex Conflict of Interest

- $$$$$ (Payments or Equity)
- Intellectual Property
- Private Equity
- Supervisory Relationships
- Institutional COI
- Often require additional disclosure
- Requires a customized approach
COI Committee Membership

- Administration
- Legal
- Faculty
- IRB Member
- Community
- No Committee
COI Committee Process

- Quorum Requirements
- Discloser Participation
- Plan Development
- Voting
- Minutes
COI Management Plans

- 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 Participants
• Firewall
• Limits to Activities
• Limits to Role (PI)
• Independent Monitoring
• Reduced or End of Payments
• Partial or Complete Divestiture
• Individual Recusal
• Complete Recusal
Managing COI Management Plans

- Database
- Track By Conflict
- Include Actual Sample Disclosures
- Flags & Ticklers
- Milestones
- Harmonize With IRB
Hypothetical Scenario

- 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

• 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

• Dr. Valentin Venticulo – 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

- Patients enrolled
- Belated disclosure
- Not in ICF
Hypothetical Scenario

• 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

- 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

• 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

• Dr. Tammy Floo – ID Specialist
• University Professor
• Thought Leader
• Research with BigPharma
• Consultant to BigPharma
• Unique & Valuable Advice
• Well Compensated by BigPharma
Hypothetical Scenario

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

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

• 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

• 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

• 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?
What Can We Expect?

- Greater focus by government
- Continuing focus by the press
- NIH audits
- OIG involvement
- Plaintiffs
COI Review at Your Institution

- 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
Thank you!

Iguidry@huronconsultinggroup.com
shorowitz@huronconsultinggroup.com