

Conflict of Interest Reporting

KUMC Office of
Compliance

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KUMC Human Research Protection Program

- Human Subjects Committee (the IRB)
- HIPAA
- **Conflict of Interest Committee**
- Data and Safety Monitoring Board
- Radiation Safety Committee
- Institutional Research Safety Committee

Conflict of Interest

- Refers to situations in which financial interests may compromise, or have the appearance of compromising scientific judgment, integrity of research data or the safety and welfare of research volunteers

Conflict of Interest Background

- 1990's – Individual conflict of interest issues gain government and public attention
- 1995 – PHS/NSF regulations on individual conflicts of interest (42 CFR Part 50 Subpart F)
- 1999 – Death of Jesse Gelsinger
- 2000 – NIH Meeting on Conflicts of Interest in Clinical Trials
- 2001 – DHHS Draft Interim Guidance includes reference to individual and institutional conflicts of interest

Comments on Gelsinger Case

- Ernest Prentice, PhD,
University of Nebraska Medical Center
Chair, Secretary's Advisory Committee
on Human Research Protections
(SACHRP)

Question

- How important is terms of legal liability is the financial presence of a conflict of interest on the part of either the investigator or the institution?

The Gelsinger Case

- Gelsinger Estate

v.

Univ. Pennsylvania,
et al.

Phila Co. Penn., CT. Com. Pl:

No. 000901885, 09-18-00

Gelsinger Factual Background

- JG suffered from a mild form of ornithine transcarbamylase (OTC) deficiency.
- JG enrolled in a gene transfer (“therapy”) trial at the University of Pennsylvania.
- On 09/13/99 JG was injected with an adenoviral vector to transfer the OTC gene.
- By 09/14/99 JG was experiencing massive organ failure and became comatose.
- On 09/17/99 JG was declared brain dead

Gelsinger Complaint (Central Issues)

Plaintiff's Contention

- JG did not meet the study enrollment criteria; his blood ammonia levels were too high.
- Defendants failed to obtain JG's informed consent.
 - The consent form failed to fully disclose the risks of the research.
 - The consent form failed to disclose the financial interests of the PI and the University in the Biotech Company (Genova), the sponsor of the study.
- Defendants violated NIH/OBA guidelines and HHS regulations.

The Defense

- “There is no defense.”

Gelsinger Case Outcome

- The Gelsinger case was ultimately settled out of court on December 7, 2000.
- The amount of the settlement is not public but is estimated to be over \$10 million.

Question

- What lessons should we have learned from the Gelsinger case?

Answer

- Financial COI can potentially increase the risk to which human subjects are exposed and impact the public's trust.
- Financial COI should be disclosed to the institution and managed appropriately.
- The PI should not have a *significant* financial interest in the company sponsoring the research.
- The consent form should disclose financial interest of the PI, and the institution, using the “reasonable person standard.”

The New Frontier

- 2001-2002 – Continued focus on individual conflict of interest issues with added awareness of institutional issues (AAU, AAMC reports—on resource list)
- May 2004 – DHHS Final Guidance Document includes both individual and institutional issues.
- Current –DHHS guidance and voluntary support by academic associations

NIH Hot Topics Spring 2006

- NIH Proactive Compliance Site Visits
 - Roles and Responsibilities
 - Training and Education
 - Financial Management
 - **Financial Conflict of Interest**
 - Invention and Patent Reporting
 - Administering and Overseeing Clinical Research

Hot Topics Continued

- NIH Targeted Site Reviews: Financial Conflict of Interest (FCOI)
 - Response to increasing public interest
 - New initiative to determine if institutions have fully implemented FCOI regulations and
 - Complied with reporting requirements

Federal COI Reporting Requirement

- At time of application: investigators submit significant financial interests to institution
- Prior to expenditure of funds: institution reports any financial COI to NIH & assures it has been managed, reduced or eliminated
- Financial COIs identified after initial report must be reported within 60 days of identification & be managed, reduced or eliminated

NIH Definition of Investigator

- The PI and any other person responsible for the design, conduct or reporting of research
- Term includes investigator's spouse and dependent children
- Not just the PI, it can be **ANYONE** (key personnel, lab technicians etc.) who is involved in the design, conduct or reporting of sponsored research

Other Funding Sources

Other funding sources, including pharmaceutical companies have similar financial conflict of interest reporting requirements

University of Kansas Board of Regents COI Reporting Requirements

- http://www.kansasregents.org/download/aca_affairs/policymanual/kborpm110702.pdf
 - Addresses research and educational issues
 - Independent observer might think actions determined by personal gain
 - Appearance of conflict depends on situation and not necessarily on the character of the individual
 - COI will occur as technology is developed and consulting increases
 - Set reporting level

Disclosure Form

- Conflict of Interest Disclosure Form
- Reporting levels: >\$10,000 or 5%
- Ownership, Compensation, Office, Fees and Commissions
- Family: spouse, children, siblings, parent, equivalents by marriage (in-laws), or other household members

Potential Individual Conflicts of Interest

- Financial, managerial or ownership interest by individual or family member in sponsoring company
- Research on product developed by company for which researcher is a consultant
- Research on a technology in which researcher holds equity or receives a share of royalties

Additional Potential Individual Conflicts of Interest

- On board of directors of a business which supports individual's research
- Research in which the sponsor dictates the content or timing of publication
- Use of students to perform services for a company in which a faculty member has an ownership interest
- Purchase of equipment, supplies or technology from a firm in which the individual has a financial or other interest

Management Strategies

- GOAL: Manage and protect human subjects
--not stop research!!
- Ideas???

Management of *Individual Conflict of Interest*

- Determine if relationship causes a conflict
- Develop plan with researcher
- Disclosure in consent form
- Study done by a PI with no conflict
- Retain the researcher as PI if “compelling circumstances”
- Modify research plan

Management continued

- Consenting done by someone with no conflict
- Remove cause of conflict:
 - Sell ownership interests/place holdings in escrow
 - Resign office or board position
 - Reduce or eliminate compensation/fees
- Oversight by DSM-EC
- Disclosure of conflict at presentations and in publications

Potential Institutional Conflicts of Interest

- University equity holdings or royalty interests in company sponsoring research
- University holds equity or receives royalties for product/technology being studied
- Industry contributions for clinical fellowships, facilities or endowed chairs
- Financial interest or board membership by institutional officials which could influence decisions made for the university

Management of *Institutional* Conflict of Interest

- Disclosure in consent form
- Clinical trials conducted at other institutions if technology developed at KU/KUMC
- Unaffiliated members on Conflict of Interest Committee

COIC Membership

- http://www2.kumc.edu/researchcompliance/rosters/COI_Committee_Roster_2005_08_18.pdf
- New unaffiliated member: Mr. Sam Malsbary

Benefit of Management Plan

- Increases subject safety by providing information at time of consenting so subject can give an informed consent
- Increases study integrity
- Addresses current and future questions related to potential and/or actual conflict of interest
- Assists researcher in meeting federal reporting requirements
- Protects reputation of researcher and institution

Consequences of Noncompliance

- Physical/monetary/psychological harm to research subjects, employees, students or trainees
- Degradation of KUMC reputation, loss of public trust
- Additional regulatory oversight resulting in greater scrutiny, expanded programmatic requirements and greater institutional investments

Conflict of Interest Disclosure Forms

- What happens to the forms? 2,534 for FY 2006
- Who has access to the information—database and forms?
- Screening process of 81 Form Bs
 - Administrative
 - Chair
 - Committee
- Management plans -- 24
- Why would a faculty/unclassified staff person not complete the reporting when requested???

Contact Information

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Questions?