

Conflict of Interest

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Jessie Gelsinger

- Eighteen year old subject enrolled in a University of Pennsylvania trial designed to test gene therapy for genetic liver disorder



Jessie Gelsinger

- Following administration of large dose of genetically-engineered viruses, Gelsinger experienced multisystem organ failure and died in September, 2000. Federal investigation following the incident revealed that monkeys given similar injections by Penn researchers before Gelsinger enrolled had experienced similar reactions, not reported to FDA, and not mentioned on consent form.



Jessie Gelsinger

- NIH sent a circular reminding gene therapy investigators that all adverse events must be reported; as a result, 652 new adverse event reports were received from 80 institutions, including reports of seven prior deaths.



Jessie Gelsinger

- Principle Investigator Dr. James Wilson and the University of Pennsylvania each held stock in Genovo, the study sponsor; Genovo was founded by Wilson and provided 20% of the funding for Wilson's lab.



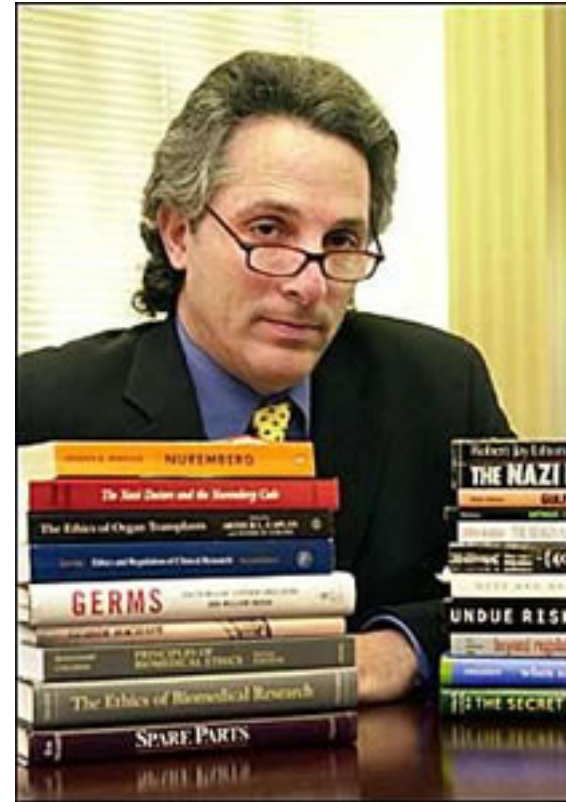
Jessie Gelsinger

- In 1995 (five years before Gelsinger's death) a University Conflict of Interest Committee had considered the Penn-Genovo-Wilson relationship and raised questions concerning conflict management procedures and liability coverage.



Jessie Gelsinger

- Alan Milstein filed a conventional malpractice claim:
- Defendants included the investigator, University, and IRB members.
- Settled (estimated) for \$ 5 million to \$ 10 million.



NIH Conference on Human Subject Protection and Financial Conflicts of Interest (August, 2000)



[Financial conflict of interest] has been a discussion for many years. However, when Jesse Gelsinger died last fall during a gene therapy clinical trial, questions were raised about the financial interests of investigators, and whether these interests clouded judgment or influenced decisions that were made.

It has never been more important to insure that adequate controls are in place to guard against improper behavior or bias, conscious or not, caused by conflicting loyalties on the part of clinical researchers.

Remarks of FDA Commissioner Jane Henney, M.D. "Human Subject Protection and Financial Conflict of Interest" (August 15, 2000)

Outline

Definitions of Conflict of Interest:

Individual Financial Conflict of Interest

Institutional Conflict of Interest

Conflict of Commitment

Institutional Obligations

(NSF, NIH)



Outline

Process and Methods for Managing Conflicts of Interest

Conflict Examples

University of Cincinnati Policies

***(Entrepreneurial Policy; Use of University Resources;
Employee Responsibility; Collateral Employment)***



Outline

Investigator Obligations (Compliance Steps at UC)

Collateral Employment

Human Subjects Research

Grant Applications

Entrepreneurial Activities

Standing Committee on Conflicts of Interest



Definitions of Conflict of Interest:
Individual Financial Conflict of Interest



Public Health Service Grants Policy Statement

“Recipient Organizations must establish safeguards to prevent employees, consultants, or members of governing bodies from using their positions for purposes that are or give the appearance of being motivated by a desire for private financial gain for themselves or others such as those with whom they have family, business, or other ties.”



Association of American Medical Colleges

“The term ‘conflict of interest’ in science refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research.”



University of Cincinnati **Conflict of Interest Policy**

“A conflict of interest may take various forms, but arises when an individual is or may be in a position to influence the University business, research, or other decisions in ways that could lead to any form of personal gain for the individual or his/her family. Conflicts and potential conflicts of interest must be disclosed and resolved.

Board Rule 3361:10-17-03



Definitions of Conflict of Interest:
Institutional Conflict of Interest



Institutional Conflict of Interest

Institutional financial conflict of interest ... may occur when the institution, any of its senior management or trustees, or a department, school, or subunit ... has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with the University.

Association of American Universities, Task Force on
Research Accountability. Report on Individual and
Institutional Financial Conflict of Interest (October, 2001)



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Institutional Conflict of Interest **(Human Research)**

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.



Definitions of Conflict of Interest:
“Conflict of Commitment”



Conflict of Commitment

A conflict of commitment arises when these professionally removed activities (e.g., outside teaching or business) come to interfere with the paramount obligations to students, colleagues, and the primary missions of the academic institution by which one is appointed and salaried. Conflicts of commitment primarily involve questions of obligation and effort, but are often tied to financial inducements. Such conflicts do not generally pose strictly legal violations, but they may constitute abridgements or compromises of institutional policy or the responsibilities attendant to retention of academic appointment.



**Executive Council of the Association of American Medical Colleges “Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research”
(February 22, 1990)**

Institutional Obligations

Public Health Service
National Institutes of Health
National Science Foundation



Public Health Service Grants Policy Statement

“Recipient Organizations must establish safeguards to prevent employees, consultants, or members of governing bodies from using their positions for purposes that are or give the appearance of being motivated by a desire for private financial gain for themselves or others such as those with whom they have family, business, or other ties.”



National Science Foundation Conflicts Policy

“An institutional conflict of interest policy should require that each investigator disclose to a responsible representative of the institution all significant financial interests of the investigator (including those of the investigator's spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.”



Process and Methods for Managing Conflicts of Interest



Managing Conflict of Interest

1. Disclose (always)

Association of American Universities, Task Force on Research Accountability. Report on Individual and Institutional Financial Conflict of Interest (October, 2001)



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Managing Conflict of Interest

1. **Disclose (always)**
2. ***Manage* the conflict (in most cases)**

Association of American Universities, Task Force on Research Accountability. Report on Individual and Institutional Financial Conflict of Interest (October, 2001)



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Managing Conflict of Interest

1. **Disclose (always)**
2. **Manage the conflict (in most cases)**
3. ***Prohibit the activity* (when necessary to protect the public interest or the interests of the University)**

Association of American Universities, Task Force on Research Accountability. Report on Individual and Institutional Financial Conflict of Interest (October, 2001)



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University of Cincinnati Policies



3361:10-17-03 Conduct and Ethics: Employee Responsibilities

§ A [Prohibits “any activity or interest that might reflect unfavorably on their own or the University's stewardship of public resources”]

§ B [Requires employees engaged in sponsored research to comply with OMB Circular no. A-21 and to conduct such research in a manner to avoid any actual or potential conflict of interest”]



3361:10-17-04 Conduct and Ethics: Use of University Resources

[Prohibits use of university property for personal benefit, including University stationery or supplies, campus mail services, information technology resources, and facilities; prohibits persons in positions of authority from requiring subordinate employees to perform personal services for anyone]



3361:30-21-02 Employment: Collateral Employment Policy

Faculty members and librarians may engage in collateral employment consisting of institutional and/or non-institutional effort, provided information regarding such employment is made known in advance to the dean of the college or division concerned or the appropriate library administrator and provided said dean or library administrator agrees that the collateral employment:



3361:30-21-02 Employment: Collateral Employment Policy (Cont.)

- 1. Does not interfere with nor is inconsistent with the performance of the individual's university duties; and**
- 2. Does not raise questions of conflict of interest in connection with other interests or work with which the individual, or the university, is involved.**



3361:10-17-01 Conduct and Ethics: Employee Financial Interests in Private Companies That Are Commercializing University Discoveries, Inventions, or Patents

[Prohibits faculty, staff, or student employees from holding an equity or other financial interest in a company to which the University has sold, licensed, or transferred an interest in a discovery or invention owned by UC without approval of a conflicts management plan by the Vice President for Research]



Ohio Revised Code § 2921.43

Soliciting or Receiving Improper Compensation

“No public servant shall knowingly solicit or accept and no person shall knowingly promise or give to a public servant either of the following: (1) ... compensation, other than as allowed by ... law ... to perform his official duties; (2) additional or greater fees than are allowed by law to perform his official duties ... [.]



Ohio Revised Code § 102.03

Restrictions During and After Employment; Bribery Prohibited; Honorarium for Personal Appearance; Reimbursement for Travel Expenses; Membership in Organizations

“No public official or employee shall solicit or accept anything of value that is of such a character as to manifest a substantial and improper influence upon him with respect to his duties ... [.]



Conflict of Interest Policy 3361:10-17-08

Examples of Non-Reportable Activities

- Royalties received for published scholarly works and other writings
- Honoraria for commissioned papers and occasional lectures
- Royalties received under institutional royalty-sharing policies
- Reasonable travel and lodging expenses related to presentations of scholarly work or academic endeavor
- Investments in mutual funds
- Participation by a faculty member in a University-approved practice corporation¹



¹ Limited to College of Medicine

Conflict of Interest Policy 3361:10-17-08

Examples of Reportable Activities

- Research on a technology developed by that individual or a member of his/her family
- Assignment of students or trainees to projects involving a for-profit entity in which the individual, a family member, or an associated entity has a financial interest
- Serving on the Board of Directors, or a scientific advisory Board of a business from which that individual receives University-supervised sponsored research support, or with which the University has a substantial contractual relationship known to the individual



Conflict of Interest Policy 3361:10-17-08

Examples of Reportable Activities (Cont.)

- Assuming any position in a not-for-profit business engaged in commercial or research activities
- Service on committees or review panels for university, government or professional organizations
- Relationships with companies which do business with the University
- Relationships with sponsors of research
- Service as an officer, director, or trustee in a business related to the person's professional field



Conflict of Interest Policy 3361:10-17-08

Examples of Reportable Activities (Cont.)

- External income- or non-income producing activities involving University students or staff
- Positions held at other institutions
- Conduct of research externally that could be conducted within the University or a University-approved affiliated practice corporation
- Making referrals to a business in which that individual, a member of his/her family, or an affiliated entity has a financial interest



Conflict of Interest Policy 3361:10-17-08

Examples of Reportable Activities (Cont.)

- Possessing a financial interest in a business which competes with services provided by the University
- Publishing or formally presenting research results or providing expert commentary without simultaneously disclosing any financial interest relating to such results or such subject



University of Cincinnati
Conflict of Interest Compliance Procedures



University of Cincinnati

Conflict of Interest Compliance Procedures

Collateral Employment: Prior to commencing outside employment, faculty/staff must seek approval by submitting a “Request for Approval to Perform Outside Activity” form (form A-128 for unclassified staff and part-time faculty; form A-128(a) for full-time faculty and librarians). In addition, all full-time faculty must submit an annual “Annual Report of Outside Activity” form (A-128(b))



Medical Center:

<http://www.med.uc.edu/facultyaffairs/content/collateral.cfm>

University of Cincinnati

Conflict of Interest Compliance Procedures

Grant Applications: Application packet must include a “Disclosure Statement Form/Conflict of Interest Report.” The form must be submitted annually, or more often if changes occur for key personnel on federal grants.

Medical Center:

<http://www.med.uc.edu/facultyaffairs/content/collateral.cfm>

West Campus:

http://www.research.uc.edu/file_PDF/conflictform.pdf



Human Subjects Research

Conflict of Interest Compliance Procedures

Faculty wishing to perform human research must submit appropriate conflict of interest form:

Medical IRB:

Institutional Review Board Conflict of Interest Policy and Statement (<http://www.uc.edu/conflictinterest.pdf>)

Social and Behavioral Sciences IRB:

Institutional Review Board – Social and Behavioral Sciences Conflict of Interest Disclosure (<http://www.med.uc.edu/irb/submission1.pdf>)



Entrepreneurship Activities

Conflict of Interest Compliance Procedures

Faculty or staff who wish to hold an equity or other financial interest in a firm which is commercializing an invention or discovery which was invented or discovered by the faculty or staff member and which is owned by the University under the operation of the University Patent Policy must follow the following procedure:



Entrepreneurship Activities

Conflict of Interest Compliance Procedures

1. Must obtain approval of the appropriate dean or department head under the Collateral Employment Policy
2. Must submit a supplemental report including:
 - a. A complete disclosure of the inventor's financial interest in the technology development company;
 - b. A conflicts management plan which addresses each of the following:
 - i. Management of University Obligations
 - ii. Proposed participation in management of the Technology Development Company;
 - iii. Limitation of equity ownership;
 - iv. Use of University facilities; and
 - v. Student employment.



Entrepreneurship Activities

Conflict of Interest Compliance Procedures

3. Must obtain approval of the Vice President for Research.
The Vice President for Research may consult with the relevant Provost and the Office of General Counsel and may make such additional conflict management requirements as are deemed necessary to approval of the inventor's proposed financial interest in the Technology Development Company.



QUESTIONS

