

School of Medicine Faculty Policies:
Conflict of Interest
Conflict of Commitment
Responsible Conduct of Research
Research and Professional Misconduct
Grievance Procedure

New Faculty Welcome and Orientation
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Presentation Topics

1. Conflict of Interest
2. Conflict of Commitment
3. Responsible Conduct of Research
4. Research and Professional Misconduct
5. Grievance Procedure

1. Conflict of Interest

- “Cold Researcher Made Profit on Quigley Shares,” January 31, 1997
- “Medical Journals Rarely Disclose Researchers’ Ties,” *Wall Street Journal*, February 2, 1999
- “Drug Trials Hide Conflicts for Doctors,” *New York Times*, May 16, 1999
- “Is Medicine for Sale?” *New England Journal of Medicine*, May 18, 2000
- “Uninformed Consent,” *Seattle Times* series, March 2001
- “Scientists Often Mum about Ties to Industry,” *New York Times*, April 25, 2001
- “A Hospital's Conflict Of Interest,” *Washington Post* (front page), June 30, 2002

Origins of Conflict of Interest (COI) in Biomedical Research

1980: Congress passes the Bayh-Dole Act, permitting universities to own inventions made with federal research support

Bayh-Dole requires universities to i) transfer inventions to commercial entities for development, and ii) to share income with inventors (e.g., faculty)

Why is conflict of interest in the spotlight again?

- 1999 - Death of Jesse Gelsinger at University of Pennsylvania – financial interests of PI and institution
- Allegations that COI at Fred Hutchinson Cancer Research Institute affected clinical trial outcomes
- 2001 - Death of Ellen Roche at Hopkins – no COI, but concern about research integrity
- Crisis of confidence in business ethics (Enron, Wall Street)
- 2003-05 - *LA Times* series, Congressional investigation, and new, more stringent ethics (COI) rules for NIH's intramural staff
- 2005 - *Seattle Times* series on physicians consulting for investment firms; allegations of insider trading and contract violations by physicians; SEC and DOJ investigations
- 2005 – *Wall St. Journal* series on institutional COI at Cleveland Clinic

Potential Impact of Financial Interests

Risks of financial interests in research:

- Bias in interpretation and reporting of research results
- Redirection of institutional resources
- Compromise in collegiality
- Risks to **human subjects research**:
 - Informed consent – potential for coercion
 - Enrollment of subjects not meeting criteria
 - Conduct of protocol
 - Under-interpretation/under-reporting of adverse events
 - Biased reporting of data

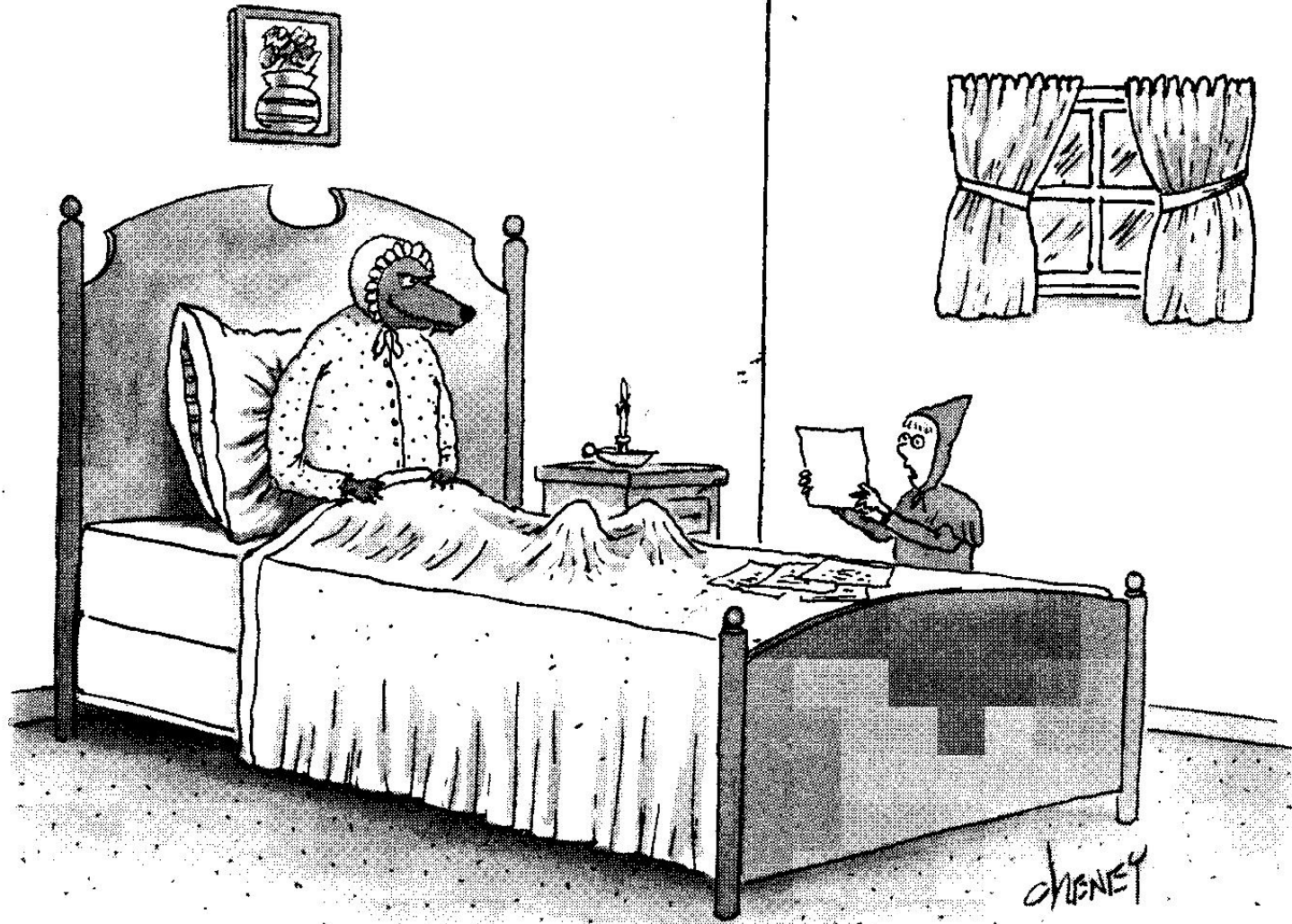
Relevant Regulations

- Federal regulations are inconsistent with one another
- Public Health Service (PHS) and National Science Foundation (NSF): grantee institutions must identify and manage, reduce or eliminate competing “significant financial interests” before expenditure of funds
- Food and Drug Administration (FDA): Applicants (companies and IND, IDE holders) must report financial interests of investigators in “covered” studies (over \$25,000 in income or \$50,000 in the value of stock) after research is completed

Other Relevant Developments

- 2001 – AAMC issues guidance on individual COI calling for *presumptive prohibition* of certain financial interests in HSR
- 2001– AAU issues guidance on COI
- 2002 – AAMC issues recommendations on institutional COI calling for rebuttable presumption against conducting human subject research at the institution under certain circumstances
- 2004 – DHHS (OHRP) issues “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection”
- 2006 – NIH initiates targeted site visits on COI
- Journals and professional societies have added or enhanced their COI policies, usually requiring disclosure

Also keep in mind: Securities and Exchange Commission’s (SEC) insider trading regulations. Biomedical researchers may be “insiders.”



*"My goodness, Grandmother, what big shares you dumped
just before these companies went belly-up!"*

Hopkins SOM

Conflict of Interest Policy

- The School of Medicine has had a COI policy for 15 years
- Adopted revised COI policy in June 2002
- New policy
 - Detailed and specific
 - Includes faculty, students, trainees, and staff
 - Sets limits for COI in HSR
 - Places final authority for COI determinations in HSR with IRB

Objectives of the Hopkins policy

- Permit appropriate engagement with industry in support of academic missions **AND**
- Eliminate, diminish, and/or manage potential and perceived risks to
 - Human research subjects/patients
 - Integrity of research results
 - Collegiality/training

JHUSOM COI Policy: A three-part process

- **Reporting** – to the institution
- **Review** – by Committee on Conflict of Interest
- **Determination/Management** – whether and, under what conditions, to permit a COI to exist

Reporting

- Required regardless of the source of funds or nature of the research
 - Federally-funded
 - Corporate sponsored
 - Human subjects research
 - Animal/basic research

Methods of Internal Reporting

- To IRB when a human subjects study is proposed
- To grants and contracts office when outside support for research is requested
- To technology licensing office in connection with agreements to license intellectual property
- To Committee on Conflict of Interest for outside consulting arrangements, etc.
- Through annual faculty appointment process
- Via web-based reporting system, anticipated launch Spring 2007

Review

- Reporting
- Review
 - At the time of reporting to the institution
 - By standing Committee on Conflict of Interest
- Determination/Management

Committee on Conflict of Interest

- Meets monthly
- 12+ senior faculty members and administrators
- Advises the Dean and IRB
- Proposed arrangements are reviewed
 - For compliance with COI policy
 - On a case-by-case basis

Considerations During CCOI Review

- Risks to rights and safety of human research subjects
- Impact on integrity of research data
- Impact on availability of research results to scientific community
- Impact on collegiality, trainees and students
- Appearance of a conflict of interest

Determination/Management

- Reporting
- Review
- **Determination/Management**

Human subjects research

- Presumptive Prohibition or
- Management

Non-human subjects research

- Rejection or
- Disclosure, stock escrow, limiting participation oversight, and/or divestiture

Determination/Management in Human Subjects Research

- Cases involving financial interests not considered “significant” are subject to review; there is no “floor” for reporting and review
- Limits on human subjects research and concurrent significant financial interests in a “financially interested company:”
 - Income > \$25,000 in 12-month period
 - Any non-publicly traded stock
 - Publicly traded stock worth > \$25,000
 - Royalty interest in a financially interested company
 - Research-based milestone payments
 - Fiduciary role (officer, director, etc.)

Determination/Management in Human Subjects Research, continued

- Requests for exceptions to presumptive prohibition will be considered by CCOI
- If allowed, COI will be subject to management
- COI management in human subject research cases will be recommended to IRB
- IRB may choose a more restrictive approach, but may not choose a less restrictive approach

Determination/Management in Non-human subjects research

- Same review process as for human subjects research
- Scrutinized by CCOI because a) need to protect research integrity, and b) in translational research, basic research results can lead to testing in humans
- Determination/management recommended to Dean
 - Rejection or
 - Disclosure, stock escrow, limiting participation oversight, and/or divestiture

“Business” Conflict of Interest

- Principle: a faculty member with a significant financial interest in a vendor company should not influence or participate in the purchase of products from that vendor.
- Policy: prior review is required “whenever a faculty member's relationship to an outside party might appear to influence either the conduct of the University's business with the outside party or the conduct of research within the University.”
- Legal issues: fraud and abuse, intermediate sanctions (IRS)
- Procedure: OPC shares data with purchasing and legal offices to ensure appropriate review of potential conflicts of interest with purchasing.

Education and Enforcement

- Education
 - Policy
http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/conflict_interest.html
 - FAQs
 - <http://www.hopkinsmedicine.org/Research/OPC/coi.html>
 - web-based training module - REQUIRED
<https://secure.lwservers.net/courseDescription.cfm?intCID=4&mode=JHMRCT>
- Sanctions for violations are prescribed under misconduct policy

Institutional Conflict of Interest

- Institutional interests - such as licensing-derived income, equity, fees - create conflicts of interest with research and other activity conducted at the institution
- Financial interests of institutional officials can create conflicts of interest with research and other institution-based activity
- OHRP, AAMC, have issued guidance
- Policy development is underway at JHU/SOM/JHHS

2. Conflict of Commitment

“Full-time faculty members of The Johns Hopkins University School of Medicine recognize that their primary responsibility is to The Johns Hopkins University. To fulfill that responsibility they are expected to devote their energies to activities that further the academic objectives of the School.”

- JHUSOM Policy on Conflict of Commitment and Conflict of Interest

Reporting of Outside Activity

- Reporting is required ...“before undertaking any commitment that may conflict or appear to conflict with the primary commitment to the University.”
 - Whenever aggregate time for all outside commitments **exceeds 26 days per year** (reporting threshold)
 - This does NOT mean faculty may automatically participate in outside activity 26 days per year
 - Whenever outside activities require a **written agreement**
 - Agreements must be reviewed by Office of Policy Coordination and approval by department director

Review of Consulting Agreements: Procedure

- Download Outside Interests Disclosure Form at <http://www.hopkinsmedicine.org/Research/OPC/forms.html>
- Obtain director's approval
- Submit completed form and agreement to OPC
- Do NOT sign the agreement; it has not yet been approved!

Review of Consulting Agreements

- OPC review examines
 - Time commitment
 - Intellectual property language
 - Proposed use of Hopkins name
 - Restrictions on other activity, such as research
 - Restrictions on publication
 - Use of Hopkins resources, facilities
 - Activity that needs review by other administrative offices
 - Inclusion of JHUSOM boilerplate
 - Conflict of Interest with research → CCOI review

COC: a shared responsibility

- Reporting outside activity is the responsibility of the faculty member
- Assessing conflict of commitment is a joint responsibility of the Dean's Office and the Department Director
- The Department Director evaluates whether the outside activity may impact fulfillment of a faculty member's Hopkins responsibilities
- The Dean's Office evaluates whether the outside activity presents a conflict of interest

3. Responsible Conduct of Research

- Supervision of students, post-doctoral fellows, and other research personnel
- Data gathering, storage, and retention
- Authorship
- Publication practices
- Laboratory guidelines

Data Gathering, Storage, Retention

- Data must be retained by the unit in which they are generated
- Original data may be moved to another institution only on prior written request to and approval by the department director
- Data must be retained for at least five years after publication
- Poor data retention practices are often at issue in research misconduct cases
- University-wide data retention policy under development

4. Research and Professional Misconduct

Research Misconduct

Policy is based on Public Health Service (PHS) regulations. PHS regulations prescribe procedure for reviewing allegations of misconduct in PHS-funded research. JHU follows same procedures if research is not funded by PHS.

Definition of Misconduct in Science

“Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”

Government-wide definition

Fabrication

Making up results and recording or reporting them

Examples:

- making up data points

- reporting experiments that were not conducted

Falsification

Manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record

Examples:

- forging human subjects' signatures on study consent forms

- omitting data when, for example, those data do not support a desired conclusion

Plagiarism

Appropriation of another person's ideas, processes, results, or words, without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts

Example:

using text written by others without permission and/or attribution

Caution: *Good Data Management and Data Retention are Essential*

- Retaining complete and clear research data can facilitate review of misconduct allegations
- Failure to retain or willful destruction of data can aggravate a finding of misconduct

Investigation – Formal Review of Allegations

“Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.”

(42 C.F.R. Part 50)

- Institution must start the investigation within 30 days of completing inquiry
- Examine documentation, data, proposals, publications, correspondence, etc.
- Conduct personal interviews of complainant, respondent, and others who may have information regarding key aspects of the allegations
- Obtain outside expertise as necessary to evaluate evidence
- Avoid real or apparent conflicts of interest among members of investigation committee
- Investigation must be objective, independent, and thorough

If investigation results in a finding of misconduct...

There will be additional review by

- Standing Committee on Discipline (SCD)

If the Dean and the SCD concur with finding of misconduct, SCD recommends disciplinary action

- Advisory Board of the Medical Faculty (ABMF)

Votes on the SCD's recommendations for disciplinary action

- Appeals may be made to Dean and then University Provost

How to Avoid Being Accused of Research Misconduct

- Adhere to accepted research standards (e.g., data retention, animal research, use of toxic substances, human subjects research protocols, authorship, etc.).
- Data retention is your best defense.
- Avoid practices that could be viewed as misconduct. Is using “boilerplate” text in a grant application ok? Did you ask the individual who wrote the “boilerplate”? In one case, failure to obtain permission or cite the author led to an 18-month long investigation.
- If in doubt, consult appropriate individuals before proceeding.

Professional Misconduct

“Professional misconduct is intentional deception or dishonesty in the professional conduct of academic duties such as, but not limited to, teaching, provision of medical care, or research activities (other than scientific misconduct); unsatisfactory performance of professional responsibilities; behavior generally unacceptable to the academic community; or failure to comply with published institutional policies or procedures, state or federal laws or regulations.” (from JHUSOM Policy on Professional Misconduct)

What type of behavior can lead to an allegation of professional misconduct?

- Failure to adequately fulfill teaching duties
- Enrolling more human subjects in a protocol than the number approved by the IRB
- Experimenting on animals without adhering to animal research standards
- Failure to disclose outside financial interests as required; failure to adhere to conflict of interest management requirements

5. Grievance Procedure

- Grievance: a complaint by a faculty member, post-doctoral fellow, member of the housestaff, or student that he or she was *adversely affected in his or her professional activities* as a result of capricious act or failure to act or violation of institutional procedure or regulation by supervisor, administrator, or school body.
- To provide a formal mechanism to resolve grievances of faculty, fellows, housestaff, or students when informal discussion is ineffective

Complaints that are NOT Grievances

- Harassment or discrimination on the basis of sex, age, race, religion, etc.
- Complaints pertaining to salary, benefits, etc.
- Complaints related to personal disputes
- Complaints whose resolution would conflict with institutional policies or applicable laws or regulations
- Complaints within the purview of other standing committees of the School or University

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