

CONFLICT OF INTEREST: THE BASICS

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ORA/GCA/Purchasing Workshop

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WHY CARE ABOUT CONFLICTS OF INTEREST?

OUHSC has an obligation to demonstrate and document good governance in order to protect the integrity and credibility of the University and to maintain the trust and confidence of our constituents.



Managing conflicts of interest is part of the University's commitment to enterprise **risk management.**



RISKS OF NONCOMPLIANCE WITH CONFLICT OF INTEREST REGULATIONS

Research

- Compromise of scientific integrity in research
- Research involving human subjects leading to death or injury
- Loss of credibility of research results
- Journals – Retractions, corrections, and/or ban from publishing

Federal

- Fines
- Withhold payments until investigation is completed
- Wholly or partly suspend, or terminate award activities
- Initiate suspension/debarment proceedings for the institution.
- Impose specific, stringent award conditions 45 CFR 75.207 for the PI or the institution

State Ethics Law

- Fines/Imprisonment
- Legislative Opinion

Reputation

- Found 46 articles in major journals (NYTimes, WSJ, LATimes, etc..) describing COI concerns or findings affecting research
- Appearance of research/academic impropriety

Other Risks

- Improper direction of student's or university employee's work
- Damaged relationships with sponsors
- Ban on PI from receiving new funding
- Improper channeling of research funds (audit finding)
- Inability to compete for specific funding
- Damaged sponsor relationships



JESSE GELSINGER (6/18/81 – 9/17/99)

- Jesse received gene therapy for a liver disease that he controlled through diet and medication
- Jesse died from multi-organ failure and brain death. The co-investigator held a 30% equity and University held 3.2% equity in Genovo which owned the rights to license the drug
- When Targeted Genetics Corp acquired Genovo, the co-investigator reportedly earned \$13.5M and the University of Pennsylvania earned \$1.4M. **None** of this was disclosed.
- Although no causal relationship was established between the financial interests and his cause of death, an undisclosed amount was paid to the family in a legal settlement



Former UK professor allegedly misused \$400,000, required students to work privately for free

A former University of Kentucky mining engineering professor pleaded guilty Thursday in federal court in Lexington to purposely defrauding UK and another employer of more than \$62,000 by creating fake invoices and double billing for his expenses.

Dongping "Daniel" Tao, 53, agreed to one felony count of wire fraud. He will be sentenced in June by Chief U.S. District Judge Karen Caldwell.

Federal sentencing guidelines, which are not mandatory, call for a minimum of probation and a maximum of 20 years in prison.

As part of a plea agreement, Tao agreed to repay \$62,000 to UK and Georgia Pacific, one of the private companies he worked for while at UK.

Read more here: <http://www.kentucky.com/news/local/education/article44552142.html#storylink=cpy>



The Wall Street Journal featured an article Describing Dr. Henschke's undisclosed conflicts of interest and subsequent corrections made to journals.

Erratum: Correction of Conflict of Interest Statement

Edward Abraham

<https://doi.org/10.1164/ajrccm.178.5.542>

PubMed: [18713850](#)

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Full Text

References

PDF

From the Editor:

In an editorial by Claudia I. Henschke published in the November 15, 2003, issue of the *AJRCCM* (1), it was stated that Dr. Henschke had no declared conflict of interest. The Editor contacted Dr. Henschke in May 2008 concerning corrections issued in April 2008 by two other journals (2, 3) regarding the conflict of interest disclosures made by her in articles and letters to the editor concerning the International Early Lung Cancer Action Project (I-ELCAP). These corrections pertained to patents and royalties, as well as funding from the Foundation for Lung Cancer: Early Detection, Prevention and Treatment. I-ELCAP was also referenced in the *AJRCCM* editorial.

Dr. Henschke provided the Editor with the following corrected conflict of interest statement for her editorial, and also commented to the Editor that the funding of her and her colleagues' work referred to in the reference section of the editorial did not include any funding from the Foundation for Lung Cancer: Early Detection, Prevention and Treatment:

C.I.H. has reported being a co-inventor of three (3) pending patent applications filed by the Cornell Research Foundation, Inc. (CRF), a subsidiary of Cornell University, from 2000 to 2003. These applications pertain to three-dimensional image rendering and analysis and/or small pulmonary nodule computer-aided diagnosis from computed tomography scans. The CRF licensed certain of these technologies to General Electric starting in 2001 and has received royalties, of which a portion has been distributed to C.I.H.

Medicine and Conflicts

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What These Medical Journals Don't Reveal: Top Doctors' Ties to Industry

Section 6: Disclosure Statement

Based on the above disclosures, this form will automatically generate a table.

Dr. Burns reports grants from Novartis, during the conduct of the dual role; grants and other from AstraZeneca, other from FOFMA, other Genentech, other from Bristol-Myers Squibb, grants from Amgen, grant Lilly, grants from Glaxo Smith-Kline, grants and other from MedImmune, grants from Pfizer, grants from Sanofi, grants from Seattle Genetics, an Medical Systems, grants from Vertex, other from TG Therapeutics, and Therapeutics, grants from InVivo Therapeutics, grants from Acerta Phar grants from Lon Oncology, other from Chugai, outside the submitter.

Doctors and Disclosures



Sloan Kettering Executive Turns Over Windfall Stake in Biotech Start-Up



Sloan Kettering's Cozy Deal With Start-Up Ignites a New Uproar



Memorial Sloan Kettering's Chief Executive Resigns From Merck's Board of Directors

HEALTH

Medicine and Conflicts

What These Medical Journals Don't Reveal: Top Doctors' Ties to Industry

Academic research publications rely on doctors to voluntarily disclose their payments from drug and health companies in a lax reporting system some say is broken.

December 6, 2016 — by CHARLES GRUNSTEIN and KATE THOMAS



WILLIAM ORLANDO FOR THE NEW YORK TIMES

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Doctors and Disclosures

A review by The New York Times and ProPublica



MICHAEL SULLIVAN FOR THE NEW YORK TIMES

Sloan Kettering Executive Turns Over Windfall Stake in Biotech Start-Up



MARIE PERLA AND CHARLES GRUNSTEIN FOR THE NEW YORK TIMES

Sloan Kettering's Cozy Deal With Start-Up Ignites a New Uproar

Latest

Q Search

Dec. 31, 2016

When Doctors Serve on Company Boards

Some hospital executives and cancer researchers sit on the boards of publicly traded companies, raising questions about whether their dual roles create a conflict of interest.

By KATE THOMAS and CHARLES GRUNSTEIN



Dec. 31, 2016

Memorial Sloan Kettering's Season of Turmoil

One of the nation's top cancer hospitals has grappled with how to bring breakthrough treatments to market while remaining true to its mission.

By KATE THOMAS and CHARLES GRUNSTEIN



Dec. 30, 2016

Top Cancer Doctor Resigns as Editor of Medical Journal

Dr. José Baselga, the former chief medical officer of Memorial Sloan Kettering Cancer Center, was asked to resign after he failed to disclose corporate ties in dozens of scientific articles.

By KATE THOMAS and CHARLES GRUNSTEIN



Sept. 29, 2016

Cancer Center Switches Focus on Fund-Raising as Problems Mount

The change highlights the challenges facing Memorial Sloan Kettering, one of the nation's most prestigious cancer centers, amid a widening crisis.

By KATE THOMAS and CHARLES GRUNSTEIN



KEY PRINCIPLES

- All OUHSC faculty, staff, and students are to act with honesty, integrity, and in the best interest of the University when performing their duties, and to abide by the highest standards.
- OUHSC allows and encourages faculty and staff to engage in outside activities and relationships that enhance the mission of the University.
- Because of this commitment, potential COIs are inevitable.

WHAT IS A CONFLICT OF INTEREST?

A conflict of interest involves risk of **benefit** and/or **bias**.

A conflict of interest arises when an employee may benefit personally (or appear to do so) from dealings with an entity or person conducting business with the University, including indirect benefits such as to family members or businesses with which the person is closely associated.

BENEFIT

BIAS

Financial or other considerations may compromise (or have the appearance of compromising) the employee's objectivity or independent professional judgment in the discharge of University duties and responsibilities.

CONFLICTS OF INTEREST CAN BE REAL – OR THEY CAN APPEAR REAL.

- If a situation looks like a conflict of interest or feels like a conflict of interest, it's likely there is some level of conflict.
- Use the “reasonable person test”:



If a reasonable, disinterested person would conclude that an individual might emphasize personal interests over other interests for which he/she has responsibility, there is, at the very least, the appearance of a conflict of interest

CONFLICT OF INTEREST AT OUHSC

- Two individual disclosure policies – apply to all employees
 - Board of Regents Policy
 - PHS (sponsor-specific)
- Annual disclosure
 - Not required by OUHSC Policy
 - Some colleges may require
- Conflict of Commitment
 - Not within scope of the COI Committee
 - Managed by department/college
- Institutional COI
 - Managed by Provost Office

POTENTIAL SOURCES FOR COI

- Purchasing and other business relationships
- Gifts
- Employment
- Research
- Technology licensing
- Activities of family members

ARE ALL CONFLICTS AUTOMATICALLY “BAD”?

- Having a conflict of interest is not necessarily a problem or a “bad thing”.
- Having a conflict of interest AND doing nothing about it is a problem!
 - In a research community, choices can be limited for certain services.
 - Sometimes, the best organization to tackle a project is the one where you have an interest.

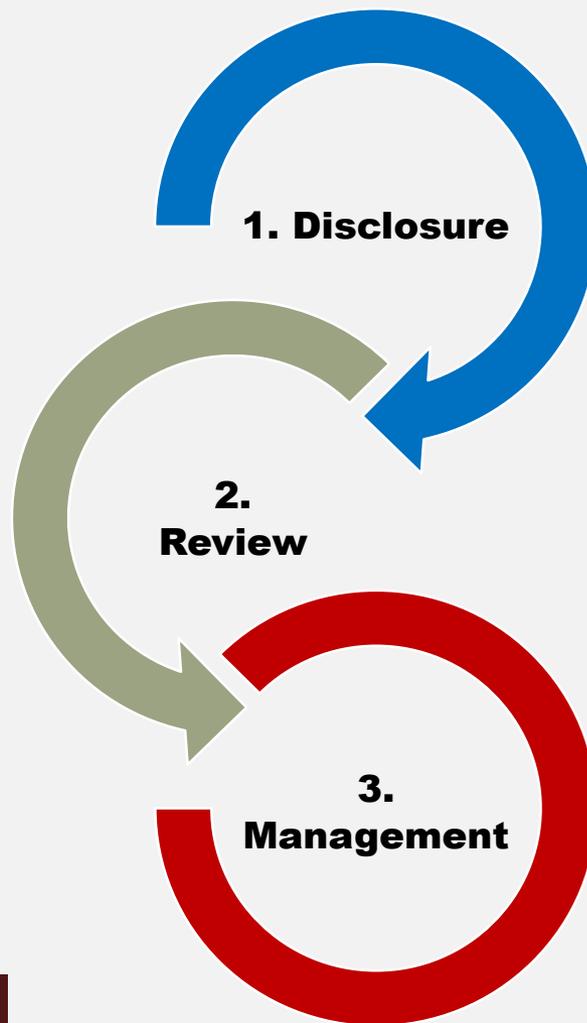


GOALS OF A COI POLICY

- Protect research participants
- Protect the integrity and credibility of the research
- Protect the institution, faculty & staff
 - Funding Status
 - Litigation
 - Reputation/Public Image
- Protect Students & Postdoctoral Fellows
- “Good Policy Practices”

OUHSC'S APPROACH TO MANAGING CONFLICTS OF INTEREST

The VPR leadership reviews disclosures to determine materiality and, where warranted, places appropriate restrictions on employee's scope of duties and/or vendor interaction.



Employees disclose real or potential conflicts as they arise, change, or require an annual update via OUHSC's COI Disclosure Form.

Management apprises the employee & supervisor of the restrictions, if any, deemed necessary to mitigate and manage the COI. Employee agrees to observe the restrictions.

MANAGING CONFLICT OR APPEARANCE OF CONFLICT

- Public Disclosure
- Monitoring by Independent Reviewers
- Modification of Research Plan
- Publication Oversight
- Strict Adherence to Data Retention
- Alternate Supervision of Students
- Full Disclosure to Students



The TAKEAWAY

- Conflicts of interest are more frequent in medical research communities. Be alert to the risk.
- A perceived conflict is as potentially damaging as a real conflict.
- Err on the side of caution. It's better to over-disclose than under-disclose.
- If you are being asked to work on projects that are not part of the University, you can let us know.



"Try this—I just bought a hundred shares."

CONTACT INFORMATION

Questions/Concerns?

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Assistant Vice President for Research
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Email: mogilvie@ouhsc.edu
website: research.ouhsc.edu

OR

Confidential Compliance Hotline
866.836.3150 (toll free)

QUIZ

IS IT A CONFLICT? IS IT ALLOWABLE?

Receiving consulting fees from a company while performing clinical research on the company's technology.

While presenting a conflict of interest, this situation may be acceptable as long as the consulting arrangement is properly documented and reviewed and the amount of the payments does not exceed specific thresholds. Exceptions may be allowed under limited conditions even if payments exceed the thresholds, with appropriate management.

Participating in institutional purchasing decisions about products made by a company in which you hold stock.

This presents a conflict that is always unacceptable

Owning stock in a company while performing research sponsored by the company.

While presenting a conflict of interest, this situation may be acceptable depending on the circumstances under which the stock was acquired and on whether the company is a large, publicly-traded company and the value of the stock does not exceed specific thresholds. Exceptions may be allowed under limited conditions even if payments exceed the thresholds, with appropriate management.

QUIZ

- **Serving on the Board of Directors for a company while receiving sponsored research from that company.**
 - This is an unacceptable conflict that is not allowable.
- **Serving on the Board of Directors of a company while participating in clinical research on the company's technology.**
 - This is an unacceptable conflict that is not allowable.
- **Holding a full-time appointment while having an executive position at a for-profit biomedical company.**
 - For full-time OUHSC Faculty, this is prohibited. For others, this may be allowable with appropriate disclosure and management.
- **Accepting a gift from a vendor.**
 - Under State law, accepting a gift from a vendor is not allowable.
- **Involving students or post-doctoral students and trainees in work that could directly benefit a company in which the faculty member supervising the students has a personal financial interest.**
 - While presenting a conflict of interest, this situation may be acceptable as long as certain approval and oversight steps are taken to ensure that the interests of the students/trainees are adequately protected.

QUIZ

- **Conducting federally-funded research that could affect the financial interests of a company in which the investigator has a personal financial interest.**
- While presenting a potential conflict of interest, this situation may be acceptable depending on whether the financial interest could directly and significantly affect the research, in which case, the financial interest must be managed, reduced, or eliminated.
- **5. Giving a company preferential access to results of OUHSC-conducted research while providing personal consulting services to that company.**
- This presents a conflict that is always unacceptable.
- **Receiving licensing milestone payments for licensed technology while performing clinical research on that licensed technology.**
- While presenting a conflict of interest, this may be acceptable if the amount of the payments does not exceed specific thresholds. Exceptions may be allowed under limited conditions even if payments exceed the thresholds, with appropriate management.
- **Being involved in the decision to hire a company in which your spouse is an employee to provide services to OUHSC.**
- This is an unacceptable conflict and so is not allowable.

REFERENCES

State Law

www.ok.gov/oec/documents/MANI10.sfi.pdf

OUHSC

Board of Regents Policy <http://research.ouhsc.edu/forms-policies/financial-conflicts-of-interest-fcoi/regents-policy-conflict-of-interest/>

Office of Research FCOI Page

<http://research.ouhsc.edu/forms-policies/financial-conflicts-of-interest-fcoi/>

NIH

42 CFR 50 Subpart F

http://grants.nih.gov/grants/compliance/42_cfr_50_subpart_f.htm

NIH FCOI Page

<http://grants.nih.gov/grants/policy/coi/index.htm>