Conflicts of Interest at NIH

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Bruce Androphy
National Institute of Environmental Health Sciences
Director of NIEHS Ethics Program
T +1 919.541.0397
bruce.androphy@nih.gov
www.niehs.nih.gov

DISCLAIMER!

The views expressed herein are those of the speaker and do necessarily reflect the position of the United States government, the Department of Health and Human Services, the Nationals Institute of Health, or the National Institute of Environmental Health Sciences.
Did You Know?

• NIH is the largest sources of funding for medical research in the world, creating hundreds of thousands of high-quality jobs by funding thousands of scientists in universities and research institutions in every state across America and around the globe. WE CURE CANCER!

• More than 80% of the NIH’s budget goes to more than 300,000 research personnel at over 3,000 universities and research institutions. In addition, about 6,000 scientists work in NIH’s own laboratories. The main campus is also home to the NIH Clinical Center, the largest hospital in the world totally dedicated to clinical research.

• Think of NIH as a large research university spending millions of dollars on research.

• How does NIH make sure that its own scientists, investigators and managers are free of conflicts of interest?

Managing Conflicts

• The NIH employs the following for making sure its scientists, investigators and managers are free of conflicts:
  – Financial disclosure;
  – Protocol review;
  – Prohibition on gifts;
  – Regulation of outside activities;
  – Limitations on sponsored travel; and
  – Vetting awards.
Conflict of Interest

• No federal employee, including special government employees, may take action on a particular matter that will have a financial benefit or loss to the employee, the employee’s spouse or minor child, organization in which the employee serves as an officer, partner or employee, or on any entity with which the employee is negotiating for prospective employment. Criminal

Financial Disclosure

• Depending on the level of the scientist or manager, financial disclosure can take several forms:
  – OGE 278 public disclosure of interest statement: For Laboratory Chiefs and above.
  – OGE 450 confidential disclosure of interest statement: For branch chiefs, many PIs.
  – NIH 717 for all investigators who conduct clinical trials.

• Each disclosure statement must be certified by the Ethics Office that there are no conflicts or that any conflicts have been addressed.

• Divestiture, ethics agreements, waivers and other actions may need to be taken.
What is to be Reported?

- For 278 filers, all sources of income for filer and spouse, all stock ownership, all trading in stock occurring within the last year, outside positions, liabilities, etc.
- For 450 filers, much of the same information without the trading in stock and no diversified mutual funds.
- For 717 filers, any stock holding in a substantially affected organization (“SAO”).
- **SAOs**
  - A biotechnology or biopharmaceutical company, a medical device manufacturer, or an entity significantly involved – directly or through subsidiary – in the research or development or manufacture of biotechnical, biostatistical, pharmaceutical or medical devices or products
  - Any organization that is comprised of a majority of SAOs (certain non-profits may be included).

Stock

- Stock is an equity interest in a company so if the scientist or investigator (or spouse or minor child or others) holds stock in a company that can be affected by the research (either positively or negatively), it is a per se conflict of interest.
- Exceptions: Diversified mutual funds; de minimis holdings of less than $15,000; de minimus holdings of less than $50,000 in a sector fund.
- For certain high ranking officials, barred from holding stocks in SAOs.
Protocol Review

- Before a new protocol can be submitted to the IRB or every time a protocol is renewed or amended, all NIH investigators working on the protocol must submit an NIH 717 or amend their previous one if more than six (6) months old.
- The NIH 717 for every investigator must be approved by the Ethics Office prior to the protocol being placed on the IRB’s calendar.
- Divestiture of other remedial actions may be required before Ethics approval is obtained.

Gifts

Question: What is a gift under federal law?
Answer: Almost anything…it can be a promise, discount, entertainment, hospitality, loan, or even a service such as training, travel, lodging, etc.

Doesn’t have to be nicely wrapped and include cash.

- BAD GIFTS:
  - From a prohibited source
  - Or provided because of an employee’s official position
  - Cannot solicit even if it is a non-gift or falls into one of the exceptions
Most Common Non-Gifts

- Modest food items and refreshments that are not part of a meal; donuts, soda, coffee, etc. (Modest means modest!).
- Items with little value such as greeting cards, plaques, certificates, trophies which are intended solely for presentation.
- Opportunities and benefits, including preferred rates and discounts, available to the public or all government employees.
- Sponsored travel (because its considered a gift to NIH and not to you!).
- Anything for which market value is paid by the employee.
- Gifts between employees but . . .

Gift Exceptions

- <$20 gifts form a single source on a single event or special occasion.
- <$50 gifts per year from a single source with no cash or investments
- Gifts based on personal relationship.
- Awards and honorary degrees subject to the approval process.
- Widely attended gatherings. (WAGs in the biz.)
- Social invitations from non-prohibited sources.
Caveat

- Even though there is an exception, “it is never inappropriate and frequently prudent for an employee to decline a gift offered by a prohibited source or because of his [or her] official position.”

Awards and WAGs

- Awards that confer a cash component or provides other value in excess of $200 must be approved in advance and, depending upon the amount, may REQUIRE approval at NIH headquarters.
- The source of the award is important to the decision whether to grant approval.
- WAGs
  - Scientists and investigators must receive prior approval for attending widely attended gatherings to make sure that the sponsor is not providing an inappropriate gift.
  - Most common situations are when companies sponsor events held separately but in conjunction with professional conferences.
Outside Activities

- Outside activities (whether compensated or not) must be pre-approved. Watch out for:
  - Cannot be employed or serve as a consultant to Substantially Affected Organizations (SAOs); bio-techs, pharma, device makers
  - Likewise for Supported Research Institutions; educational or non-profit research institutes that receive NIH grants or contracts; and
  - Health Care Providers and Insurers; hospitals, HMOs, health insurers, etc.
  - Service on boards of directors. Under current law, cannot serve as an officer as part of one’s official duty.

Sponsored Travel

When an Entity Other than the Government Offers to Pay

- In 2010, Senator Grassley, after receiving a complaint from NCI's former ethics officer, requested information as to all of NCI's scientists receiving sponsored travel.

- What are the issues?
- Whether by accepting the sponsored travel, the agency's operations and independence could reasonably be called into action.
- Who is providing the sponsored travel?
- What is the government's interest in the employee attending?
- What is the nature of the benefits to be provided (anything in excess of what the employee is entitled to will be considered an illegal gift)?
- Making sure that the trip is not a junket to a luxury destination.
NEW – STOCK ACT

• On April 4, 2012, President Obama signed the Stop Trading on Congressional Knowledge (STOCK) Act.
• Effective immediately, all 278 filers must report job negotiations within 3 days.
• By August 31st, all 278s filed in 2012 must be posted on web.
• All transactions in stocks must be reported within 30 days of transaction.

2011 Ethics Loser

• US v. Chen Yi Liang
• Former FDA chemist.
• Alleged insider trading based on non-public information.
• Charged with security fraud and filing false disclosure statements.
• Sentenced to 60 months in prison and $3.7 million in forfeiture.
Hypo #1

- You are reading the Science Section of the newspaper when you notice an article about Novarmerk’s new controversial wonder drug that is in clinical trials and that Dr. Grant Grabber, one of your top scientists and a Lab Chief, is listed with his University affiliation and as a paid consultant to Novamerk.

Dr. Grabber is quoted in the article as saying that, while he has is not associated with any of the clinical trials of the wonder drug, he has read the initial results and believes that FDA approval is in the “bag.” Novamerk’s stock rises 20% by the end of the day.
• You make inquiries and learn that Dr. Grabber has a half million dollar “consulting” contract with Novarmerk including stock options. You also learn that there is a major clinical trial in his Lab that is reviewing the safety of one of the products of Novarmeck’s main competitor, although Dr. Grabber is not involved.

Hypo #2

• Dr. Tre Hugger, one of your leading environmental scientists and an expert toxicologist, has been seen on tv, twitter and you tube, speaking against a planned State development to build a tech park and highway on behalf of Enough Growth. He is listed with his University affiliation. Enough Growth, on its website, calls itself a radical anti-growth organization which advocates for “active creative resistance.”
• You get a call from the University President who in turn received a call from the Chair of the Board of Trustees who received an angry call from the Governor’s Office. Development of the tech park and highway are central to the Governor’s plans for economic recovery.

Hypo #3

• Sally Dunk, your beloved women’s basketball coach, is on billboards as spokesperson for Hometown Bank wearing her University coaching uniform and stating that all good University basketball supporters should bank at Hometown.
• You also learn she has contracted with Apuma in which University players can only wear Apuma basketball sneakers. She also is driving a new sports car which was a gift from Frank Sponsor, the CEO of the construction company building the new sports arena. Sally had nothing to do with the awarding of the contract.

• Sally already earns $300,000/year from the University. You are approached by the Friends of Women’s Basketball, a closely affiliated but separate entity from the University, whether it can supplement Sally’s salary because there is a rumor that another University is trying to lure her away.
The Citations

- Gifts from Outside Sources: 5 CFR 2635.201
- Conflict of Interest; 18 USC 208
- Supplemental rules for NIH employees; 5 CFR Part 5501
- Appearance of Conflict: 5 CFR Part 2635.502

Thank You!

Questions?