SPA OPEN FORUM

Conflicted about Conflicts?

December 9, 2016
Agenda

• Background
• Recent Issues
• Questions/How can we help?
Understanding COI

**Primary interest:** Determined by professional duties of physician, researcher, teacher

- Normally good agreement about what these duties are and that they should be the primary consideration in any professional decision about the health of patients, the integrity of research

**Secondary interest:** Examples include financial gain, desire for professional advancement, wish to do favors for family or friends

- Usually not wrong by itself. May even be a necessary and desirable part of professional practice. Only its relative weight in professional decisions is problematic.

**Goal:** Not to eliminate or reduce financial or other gains. Rather, to prevent these secondary factors from dominating – or appearing to dominate – the relevant primary interest when making professional decisions.
Conflict of Interest:
A few common misconceptions

- A conflict of interest does *not* imply wrong-doing
- A conflict exists whether or not a particular individual is actually influenced by secondary interest.
- It exists if the circumstances are reasonably *believed* to create a risk that decisions may be unduly influenced by secondary interests
- Conflicts can be mitigated (or managed) but they still exist.
Who is an “Investigator”?

*Investigator* means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of the research..., which may include, for example, collaborators or consultants.
Requirements for the Investigator

✓ report significant financial interests (including sponsored travel) related to *institutional responsibilities* before grant submission—HMS does this through the research certification;

✓ submit updates within 30 days of discovering or acquiring new interest—update certification;

✓ submit annual update of all interests—annual certification.

✓ complete training on the PHS regulations and HMS COI policy before participating in research and every four years thereafter—It has been 4 years since PHS regs so we are actively reminding investigators about this training.

✓ comply with all management required by HMS.
PHS Regulations: Requirements for the Institution

✓ Maintain policy on public website

✓ Review reported significant financial interests to determine:
  • Whether interests are related to PHS proposed research
  • If related, determine whether financial interests pose a financial conflict of interest (FCOI)

✓ Manage, Reduce or Eliminate any identified FCOIs

✓ Report identified FCOIs to NIH: Detailed report includes value of the financial interest (in increments), nature of the FCOI, description of how FCOI relates to PHS funded research, and key elements of the Institution’s management plan

✓ Public Accessibility: Institutions required to make available FCOIs held by senior/key personnel via (i) publicly accessible website or (ii) written response to any requestor within five business days
Chocolate Milk


Lander’s History of CRISPR

Dr. Lander wrote a perspectives piece in Cell entitled “The Heroes of CRISPR” and was subsequently lambasted for failing to disclose a conflict of interest. While he does not have a personal conflict of interest, he directs the Broad Institute which has filed patents related to CRISPR (and which are subject of the extensive patent litigation between Carpentier, Doudna and Zhang. (http://www.cell.com/cell/pdf/S0092-8674(15)01705-5.pdf)

Geneticist Embroiled in Conflict of Interest Controversy, Luca F. Schroeder, CRIMSON January 29, 2016
(http://www.thecrimson.com/article/2016/1/29/broad-geneticist-criticized-research/)
SBIR/STTR

- Research Scientist Homayoun Karimabadi (UCSD)—SciberQuest—NASA and Airforce SBIR as well as NSF-entered plea agreement to settle felony wire fraud charges. Will forfeit $180,000 and face additional fine at sentencing.

- Professor Yujie Ding (and his wife as President of company) (Lehigh)—ArkLight—NASA SBIR—sentenced to prison for a year and a day and ordered to repay $72,000 to NASA, pay a $3,000 fine and serve a year of supervised release.
Questions?

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