

Research Administration Forum XIII

Gila Budescu, PhD., Director, SR-PD
Marta I. Torruella, Associate Director, SR-PD
Teresa Solomon, Associate General Counsel

Sponsored Research and Program Development

www.rockefeller.edu/sr-pd

May 17, 2012



Financial Conflict of Interest Training



New University Policy

- In 2011, the Public Health Service replaced its 16 year old financial conflict of interest rules with new requirements to further foster public confidence in the objectivity of research. The new rules respond to the growing number of relationships between industry and PHS-supported institutions and investigators.
- The University's 2012 Financial Conflict of Interest and Commitment Policy brings the University into compliance with the new federal requirements.



The Rules Cover All Investigators

- **An investigator is:**
 - any person in or collaborating or consulting with a laboratory, regardless of title or position, who is responsible for the design, conduct, analysis or reporting of research.
- **An investigator's institutional responsibilities are:**
 - his/her professional responsibilities on behalf of the University.
 - Examples are research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Institutional Review Board or a Data and Safety Monitoring Board.

Significant Financial Interests:

One or more of the following 4 categories of financial interests of an investigator (and her/his spouse and dependent children) that reasonably appear to be related to the investigator's institutional responsibilities:

1. Publicly traded entities:

- (a) Remuneration (e.g., salary, consulting fees, honoraria, paid authorship) from the entity in the 12 months prior to disclosure; and/or
- (b) Equity (e.g., stock, stock options, other ownership interest) held as of the date of the disclosure
- (c) that when combined (remuneration + equity) exceeds \$5,000;

2. Non-publicly traded entities:

- (a) All remuneration from the entity in the 12 months prior to disclosure that, when totaled, exceeds \$5,000 and/or
- (b) Any equity interest in the entity;

And...

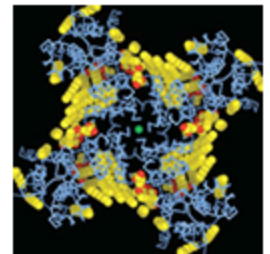


Significant Financial Interests (continued):

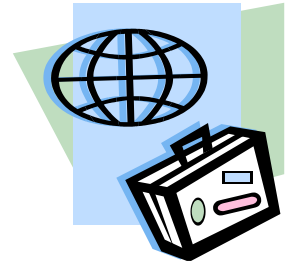
3. IP Rights and Interests:

- **Income exceeding \$5,000** received in the 12 months prior to disclosure through intellectual property rights and interests (e.g., patents, copyrights) **from any source other than the University or HHMI;**

And...



Significant Financial Interests (continued):



4. Travel

- reimbursed or sponsored travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available,
- **but NOT travel:**
 - reimbursed or sponsored by a federal, state or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.



SFI also does NOT include:

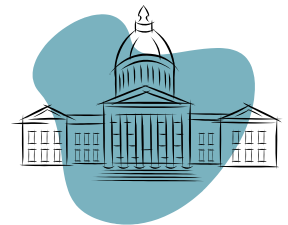
- Salary, royalties or other remuneration from The Rockefeller University or HHMI;
- Income from investments such as mutual funds or retirement accounts so long as the investigator does not directly control these vehicles' investment decisions;

OR...

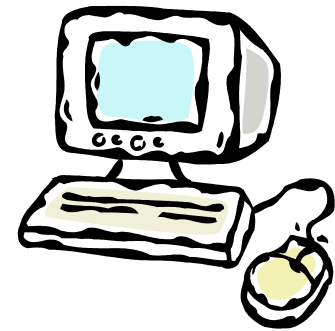


SFI also does NOT include: (continued):

- **Income from**
 - seminars, lectures, teaching engagements, service on advisory committees or review panels for a federal, state or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, a research institute affiliated with a U.S. institution of higher education.



Disclosure



- **Annual Disclosure**
 - All investigators must submit **annually** the University's electronic Significant Financial Interest Disclosure Form.
- **Updates**
 - Investigators must **update SFI disclosures within 30 days** of acquiring or discovering a new or previously unreported SFI.
- SFI disclosure must be up-to-date **before an investigator's grant application can be submitted to the Public Health Service (NIH).**

IRB and HHMI requirements stay the same

- SFI disclosure will not substitute for the required statements that accompany Institutional Review Board filings.
- Howard Hughes Medical Institute (HHMI) Investigators will continue to meet separate HHMI disclosure requirements.



FCOI Committee

- The Faculty Conflict of Interest Committee manages implementation of the University's financial conflict of interest policy.
- The Committee, appointed by the President on the advice of Academic Council, is comprised of tenured faculty members who serve staggered multi-year terms.



Identifying Conflict

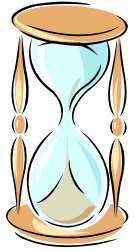
- Each Significant Financial Interest Disclosure Form will be reviewed by the administrative office for the Faculty Conflict of Interest Committee.
- The review will determine whether reported SFI reasonably appear to be related to the investigator's research and other institutional responsibilities and, if so, whether a financial conflict of interest exists.

Financial Conflict of Interest Defined

- A **financial conflict of interest** exists when an investigator's Significant Financial Interest could directly and significantly affect the design, conduct, analysis or reporting of the investigator's research.

Managing a Conflict

- The Faculty Conflict of Interest Committee will work with an investigator who has a conflict to secure his/her agreement to eliminate, reduce or manage the conflict.
- No federal funds awarded can be spent until all financial conflicts of interest related to a grant have been eliminated, reduced or managed.



Required Reports to Federal Funders

- Within 60 days of receiving **an update from an investigator disclosing new SFI while doing federally-supported research**, the University must review the disclosure, determine whether a conflict exists, and, if so, address it, reporting to the Public Health Service when the process is completed.



Federal Law Requires:

- When an **existing financial conflict of interest** of an investigator engaged in federally-funded research is **not timely identified or managed** due to the investigator's disclosure failure or to the University's conflict management failure, **a documented institutional audit of the investigator's activities must be undertaken** by the University to identify any bias in the design, conduct, analysis or reporting of the investigator's research.
- The University must notify the federal granting agency of any bias found in the funded research and submit a mitigation report. Additional **corrective and disclosure measures may be required**.

Requests from the Public

Federal law requires that within 5 business days of receiving a written request from the public for information about federally-funded research involving a conflicted investigator, **the University will reply in writing, giving the investigator's name and title or role on the research project, the entity in which the investigator holds a Significant Financial Interest, and the nature and approximate dollar value of the Significant Financial Interest, in dollar ranges, if known.**

Training



- Federal regulations require that, no later than **August 24, 2012**, each investigator must complete training in the new federal requirements prior to engaging in federally-funded research.
- Every University investigator is required to be re-trained on the regulations at least every four years.

Certification

Please click to certify that you have completed your training.



Additional Information:

- NIH FCOI Website: <http://grants.nih.gov/grants/policy/coi/>
- Federal Rules: http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- University COI Website: <http://inside.rockefeller.edu/conflictinterest/>