The Revised
Public Health Service (PHS)
Conflict of Interest Regulations
Responsibility of Applicants for Promoting Objectivity in
Research

Elizabeth Bankert, Assistant Provost
Jill Mortali, Director, OSP
Tammy Muccio Hickox, JD, Conflict of Interest Officer
Public Health Service Agencies

- **NIH** National Institutes of Health
- **AHRQ** Agency for Health Care Research & Quality
- **ATSDR** Agency for Toxic Substances and Disease Registry
- **CDC** Centers for Disease Control & Prevention
- **FDA** Food & Drug Administration
- **HRSA** Health Resources & Services Administration
- **IHS** Indian Health Service
- **SAMHS** Substance Abuse & Mental Health Services Administration
- **OASH** Office of the Assistant Secretary for Health
- **ASPR** Assistant Secretary for Preparedness and Response
- **BARDA** Biomedical Advanced Research and Development Authority

Identifying PHS funding agencies remains a difficult task. Please contact your Grants Officer with questions.
• Background

• Revised Public Health Service (PHS) Rules

• Dartmouth COI Implementation

• In response to accelerating commercialization of research, PHS/NSF Rules were implemented in 1995

• Goal of 1995 COI Rule is the same as the goal of revised rule: To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research .... will be free from bias resulting from Investigator financial conflicts of interest.
Senator Grassley on 1/18/08:

“Universities receive NIH dollars with the understanding that they will manage their researchers’ conflicts of interest...

Universities need to take this issue more seriously, and the NIH should monitor its grants more closely for this problem.”
Response from NIH

• Important not to stifle relationships between academic and industry

• However, objectivity in research is also very important

• Implement rules to broaden scope of disclosure and reporting
Dartmouth Response to New Rules

- Conflict of Interest Officer
- Revised COI Policy
- Enhancements to interim on-line reporting tool
- On-line education

*****

- RAPPORT: on-line system - will merge OSP and Human Subject Research reporting.
- Full implementation of RAPPORT (Grants management, IRB, COI) is expected in 2014
Revised PHS Rules

Institutional Responsibilities
Significant Financial Interests
Reportable Financial Conflicts of Interest
Travel
Transparency
Education
Summary of Major Changes

**Institutional Responsibilities (IR):** Report financial interests related to Institutional Responsibilities – not just those related to your research

**Significant Financial Interest (SFI):** New definition and threshold

**Reportable Financial Conflict of Interest (FCOI):** The financial interest affects research and PHS agency report, transparency required

**Travel:** Report travel paid by outside entity on behalf of the investigator (does not include travel paid for by the college, federal agencies, etc.)

**Transparency: Public accessibility** (Reportable Financial Conflicts of Interest)

**Education Requirement:** Initial (this session), every four years, change in policy, or non compliant
Institutional Responsibilities (IR)

Institutional Responsibilities are your professional responsibilities on behalf of the Institution, including:

- research
- consulting
- teaching
- professional practice
- institutional committees (e.g. IRB, DSMB)
- academic administration

Annual disclosure, for the preceding twelve months, of any significant financial interests related to your Institutional Responsibilities
Significant Financial Interests (SFI)

Significant Financial Interests DO NOT include:

- Income from a grant held at Dartmouth/D-H
- income from mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions
- income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher Education in the US
- income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education in the US
Summary Significant Financial Interests (SFI)
Related to your: Institutional Responsibility (IR)

Do you have:

a. Any equity in or receive remuneration from a publicly held entity related to your IR?
   - If your equity is worth more than $5k, disclose it
   - If remuneration received is more than $5k, disclose it
   - If the equity interest plus any remuneration received is more than $5K, disclose it

b. Any equity interest in or receive remuneration from a privately held company related to your IR?
   - If you have any equity in privately held company, disclose it
   - If remuneration received is more than $5K, disclose it

Remuneration is payment for services (not salary):
   e.g. consulting fees, honoraria, paid authorship, royalties

c. Intellectual Property: if related to your IR, disclose it (except authorship in scholarly works where no royalties received)

d. Travel: if over $5k, related to your IR, and sponsored/reimbursed on your behalf, disclose it
Significant Financial Interests (SFI)

**Travel**
Reimbursed or sponsored travel in excess of $5,000 from the same entity over the past 12 months (or anticipated over the next 12 months) and related to your institutional responsibilities

Does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education in the US.

- Disclose in advance (e.g., at annual disclosure)
- **OR**
- Within 30 days of travel
Reportable Financial Conflict of Interest (FCOI)

A reportable Financial Conflict of Interest is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

When you disclose, the COI Officer, and, if necessary, the COI Committee, will review your disclosures and determine whether there is a conflict of interest, and whether or not it is reportable.

Management Plans used for FCOI and for situations not reaching the reportable level.
Pop Quiz

Do I need to disclose the 1% equity that I own in a privately held startup company?

Answer: “It depends”
Depends on what?

It depends on whether or not the startup company is related to your Institutional Responsibilities.
If related, you must disclose (any equity in private company)
If not related, you do not need to disclose

Note: If you do disclose, it does not necessarily follow that the equity interest is a Financial Conflict of Interest (FCOI) which must be managed and/or reported to a sponsoring agency.
Who Discloses?

You: includes your spouse and dependent children

Key personnel:
Principal Investigator, Project Director, any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research which may include, for example, collaborators or consultants.

It is the responsibility of the investigator to ensure that key personnel on his/her projects are aware of COI policies.

Individuals identified in the grant application, progress report, or any other report submitted to the PHS by the Institution.
When to Disclose

1) no later than at the time of application for PHS-funded research

2) within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest

3) at least annually during the period of award
Annually
Disclose significant financial interests related to Institutional Responsibilities
You’re done until you have an update or it’s time to submit a proposal!

Upon Proposal Submission
• Review significant financial interests from annual disclosure and update if necessary
• Indicate whether each significant financial interest is related to the proposal
COI Officer will review significant financial interests (even those indicated “not related”) and obtain more info as needed

If there may be a conflict of interest
COI Committee will
• review significant financial interests,
• determine whether there is a Financial Conflict of Interest, and
• determine whether a Financial Management Plan is needed
A conflict of interest is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research

If there is a reportable financial conflict of interest
• Report to the sponsoring agency
• Make available to the public upon request
You’re done until your next annual disclosure, you have an update, or proposal submission!
Transparency (Public Accessibility)

If it is determined that there is a reportable Financial Conflict of Interest (FCOI), information that the Institution makes available upon request via written response (within 5 days) shall include the following:

• Investigator's name

• Investigator's title and role with respect to the research project

• name of the entity in which the significant financial interest is held

• the nature of the significant financial interest

• approximate dollar value of the significant financial interest (e.g. $5-10K, $10-20K, etc.)
Options for Managing Financial Conflicts of Interest include but are not limited to:

- Public disclosure (e.g., when presenting or publishing)
- Consent form disclosure
- Independent monitor
- Modification of the research plan
- Change of personnel or personnel responsibilities
- Disqualifications of personnel from participation in all or a portion of the research activities
- Reduction or elimination of the financial interest (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts
How do I disclose my Significant Financial Interest (SFI) related to my Institutional Responsibilities (IR)?
The Dartmouth COI reporting system has been updated to comply with the new PHS COI rules.

One Final Pop Quiz

Professor Plant is a biology professor with NIH funding.

She owns 25% equity in an ice cream shoppe.

Should she disclose? The ice cream shoppe is a privately held company, however, Professor Plant determines it does not relate to her Institutional Responsibilities - no disclosure is required.

She also receives $2,000 per year in royalties from a book she authored entitled: The Biology of Plants in the Amazon.

Should she disclose? Professor Plant determines the book does relate to her teaching, but the amount is not over $5,000 – no disclosure is required.

She also plans to travel to the Amazon. The Society for Plants in the Amazon is paying for her trip.

Should she disclose? Professor Plant determines the trip is related to her research and the trip is being paid for on her behalf - disclosure is required.
Thank you for your time and attention

See you in four years
or
if the policy changes
(or if you are non-compliant)