Financial Conflicts of Interest (FCOI)
Policy Training for Investigators
@BMC: ALL research
@BU: in Public Health Service-Funded Research
(funded by AHRQ, ATSDR, CDC, FDA, HRSA, HIS, NIH, SAMHSA
+ AHA, ACS, AF, SGKF, ALR, which have also incorporated the new rules)

Boston University and Boston Medical Center
Office of Research Compliance
Conflicts of Interest

Updated August 24, 2012
To protect the objectivity of Public Health Service (PHS)–Funded research from personal bias of researchers relating to their private financial interests (i.e., financial conflicts of interest),

the federal government (DHHS) has adopted specific rules (45 CFR Part 50 Subpart F; 45 CFR Part 94),

and also, requires certain institutions (like BU and BMC) to have them.

One of the rules is for research investigators to become familiar with the institutional policy and their responsibilities under it.

That is the purpose of this training.
Boston University and Boston Medical Center
FCOI rules for PHS-Funded research apply to:

“Investigators” -

• those responsible for the design, conduct, or reporting of Public Health Service (PHS)-Funded Research at BU and all research at BMC, regardless of title or position.
• Usually requires independent judgment, critical thinking and/or the recording of significant data from personal observation. Technicians, couriers, persons only engaged in anonymized data entry, and similar type roles that involve no added personal evaluative element to the Research may be excluded from this definition.

Doing “Research” -

• a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research,
• Including a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award, but
• Not including Phase 1 Small Business Innovative Research ("SBIR") or Small Business Technology Transfer ("STTR") applications or awards funded by the PHS.
The 4 major FCOI policy responsibilities of Investigators are:

1) **Become familiar** with the policies. ✔

2) **Complete training** prior to engaging in research and **every four years** thereafter. BU/BMC may require training under other circumstances such as an investigator’s failure to properly disclose significant financial interests (SFIs) or noncompliance with a management plan. ✔
3) Complete training and **disclose** all **significant financial interests** (SFIs) that are related to your **institutional responsibilities** prior to submission of a research application, annually, and within 30 days of discovering or acquiring a new significant financial interest.

- **Disclose** via Financial Interest Disclosure forms at [www.bu.edu/orc/coi/forms/](http://www.bu.edu/orc/coi/forms/)
- **Significant financial interests** include outside remuneration, travel reimbursements, equity interests, and income in connection with intellectual property rights/interests, apart payment from BU/BMC as salary.
- **Institutional responsibilities** means an investigator’s professional responsibilities on behalf of BU and/or BMC, including but not limited to research, research consultation, teaching, professional practice, and administration such as service on committees, boards and panels.

Continue ➔
4) Comply with any management plan issued by BU/BMC as a result of a significant financial interest review and financial conflict of interest finding. Retain documentation that demonstrates compliance, and submit documentation, as requested.
Significant Financial Interests (SFI) to Disclose

Each “investigator” who is planning to participate in PHS-Funded research at BU or any research at BMC must disclose the following SFIs, if they are related to one’s institutional responsibilities, to BU’s Office of Research Compliance no later than the time of application for research funding:

- **Outside remuneration** in the last 12 months preceding disclosure such as salary (not BU/BMC salary), consulting fees, honoraria, and paid authorship fees, starting at $5,000/year aggregated.

- **Equity interests** such as stock or stock options ($5,000 minimum value for public equity or any private equity).

- **Royalties related to intellectual property rights** paid by any source other than BU or BMC, starting at $5,000 in value.
SFIs to Disclose (continued)

Each investigator must also disclose, no later than the time of applying for research funding:

- Any **reimbursed or sponsored travel** (e.g. air and taxi fare, car rentals, etc.) paid by an entity, including non-profit organizations, but **not including** travel sponsored by or reimbursed by:
  - a government agency,
  - a U.S. institution of higher education or
  - a research institute affiliated with one,
  - a medical center, or an academic teaching hospital.
The following are not required to be disclosed:

1. Salary, royalties, or other remuneration paid by BU or BMC to you, your spouse, or your dependent child, if recipient is currently employed/appointed to BU/BMC.

2. Income from investments in mutual funds or retirement accounts, as long as you, your spouse, or your dependent child, does not make the investment decisions.

3. **Payment for services** (honoraria, advisory committees, review panels, etc.) or **travel expenses** paid by a U.S. federal, state, or local government agency, a U.S. institution of higher education or a research institute affiliated with one, a U.S. medical center or academic teaching hospital.

Now, a bit on financial conflicts of interest in general...
When investigators do research, financial conflicts of interest (FCOIs) naturally emerge.

Financial Conflict of Interest (FCOI), generally -

- Where \{private interests\} compromise or have the potential to compromise the exercise of [professional judgment] or obligations, or may be perceived as doing so.

FCOIs under BU and BMC’s policy -

- Where the \{financial interests\} of an Investigator, the Investigator’s spouse or dependent children, could directly and significantly affect the [design, conduct or reporting or research], or may be perceived as doing so.

How do we find financial conflicts of interest?
We Examine Significant Financial Interest Disclosures for FCOIs

BU’s Office of Research Compliance Conflict of Interest Unit determines whether an investigator’s significant financial interests -

• could *directly* and *significantly* affect the research, or
• is in an entity whose financial interest could be affected by the research.

If either bullet point is present, a **financial conflict of interest (FCOI)** exists.

Then what happens?
If an FCOI exists, a management plan is developed prior to spending $. 

Prior to the expenditure of any research funds, BU/BMC is required to develop and implement a management plan to reduce or eliminate the affect of the financial conflict of interest, and to ensure, to the extent possible, that the research will be free from bias.

A faculty review committee will recommend a management plan based on all case facts and circumstances and the Associate Vice President for Research Compliance will make the final decision.

Common elements of management plans include:

• Public disclosure of the FCOI in publications and presentations.
• Disclosure to human subjects participating in the research.
• Informing other research team members.
• Appointment of an independent third party to monitor the research.
• Change of personnel or personnel roles in the research.
Investigators must comply with the Management plan

The investigator is required to confirm agreement with the institution’s management plan, and the institution is required to monitor the investigator’s ongoing compliance with the management plan on an annual basis during the period of the research award.

Therefore, it is the responsibility of the investigator to verify compliance by retaining documents such as notices to journal editors or conference audiences, consent forms from human subjects research, or notices to laboratory personnel, and also, submitting them when requested.
Summary

☑ Take the training (this is it)
☑ Disclose Significant Financial Interests annually and within 30 days of identifying or acquiring a new interest (that is next)
☑ Comply with management plans and maintain documentation of compliance (only if an FCOI is found)
☑ Visit the Research Compliance Conflicts of Interest website at bu.edu/orc/coi/ for more details on the policy as well as contact information.
Next steps:

1) **Complete the Quiz** - click on “Course Documents” at the far left, then click on “Quiz Questions”

2) If you have not yet done so, **complete the financial interest disclosure forms** at http://www.bu.edu/orc/coi/forms/ and send them as a PDF via email to coi@bu.edu

Questions? Email coi@bu.edu