

Keeping Research Transparent and Unbiased by Managing Potential Conflicts of Interest

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Learning Objectives

- Understand the importance of identifying and mitigating financial conflicts of interest in research
- Understand the process for disclosure of potential conflicts of interest at BMC and BU
- Understand how BMC and BU manage conflicts of interest in research
- Identify the presenters as sources of information about conflicts of interests

Importance of Managing Conflicts

Key Assumptions

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Companies have an obligation to their investors as well as to the public

Industry and physicians have a shared interest in improving the public health

Definition of Conflict of Interest

A set of circumstances that creates a ***risk*** that ***judgment*** or actions regarding a ***primary*** interest will be ***unduly influenced*** by a ***secondary*** interest

Conflicts of Interest

Perceived or actual conflicts of interest exist for individuals and institutions

- Financial (e.g., fee for service, ownership of clinical services by MD' s)
- Professional (e.g., promotion, publication, grants)
- Familial (e.g., spouse, children)

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Financial COI may impact:

- research integrity
- purchasing decisions
- clinical decision making
- supervision of trainees

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Perception of a COI is sufficient to prompt a management strategy

Does Disclosure of COI Lessen Impact of Conflict?

- May make physicians less likely to develop COI's
- Honesty associated with higher levels of trust BUT perception that profit motives may be influencing recommendations *reduces trust*
- Increase pressure to follow the advisors advice? Don't want to offend?
- Patients with prostate cancer were 3x as likely to accept their surgeon's advice if the surgeon disclosed their specialty bias
- Surgeons who disclosed specialty bias also gave stronger recommendation for surgery (Shah, et al. PNAS 2016)

Conflicts of Interest – Recent Publicity

The New York Times

Medicine's Financial Contamination

Disclosure rules may seem arcane, but money corrupts medical research.



The Washington Post
Democracy Dies in Darkness

Industry has too much influence in medicine. It's time to end that.

The Boston Globe

Boston hospitals warn doctors to disclose industry ties

Bloomberg
Doctors Like to Think Big
Pharma Doesn't Sway
Them. It Does.

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure Responsibilities

- A. Investigators must disclose outside financial interests that reasonably appear to be related to institutional responsibilities**

Conflicts of Interest Terms (I)

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- **Related to institutional responsibilities:** related to professional responsibilities on behalf of BMC or BU, e.g., research, teaching, professional practice, service on committees or panels

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INSPIR Conflicts of Interest Attestation

5.2 Conflict of Interest Disclosure

I confirm that **all** those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, will, before this application is submitted, have completed the required financial interest disclosure through **COI Smart** for **Boston Medical Center** or through the **Financial Interest Disclosure form** for **Boston University**. NOTE: The IRB considers any missing financial interest disclosures to be noncompliance by the Principal Investigator.

I confirm

Conflicts of Interest Disclosure Responsibilities

- A. **Investigators** must disclose **outside financial interests** that reasonably appear to be **related to institutional responsibilities**
- B. Institutions must determine if any **Significant Financial Interests** that are **related to the research** constitute **Financial Conflicts of Interest** that must be **managed**

Conflicts of Interest Terms (II)

- **Significant Financial Interest (SFI)**: complicated (see slides 24&25); generally, investigator, spouse, or dependent children receiving >\$5,000 or having any equity

Significant Financial Interest (as defined by Boston Medical Center and Boston University policies on research conflicts of interest) means:

1. A financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's spouse or dependent children), that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - a. With regard to a publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship fees). Equity interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - b. With regard to a non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000 or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interests);
 - c. Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests; and

2. Exceptions: “Significant Financial Interest” does not include the following financial interests:
- a. Salary, royalties, or other remuneration paid by Boston Medical Center or Boston University to the Investigator, if the Investigator is currently employed or is otherwise appointed by the Institution making the payment;
 - b. Intellectual property rights assigned to either Boston Medical Center or Boston University and agreements to share in royalties related to such rights;
 - c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - d. Income from seminars, lectures, teaching engagements, sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; and
 - e. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Conflicts of Interest Terms (II)

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- **Related to the research:** amount of the interest and/or the company providing the interest could reasonably be affected by the outcome of the project

Conflicts of Interest Terms (II)

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- **Related to the research:** amount of the interest and/or the company providing the interest could reasonably be affected by the outcome of the project
- **Financial Conflict of Interest (FCOI):** a related Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Research.

Conflicts of Interest Terms (III)

- **Manage:** actions to keep the design, conduct, and reporting of research free from bias; may include disclosures, restrictions on investigator responsibilities, divestiture of SFI, and/or an independent monitor.

Conflicts of Interest Training

- Investigators involved in PHS Projects must complete Financial Conflicts of Interest Training every 4 years.
- Training is through CITI

BMC Financial Conflicts of Interest Process

BMC Process for Investigators

A. Investigators must disclose **outside financial interests that reasonably appear to be **related to institutional responsibilities****

- How: Complete COI Smart form

- When:

Whichever
comes first

- Physicians & Investigators – annually/newly hired/new interest
- Funded BMC projects – before 1st proposal submission
- Unfunded BMC projects – before 1st IRB submission

BMC Process for Institution

B. Institutions must determine if any **Significant Financial Interests** that are **related to the research** constitute **Financial Conflicts of Interest** that must be **managed**

- Compliance office analyzes SFIs
 - Unrelated: administratively cleared
 - Related: Faculty committee (full committee or designated member) determines either (1) cleared as no potential bias or (2) needs management plan
- Clearance or management plan prior to release of funds/IRB approval

BU Financial Conflicts of Interest Process

BU Process for Investigators

A. Investigators must disclose **outside financial interests that reasonably appear to be **related to institutional responsibilities****

- How: Submit BU FCOI Disclosure form via Sharepoint or Submit Paper Disclosure Form “for each project”
- When: At the time of proposal application or IRB submission and then annually, regardless of sponsor, or if new significant financial interests emerge within that timeframe

Why some PIs routinely forget to disclose or disclose late

- Busy with the science of research
- No time for bureaucracy
- Not receiving regular reminders from the compliance office
- Not receiving regular reminders from department assistant

How you can help drive timeliness

- Add to PI Outlook calendar, important dates, including FCOI disclosures.
- Set aside ½ a day every 2 weeks, or one day a month to check to make sure your PI is in compliance. Meet with PI to discuss. Set Outlook reminders. Set up the forms as much as you can and only have PI fill in what is necessary.

BU Process for Institution

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Questions???

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Contacts

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