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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Industry relationship with clinical investigators is critical to improving the public health
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Physicians have an obligation to individual patients and populations - but not to commercial interests
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Physicians have an obligation to individual patients and populations - but not to commercial interests.

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
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)

• **Investigator**: person who is responsible for the design, conduct, or reporting of research
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- **Outside financial interest**: income or equity; commonly consulting, stock, equity, travel, honoraria, patents.
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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
Conflicts of Interest Disclosure Responsibilities

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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)

• **Significant Financial Interest** (SFI): complicated (see slides 24&25); generally, receipt of >$5,000 or any equity by investigator, spouse, or dependent children

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

Whichever comes first
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
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

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

• Research Integrity 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
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
Contacts

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