Research Financial Conflict of Interest Review Process

By BU or BMC COI Office and BU/BMC Faculty Review Committee on Research Financial Conflicts of Interest

This document describes the process for reviewing outside interests to determine if they pose a financial conflict of interest for research projects. It may also prove useful for investigators who are considering what restrictions on their future research may ensue if they enter into a consulting or other relationship with a drug or device company.

Related Policies

[Boston University](https://www.bu.edu/researchsupport/forms-policies/investigator-financial-conflicts-of-interest-policy-for-research/)

[Boston Medical Center](https://www.bmc.org/sites/default/files/Research/Policy-9-23-000.pdf)

1. **Disclosure of related outside activities**

Investigators must disclose if they, or their spouse or dependent child have any financial interests (income or equity) as the result of any outside activities in the most recent 12 months that are or appear to be related to the investigator’s professional expertise.

* “Are or appear to be related” means associated with the investigator’s area of professional expertise or related to their role at BMC or BU. An outside activity is related if the investigator has been asked to participate because they are a professional in the field in which they work on behalf of BMC or BU or because of the role they perform for BMC or BU. Relatedness is not always a bright-line determination.
* “Professional expertise” means an investigator’s expertise associated with their institutional responsibilities, including research, clinical care, education, purchasing, administrative, institutional committee memberships, service on panels such as IRBs and DSMBs, and any other activities that are performed for either BMC or BU.

If NO: end of process

If YES: COI program evaluates the magnitude of each interest (step II)

1. **Magnitude of interest from outside activities**

The BU or BMC COI program determines whether an outside activity is associated with any of the following interests:

1. Remuneration > $5,000
2. Equity valued > $5,000 in a publicly traded company
3. A combination of remuneration + equity > $5,000
4. Equity of any amount in a non-publicly traded company
5. Income of any amount from intellectual property rights not assigned to BMC or BU
6. Travel > $5,000
* “Remuneration” includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship fees); it does not include income from seminars, lectures, teaching engagements, service on advisory committees or review panels sponsored by one of the following within the United States: 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, a research institute that is affiliated with an Institution of higher education.
* “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; it does not include 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.
* “Travel” means reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available).

If NO: end of process for this interest

If YES: interest is a “Significant Financial Interest;” COI program evaluates relatedness (step III)

1. **Relatedness of interest to the research project**

The COI program determines whether the interest is related to any of the investigator’s research projects.

* An Investigator's interest is considered to be related to a research project when the interest could be reasonably affected by the research (for example, the interest is an intellectual property right used in the research; the value of the interest may be impacted by the outcome of the research) or is in an entity whose financial interests could be reasonably affected by the Research (for example, the entity makes or owns a drug, device, technology, or intellectual property used in the research; the entity is the sponsor of the research)

If NO: end of process for this interest

If YES: COI committee will evaluate potential for bias (step IV) (Either full committee or designated member review)

1. **Potential for bias**

The COI committee evaluates the real and potential magnitude of the interest to (1) bias the investigator’s work or the integrity of the data, (2) create an appearance of bias or (3) have a negative impact on the public’s trust in research, particularly research involving human subjects.

If VERY LOW: no management plan required for this interest

If LOW, MODERATE or HIGH: evaluate unique qualifications (step V)

1. **Unique qualifications**

The investigator is asked to complete a “Compelling Circumstances” questionnaire, including answering whether the research could be conducted by another investigator (either at BU/BMC or another institution), and if not, why the investigator is uniquely qualified through expertise, laboratory resources, and/or patient population to perform the work as safely and effectively.

If investigator IS uniquely qualified: evaluate management strategies (step VI), generally *not including* modifications to their role in the research.

If investigator IS NOT uniquely qualified: evaluate management strategies (step VI), generally *including* modifications to their role in the research, up to and including recusal from any involvement as an investigator.

1. **Management strategies**

The COI Committee may choose a combination of the following steps that are appropriate to manage the interest so as to prevent bias or the appearance of bias:

1. *Disclosure* – Disclosure is a method to promote trust by establishing transparency, showing that the investigator recognizes their potential conflict of interest, and allowing the recipients of the disclosure assess the significance of the conflict, and to watch out for and take steps to mitigate possible bias. Recipients of the disclosure include research colleagues, chairs/chiefs/deans, sponsors, human subjects, and the wider scientific community.
2. *Independent Scientific Reviewer* – an Independent Scientific Reviewer is a qualified, independent scientist who will review the protocol design and/or or the acquisition, analysis, interpretation, and/or reporting of data in order to provide an assurance that findings and conclusions reached are supported by the data presented, and to assure that the content is consistent with applicable scientific standards
3. *Safe Haven Monitor* – a Safe Haven Monitor is an independent faculty member who establishes a relationship with trainees and other investigators working under the oversight of the investigator to identify and address their concerns about the conflict.
4. *Partial recusal* – recusal from certain roles (e.g., principal investigator, recruiting, consenting, and/or interacting with human subjects; the protocol design and/or the acquisition, analysis, interpretation, and/or reporting of data) can prevent bias or the perception of bias.
5. *Total recusal or divestiture* – the conflict of interest cannot be managed by any combination of the above steps, and the investigator may not participate in the research until 12 months has passed since the last income or equity creating the conflict.

**Relationships with drug/device companies**

Many of the cases that progress to step IV for Committee consideration consist of situations where an investigator has an interest in a drug or device company and proposes to do research sponsored by that company. By definition, the interest is related to the research project, and so the potential for bias must be evaluated. **It is important to keep in mind that every decision by the BU/BMC Faculty Review Committee on Research Financial Conflicts of Interest is based on the particular set of facts of the case in question. Thus, the general trends below do not assure a similar outcome in a similar-appearing case in the future.**

*Types of interests where the potential for bias may be considered LOW* (can often be managed)

* The investigator owns stock in the publicly-traded company
* The investigator is a member of a medical/safety monitoring body or endpoint/events adjudication committee for a clinical trial (separate from the research in question) sponsored by the company
* The investigator provides centralized evaluation for a clinical trial (separate from the research in question) sponsored by the company
* The investigator provides lectures/training (where they control the content) supported by the company

*Types of interests where the potential for bias may be considered MODERATE or HIGH* (usually manageable only if the investigator is uniquely qualified)

* The investigator owns stock or stock options in the privately-traded company
* The investigator has a leadership position in the company
* The investigator owns patents licensed by the company
* The investigator receives royalties from the company
* The investigator provides advice to the company on product development/research direction

*Types of interests where the potential for bias would likely be considered MODERATE or HIGH but no cases have recently come before the committee* (possibly because investigators recognize the potential for conflict and do not seek to perform related research)*:*

* The investigator is a member of a the steering/executive committee for a clinical trial (separate from the research in question) sponsored by the company
* The investigator was involved in writing the protocol for the company
* The investigator provides legal consulting on a case involving the company
* The investigator is a member of the company’s grant review panel