

PRIMARY REVIEWER GUIDANCE FORM

Primary Reviewer: _____

Investigator:
Disclosure Number(s):
Date of Review:

Guidance:

BU Policy on Investigators' Conflicts of Interest defines "*Significant financial interest*" as anything of monetary value, including a salary, consulting fee, honorarium or other payment for service; equity interests, including stocks, stock options or other ownership interests; and intellectual property rights, including patent rights owned by the investigator or on which a clinical investigator is a named inventor (whether licensed or not), copyrights and royalties.

This Policy, however, excludes from consideration the following items:

- (a) salary, or other remuneration (not including royalties) from Boston University;**
- (b) income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities**
- (c) income from service on advisory committees or review panels sponsored by public or non-profit entities;**
- (d) salary, royalties or other payments from a single entity (or group of affiliated entities) that, when aggregated for the investigator and members of his immediate family over the next twelve months, are not expected to exceed \$10,000.**

1. Several factors to consider in conducting your review are the:
 - a. nature of the research,
 - b. magnitude of the financial interest and the degree to which it is related to the research,
 - c. extent to which the interest could be directly and substantially affected by the research,
 - d. extent to which the academic programs under the supervision of the investigator may be affected by the interest, and
 - e. degree of risk to the human subjects, if any

2. In conducting your review, you may:
 - Contact Investigator to discuss, preliminarily, the facts relevant to whether a conflict of interest exists.
 - Request additional information from the Investigator, ORCHIP, the Office of Technology Development or the Office of Research Administration/Sponsored Programs/Grants Administration that may be necessary to your review. (E.g. a copy of the program description or abstract, a copy of any contract between the University/BMC and the funding source, etc.)

3. Your report below should supplement the information already contained in the investigator's Disclosure and Addendum.

4. Please be prepared to share your comments and recommendations with the Committee during the meeting at which this project is discussed. Feel free to discuss your tentative views, or any questions you may have, with Assistant Provost Susan Frey, J.D. (414-4736) or with Associate General Counsels Rita Gyls (BMC) (638-7950), Diane Gardener (BUMED) (353-2191), Dennis Hart, (CRC) (353-2326).

Primary Reviewer's Comments/Recommendations:

I. Background: Research

1. What is the nature of the research at issue?

2. This research Does Does Not involve human subjects. If the research is human subject research, does it involve clinical testing in humans of a drug or device? What is the risk posed to human subjects?

3. Will students or trainees be involved in the research? If so, to what extent?

II. Financial Interest*

1. What is the nature and magnitude of the investigator's significant financial interest?

2. If the investigator's SFI is in a company, will the company benefit from a particular result from this research? Does the company potentially benefit if the research to proves anything in particular?

II. Research Funding

1. If there are any restrictions on publication or sharing of research results imposed by the funding agency, could these restrictions inappropriately affect the academic program of trainees or the openness of research in the investigator's department?

III. Recommendation

1. Do you think a conflict of interest exists? YES NO

1A. If not, briefly explain why:

2B. If so, please provide suggested text, as indicated in the appended *Examples*, for the Committee's determination letter that will be forwarded to the Provost with recommendations on how to proceed with elimination, management or reduction of the conflict

3. Specify below what you propose as an appropriate remedy to manage, reduce or eliminate this conflict of interest? If management is appropriate, at what level? (Feel free to propose a different method of management tailored to this situation.)

NOTE: Levels of managements (cumulative from 1-5) that the Committee has used in the past include:

- (1) Disclosure of SFI to Dean or Chairperson of Dept.,
- (2) Dear Colleague letter notifying all members of the research team of the SFI,
- (3) Disclosure of SFI in publications,
- (4) Annual report to the Committee, and
- (5) Subcommittee review

4. *If this is human subject research*, give careful scrutiny to whether management is appropriate, as opposed to elimination of the conflict. If management is recommended, it may be appropriate to recommend that the conflicted investigator not serve as Principal Investigator for data collection or analysis, but that an independent investigator be appointed to oversee and carry out these functions.

For human subjects research, please indicate if you recommend the substitution of an independent investigator: YES NO

Examples of Decision-Letter Text:**Example 1 – EQUITY INTEREST:**

Professor X has a financial interest related to the BUMC research project that is the subject of his Disclosure. The financial interest is through his equity interest in OsteoCompany(Company). Professor X has stock options for 1,000 shares, valued at less than \$10,000 in Company. Professor X also consults for Company, but his consulting income has not exceeded \$10,000 annually. The Company is interested in the research at BUMC because it involves studies designed to evaluate the effectiveness of the device (implanted plug) provided by the Company to help prevent bone loss before and after hip replacement surgery. Human subjects are involved in the research, and the risk of the procedure is that associated with implantation of a plug. Company provides research support for costs of enrollment of patients, and provides the devices (plugs) for use in the research. Students are not involved in the research.

Example 2 – CONSULTING FEES:

Professor Y has a financial interest related to the BUMC research project that is the subject of his Disclosure. The financial interest is through a relationship with CardioCompany (Company) and consists of: Professor Y’s consulting income from the company in 2004 was \$15,000 and he expects to receive \$15,000 in 2005. The Company is interested in the research at BUMC because the Company provides research support for it. The University’s sponsored research agreement with the Company gives Company rights to any discoveries made in the sponsored research. In the Company- sponsored research, Professor Y is researching the mode of action of Agent C in heart failure. This is “a drug metabolism study” in the field of interest of the Company. The involvement of human subjects is minimal, and involves only a blood draw from healthy subjects. Post-doctoral students work on Professor Y’s NIH-funded research (not the subject of this disclosure), and will occasionally do work on Company-funded research.

Example 3 – INTELLECTUAL PROPERTY & EQUITY INTERESTS:

Professor Z has a financial interest related to the CRC research project that is the subject of his Disclosure. The financial interest is through her equity interest in GenCompany (Company). Professor Z owns stock and stock options in the Company constituting approximately 13.3% of the company and valued at approximately \$110,000. The University owns equity in the Company. Professor Z does not receive any remuneration from the Company for services. The Company is interested in the research at CRC because it is the licensee from Boston University of patent rights on inventions made by Professor Z at Boston University. The Company does not provide research support for Professor Z’s research at CRC and does not have legal rights in the work-product of the CRC research; however, the research is in the field of interest of the Company. Professor Z states that “the results could benefit the company and ultimately increase its value.” Human subjects are not involved in the research. Three postdoctoral trainees will work on the research at BUMC.