

BRYN MAWR COLLEGE

FINANCIAL CONFLICT OF INTEREST IN RESEARCH POLICY

Trustees, officers, deans, directors, faculty and staff all serve the educational and public purposes to which the College is dedicated. Accordingly, all such members of the College community have a clear obligation to conduct the affairs of the College in a manner consistent with those purposes and to make all decisions based on the desire to promote the best interests of the College. Further, as stated by the National Institutes of Health, the College must promote “objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research...will be free from bias resulting from Investigator financial conflict of interest.”

This statement recognizes and affirms the tradition and expectation that members of the College community will conduct their relationships with each other and the College with candor and integrity. It confirms the College policy that faculty and other employees who accept full-time appointments have a primary commitment to the College and that they will be sensitive to the possible adverse effects of their external activities. It is recognized, however, that the quality of teaching, research, and the administration of College programs may be enhanced when members participate in extramural activities, so long as their primary commitment to the College is not adversely affected.

The following policies and procedures will permit members of the faculty, staff, and administration to identify, evaluate, and correct or remove real, apparent, and potential conflicts of interest and commitment. The appearance that a conflict may be present may be as important as the reality. These guidelines define general College policy and procedures regarding conflicts of interest in relationship to sponsored projects involving research, education, and College service. Their purpose is to protect the credibility and integrity of the College's faculty and staff so that public trust and confidence in the College's sponsored activities is ensured.

In accordance with Federal regulations, including but not limited to Public Health Service (PHS) regulations, the College has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator. Thus, the College requires that investigators disclose any Significant Financial Interest that would reasonably appear to be directly and significantly affected by an actual or potential conflict of interest in relationship with a sponsored project.

A. Definitions

A Financial Conflict of Interest (FCOI) exists when the College reasonably determines that an Investigator's Significant Financial Interest (SFI) is related to a research project funded by an external sponsor, and that SFI could directly and significantly affect the design, conduct, or reporting of the research. A potential FCOI occurs when there is a divergence between an individual's private interests

and his or her professional obligations to the College such that an independent observer might reasonably question whether the individual's professional actions or decisions are influenced by considerations of personal gain, financial or otherwise.

Investigator means the principal investigator/project director, co-principal investigators, and any other person at the College who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor.

SFI means anything of monetary value, including, but not limited to:

A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's College responsibilities:

(i) With regard to any publicly traded entity, SFI 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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;

(ii) With regard to any non-publicly traded entity, SFI 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 option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

In addition, Investigators also must disclose the occurrence of any reimbursed or sponsored travel related to their College responsibilities (and reimbursed or sponsored travel of the Investigator's spouse and/or dependent children) over the previous twelve-month period, with such disclosure updated within thirty days of each subsequent occurrence, unless those expenses have been reimbursed 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. This travel-related disclosure preliminarily must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. The Office of Sponsored Research will request further information if needed.

SFI does not include:

- (1) Salary, royalties, or other remuneration paid by the College to the Investigator if the Investigator is currently employed or otherwise appointed by the College;
- (2) Income from seminars, lectures, or 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;
- (3) 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;
- (4) Financial interests that do not meet the monetary/equity thresholds set forth in Sections (i) and (ii) of the definition of SFI, above; or
- (5) Intellectual property rights assigned to the College and agreements to share in royalties related to such rights.

Provided, however, that the exclusions in items (1), and (4) shall not apply if the compensation or transfer of an equity interest is conditioned upon a particular outcome in a sponsored research project.

B. Guidelines

1. Each Investigator is required to disclose the following SFI:

- (i) Any SFI of the Investigator (and/or of his/her spouse and/or dependent children) that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
- (ii) Any SFI of the Investigator (and/or of his/her spouse and/or dependent children) in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

Regardless of the above minimum requirements, an Investigator, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

2. The Office of Sponsored Research will annually contact those Investigators who have a federally funded grant and request completion of the Financial Interests Report. At that time, the Investigator will be provided with a link to this Financial Conflict of Interest Policy, which contains the applicable Federal regulations. A link will also be provided to the PHS Tutorial. Investigators who are grant-funded will be required to complete the tutorial once every four years and submit the certification of completion available at the end of the tutorial to the Director of Sponsored Research prior to proposal submission.

3. Each Investigator who has any SFI requiring disclosure shall complete a Financial Interests Report and attach all required supporting documentation. The completed Report must be submitted with the proposal and the Proposal Transmittal and Approval Form (collectively, the Disclosure Packet) to the Director of Sponsored Research prior to the proposal submission to the potential Federal funding agency.

4. As required by Federal regulation, all SFI must be disclosed prior to the time a proposal is submitted. All financial disclosures must be updated by Investigators during the period of the award, at least annually, and within thirty days of discovering/acquiring new SFI.

5. The Director of Sponsored Research, or official designee, shall perform an initial review of the Disclosure Packet to determine whether an actual or potential FCOI exists. If an initial determination is made that SFI exists that could affect, or appear to affect, the design, conduct or reporting of federally funded activities, then the Disclosure Packet will be referred to the Provost. The Provost shall determine what conditions or restrictions, if any, should be imposed by the College to manage actual or potential conflicts of interest arising from disclosed SFI.

6. Prior to consideration by the Provost, the Investigator, in cooperation with the College, shall develop and present to the Provost a Conflict of Interest Management Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by SFI. At a minimum, the Management Plan shall address such issues as:

- (1) Public disclosure of SFI;
- (2) Review of research protocol by independent reviewers; and
- (3) Monitoring of research by independent reviewers.

The Provost shall review the Management Plan and approve it or add conditions or restrictions which may include the following:

- (1) Modification of the research plan;

(2) Disqualification from participation in all or a portion of the proposed research to be funded;

(3) Divestiture of Significant Financial Interests; or

(4) Severance of relationships that create actual or potential conflicts of interest.

If the Provost determines that there is a potential FCOI, but that imposing the above-referenced conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from SFI are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Provost may recommend that, to the extent permitted by Federal regulations, the research go forward without imposing such conditions or restrictions.

7. The approved Management Plan shall be incorporated into a Memorandum of Understanding between Bryn Mawr College and the Investigator, that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the Business Enterprise or Entity. The Memorandum of Understanding shall be signed by the Investigator, the Department Chair and the Provost. The Director of Sponsored Research will certify that actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated in accordance with these Guidelines prior to expending any funds from the applicable federal award, or they will be disclosed to the sponsoring agency for action.

8. Records of Investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Office of Sponsored Research until three (3) years after the date of submission of the final expenditure report, other dates as listed in 45 C.F.R. 74.53(b) and 92.42(b), or the resolution of any government action that arises involving those records, whichever comes latest.

9. Whenever an Investigator has violated this policy or the terms of an applicable Memorandum of Understanding, the Provost shall within 120 days of the discovery of that violation (i) complete a retrospective review of the Investigator's activities and funded research to determine whether there was bias in the design, conduct, or reporting of the research, (ii) document this review, and (iii) document the determination whether during the period of noncompliance with the Memorandum of Understanding there was bias in the design, conduct, or reporting of the research. If such bias is found, the Director of Sponsored Research will submit a report to any applicable funding agency, setting forth the impact found on the research and the College's plan to eliminate/mitigate that impact. Further, the Provost may recommend sanctions, which may include

disciplinary action. The Provost's recommendations on sanctions shall be presented to the President, who shall enforce any disciplinary action.

10. Collaborators from other institutions must provide a certification that their institutions are in compliance with federal policies regarding Investigator SFI disclosure and that their portion of the project is in compliance with their institutional policies. If a Collaborator is a subrecipient of any external funding received by the College, the written agreement between the College and that Collaborator must include a statement indicating whether the College's or the Collaborator's institutional FCOI policy applies.

C. Regulatory Authority

This policy implements the requirements of 42 C.F.R. 50, Subpart F and 45 C.F.R. 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

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