#### **BRYN MAWR COLLEGE**

#### FINANCIAL CONFLICT OF INTEREST IN RESEARCH POLICY

#### Introduction

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.

These guidelines define general College policy and procedures regarding conflicts of interest in relation to sponsored projects involving research, education, and College service; however, the policy sets a standard for all College activity and conflict of interest. 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.

## **Policy Need**

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 the 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.

#### Scope

This policy applies to any member of the College community who submits a research proposal to any government agency either directly or through a subcontract.

# **Definitions**

Sponsor	An external entity that provides funding for a research
•	project through a formal agreement with the research
	Institution.
Investigator	The researcher and any other person, regardless of
	title or position, who is responsible for the design,
	conduct, or reporting of government funded research.
	Includes collaborators and consultants and those who
	plan to participate in or who participate in government
	funded research.
Institution or the College	Bryn Mawr College
Financial Conflict of Interest	A financial conflict of interest exists when the
(FCOI)	Institution's designated official(s) reasonably
(1 331)	determines that an Investigator's significant financial
	interest (SFI) could directly and significantly affect the
	design, conduct, or reporting of government funded
	research.
Significant Financial Interests	See below for "What is a Significant Financial
(SFI)	Interest?" and "What is not a Significant Financial
(31.1)	Interest"?
Designated Official	Individual designated by Bryn Mawr College to oversee
Designated Officiat	the financial conflict of interest process, including
	solicitation and review of disclosures of significant
	financial interests and identify FCOIs per the
	regulatory criteria provided in 42 CFR 50.604(f) and as
	stated within the Policy. The Designated Official at
	Bryn Mawr College is the Director of Sponsored Research
DUE	
PHS	Public Health Services of the U.S Department of
	Health and Human Services, and any components of
	the PHS to which the authority involved may be
	delegated, including the <b>National Institutes of Health</b>
Foreign Financial Interests	(NIH).
Foreign Financial Interests	Investigators must disclose all foreign financial interests (which includes income from seminars,
	•
	lectures, or teaching engagements, income from
	service on advisory committees or review panels, and
	reimbursed or sponsored travel) received from any
	foreign entity, including foreign Institutions of higher
	education or a foreign government (which includes
	local, provincial, or equivalent governments of another
	country) when such income meets the threshold for
	disclosure.

### **Disclosure Requirements**

## What is a Financial Interest (FI)?

A Financial Interest is anything of monetary value, whether or not the value is readily ascertainable. Financial Interests must be considered if/when they <u>directly and</u> significantly affect the design, conduct, or reporting of sponsored research.

# What is a Significant Financial Interest (SFI)?

Significant Financial Interest is when a Financial Interest includes any of the following:

- 1) A domestic or foreign financial interest consisting of <u>one or more</u> 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 institutional responsibilities performed on behalf of Bryn Mawr College:
  - i) With regard to any 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. 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, 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 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. or income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education."

### What is not an SFI?

- 2) The term significant financial interest does NOT include
  - i) Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution,

- including intellectual property rights assigned by the Institution and agreements to share in royalties related to such rights;
- ii) Ownership interests in the Institution, held by the Investigator if the Institution is a commercial or for-profit organization and such interests are excluded from the SFI definition per regulation;
- iii) 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;
- iv) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the US, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education;
- v) Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States (U.S), a U.S Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S Institution of higher education.
- 3) Investigators must disclose the occurrence of any reimbursed or sponsored travel that exceeds \$5,000 (i.e. that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary values may not be readily available) related to the Investigator's Institutional responsibilities. The disclosure of reimbursed or sponsored travel should include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- A federal, state, or local government agency located in the United States
- A United States Institution of higher education
- An academic teaching hospital
- Medical center
- A research institute affiliated with a United States Institution of Higher Education

Note: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

#### **Procedures**

#### **Pre-Award Disclosure**

If conducting research on a government funded grant, all Significant Financial Interests must be disclosed prior to the time a proposal is submitted.

- 1) Prior to proposal submission, Investigators shall disclose
  - a. Any Significant Financial Interests 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
  - b. Any Significant Financial Interests 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

2) Collaborators from other institutions must provide a certification that their institutions are in compliance with government 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.

## Mitigation Procedures if SFI exists

If a Financial Interest deemed to be a Significant Financial Interest exists, the Investigator will follow the following procedures:

- 1) If a SFI is identified that poses a FCOI, the Investigator will work collaboratively with the Provost and Designated Official to create a Management Plan. Steps to mitigate the FCOI could include, but are not limited to the following:
  - a. Public disclosure of financial conflicts of interest (when presenting or publishing research)
  - For research involving human subjects, disclosure of financial conflicts of interest directly to participants

- c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI
- d. Modification of research plan
- e. Change of personnel or personnel responsibilities,
- f. Reduction or elimination of the Financial Interest (i.e. sale of an equity interest)
- g. Severance of relationships that create financial conflicts
- 2) 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 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.

## **Post-Award Disclosure and Reporting**

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.

- 1) The Office of Sponsored Research shall annually distribute the Financial Conflict of Interest form to all government funded Investigators. The Investigator will be provided with a link to both the Form and the written Policy. A link will also be distributed for the required training for any PHS/NIH-funded Investigators (see Training Requirements below).
- 2) Each Investigator shall complete and sign the Financial Conflict of Interest Form and attach all required supporting documentation, as needed.

# **Training Requirements**

All Investigators will be made aware of the Policy and procedures for FCOI reporting.

PHS/NIH-funded investigators: In fulfillment of the FCOI training requirements of the FCOI regulation, BMC requires that NIH-funded Investigators complete the NIH's Financial Conflict of Interest tutorial in accordance with the requirements and expectations of this Policy. All PHS/NIH-funded Investigators must print a certification of completion at the end

of training and retain it for audit purposes. Investigators may also email the completed certificate to <a href="mailto:grants@brynmawr.edu">grants@brynmawr.edu</a> for storage.

**NSF-funded investigators and others**: Sponsored Investigators from other government funding agencies have the option to complete the NIH tutorial.

#### **Maintenance of Records**

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.

# **Violations of Policy**

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.

# **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.

**Effective Date:** 

Last Updated: 10/22/2025

Policy Contact: Director of Sponsored Research (grants@brynmawr.edu)